MicroBioLogics
217 Osseo Ave. No. • St. Cloud, Minnesota 56303
(320) 253-1640 • (800) 599-BUGS (2847) • Fax (320) 253-6250
www.microbiologics.com

DECLARATION N°: 104/01

#85.

EC DECLARATION OF CONFORMITY

In Vitro Diagnostic Medical Devices for Professional use

We

MicroBioLogics
217 Osseo Avenue North,
St. Cloud, MN 56303

having designated :
Medimark Europe Sarl ,
11 rue Emile Zola – 38033 Grenoble Cedex 2 - France
As our European Authorized Representative

having our Quality Management System been certified against ISO 9001:2000 standard (Certificate N° C2001-01537 issued on 12/14/2001 by Perry Johnson Registrars, Inc;

Applying in full or partially the following standards: ANSI ISO ASQ 9001:2000, EN 46001, EN 375, EN ISO 14971, ISO 15223.

insure and declare under our sole responsibility that the In Vitro Diagnostic Medical Devices specified in the attached list to which this declaration relates are in conformity with the applicable requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

This declaration is made in accordance with Annex III of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and is valid for an undetermined period of time .

SAINT CLOUD, MN USA 10/04/2002

Name of the authorized person: Gerald Tjernagel
Title : Executive Vice-President
Executive Representative
Signature: Gerald Tjernagel

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List of In Vitro Diagnostic Medical Devices in relation with the above declaration

Device designation	EDMS Class N°
LYFO-DISK® MICROORGANISM Individual Lyophilized Microorganism Preparations (List 1 of cat N° attached)	14 50 01 90 00
KWIK-STIK ® MICROORGANISM Individual Lyophilized Microorganism Preparations (List 1 of cat N° attached)	
LYFO-DISK® MICROORGANISM Individual Lyophilized Microorganism Sets (List 2 of Cat N° attached)	
KWIK-STIK ® MICROORGANISM Individual Lyophilized Microorganism Sets (List 2 of Cat N° attached)	
KWIK-STIK PLUS ® Reference Stock cultures with Limited Passages from Reference Cultures (List 3 of Cat N° attached)	

SAINT CLOUD, MN USA 10/04/2002

Name of the authorized person: Gerald Tjernagel
Title : Executive Vice-President
Executive Representative
Signature: Gerald Tjernagel

LIST 1
INDIVIDUAL MICROORGANISMS

DECLARATION N°: 104/01.

MICROORGANISM	ATCC#	MBL#
Acinetobacter		
A. baumannii	19606	0357
A. haemolyticus	19002	0609
A. lwoffii	15309	0468
A. lwoffii	17925	0973
A. species	49137	0636
A. species	49139	0635
A. species	49466	0934
Actinobacillus		
A. pleuropneumoniae	27088	0658
A. pleuropneumoniae	27090	0789
Actinomyces		
A. odontolyticus	17929	0939
A. pyogenes	19411	0660
A. pyogenes	49698	0966
A. viscosus	15987	0750
Aerococcus		
A. viridans	700406	0746
Aeromonas		
A. caviae	15468	0807
A. hydrophila	7966	0870
A. hydrophila	35654	0910
A. hydrophila	49140	0637
A. salmonicida	33658	0788
Available in DuoPak only.		
Alcaligenes		
A. faecalis	8750	0402
A. faecalis	35655	0911
Aspergillus		
A. niger	16404	0392
A. niger	16888	0245
Bacillus		
B. brevis	8246	0798
B. cereus	10876	0998
B. cereus	11778	0256
B. cereus	13061	0999
B. cereus	14579	0200
B. licheniformis	12759	0812
B. licheniformis	14580	0799
B. megaterium	14581	0201
B. polymyxa	842	0883
Refer to Paenibacillus polymyxa		
B. sphaericus	4525	0810
B. stearothermophilus	7953	0871
B. stearothermophilus	12980	0872
B. subtilis	6633	0486
B. subtilis	9372	0953
Bacteroides		
B. distasonis	8503	0618
B. fragilis	23745	0940
B. fragilis	25285	√0320 #85.9.
B. ovatus	8483	0400
B. thetaiotaomicron	29741	0319
B. uniformis	8492	0619
B. ureolyticus	33387	0908
B. vulgatus	8482	0445
B. vulgatus	29327	0848
Blastoschizomyces		
B. capitatus	10663	0482
Bordetella		
B. bronchiseptica	4617	0671
B. bronchiseptica	10580	0655
B. parapertussis	15311	0842
B. pertussis	8467	0489
B. pertussis	9797	0843
Branhamella		
B. catarrhalis	8176	0622
Refer to Moraxella (Branhamella) catarrhalis		
B. catarrhalis	25238	0951
Refer to Moraxella (Branhamella) catarrhalis		
B. catarrhalis	25240	0403
Refer to Moraxella (Branhamella) catarrhalis		
B. catarrhalis	49143	0642
Refer to Moraxella (Branhamella) catarrhalis		
Brevundimonas		
B. diminuta	11568	0754
B. diminuta	19146	0805
Budvicia		
B. aquatica	51341	0213
Burkholderia		
B. cepacia	25416	0488
B. cepacia	25608	0836
B. pickettii	49129	0641
Refer to Ralstonia pickettii		
Campylobacter		
C. jejuni	29428	0325
C. jejuni	33291	0481
C. jejuni	49943	0251
Candida		
C. albicans	2091	0896
C. albicans	10231	0443
C. albicans	14053	0332
C. albicans	24433	0800
C. albicans	26790	0672
C. albicans	60193	0425
C. albicans	66027	0981
C. albicans	90029	√0250 #85.19
C. glabrata	2001	0992
C. glabrata	15126	0737
C. glabrata	64677	0226
C. glabrata	66032	0986
C. guilliermondii	6260	0738
C. kefyr	2512	0990
C. kefyr	4135	0769
C. kefyr	66028	0982
C. kefyr	204093	0777
C. krusei	14243	0809
C. lusitaniae	34449	0774
C. magnoliae	201379	0770
C. membranaefaciens	201377	0772
C. membranaefaciens	201378	0773
C. parapsilosis	22019	0726

LIST 1
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MICROORGANISM	ATCC#	MBL#
C. tropicalis	750	0847
C. tropicalis	9968	0897
C. tropicalis	13803	0450
C. tropicalis	66029	0983
C. tropicalis	201380	0767
C. tropicalis	201381	0768
C. utilis	9950	0779
Capnocytophaga		
C. sputigena	33612	0749
Chryseobacterium		
C. meningosepticum	13253	0971
Citrobacter		
C. braakii	43162	0478
C. freundii	8090	0315
C. freundii	43864	0229
Clostridium		
C. baratii	27638	0751
C. beijerinckii	8260	0244
C. bifermentans	638	0828
C. difficile	9689	0329
C. difficile	43593	0833
C. histolyticum	19401	0327
C. perfringens	3624	0257
C. perfringens	12915	0801
C. perfringens	12919	0674
C. perfringens	13124	0318
C. sordellii	9714	0331
C. sporogenes	3584	0676
C. sporogenes	11437	0487
C. sporogenes	19404	0317
C. thermosaccharolyticum	7956	0728
Refer to Thermoanaerobacterium		
Corynebacterium		
C. diphtheriae	13812	0844
C. pseudodiphtheriticum	10700	0965
C. pseudodiphtheriticum	10701	0884
C. species (Group A)	49676	0964
Refer to Exiguobacterium species (Group A)		
Cryptococcus		
C. albidus	34140	0451
C. albidus	66030	0984
C. humicolus	9949	0972
C. laurentii	18803	0333
C. laurentii	66036	0991
C. laurentii	76483	0916
C. neoformans	32045	0334
C. neoformans	66031	0985
C. neoformans	76484	0915
C. neoformans	204092	0781
C. uniguttulatus	66033	0987
Deinococcus		
D. radiodurans	13939	0210
Delftia		
D. acidovorans	43868	0230
Deposited as Pseudomonas		

MICROORGANISM	ATCC#	MBL#
Edwardsiella		
E. tarda	15947	0845
Eggerthella		
E. lenta	43055	0936
Formerly Eubacterium lentum		
Enterobacter		
E. aerogenes	13048	0306
E. aerogenes	35029	0399
E. cloacae	13047	0323
E. cloacae	23355	0313
E. cloacae	35030	0388
E. cloacae	49141	0639
E. cloacae	700323	0755
E. sakazakii	51329	0756
Enterococcus		
E. avium	14025	0387
E. avium	49464	0857
E. casseliflavus	700327	0761
E. durans	6056	0651
E. durans	11576	0623
E. durans	49135	0624
E. durans	49479	0935
E. faecalis	7080	0497
E. faecalis	19433	0367
E. faecalis	29212	0366 √ #85.7
E. faecalis	49452	0941
E. faecalis	49532	0753
High level Gentamicin-resistant and Streptomycin-sensitive		
E. faecalis	49533	0752
High level Gentamicin-sensitive and Streptomycin-resistant		
E. faecalis	51299	0959
Low-level Vancomycin resistant		
E. faecium	6569	0677
E. faecium	27270	0679
E. faecium	35667	0968
E. faecium	49032	0980
E. gallinarum	49573	0895
Motile strain		
E. gallinarum	700425	0745
E. hirae	8043	0650
E. hirae	10541	0678
E. saccharolyticus	43076	0223
Deposited as Streptococcus		
Erysipelothrix		
E. rhusiopathiae	19414	0661
Escherichia		
E. coli	4157	0433
E. coli	8739	0483
E. coli	10536	0680
E. coli	11229	0681
E. coli	11775	0465
E. coli	13706	0747
E. coli	13762	0682
E. coli	14948	0202
E. coli (Genotype B)	23848	0203
E. coli	25922	√0335 #85.15

LIST 1
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MICROORGANISM	ATCC#	MBL#
E. coli	33605	0887
E. coli (JM101)	33876	0204
E. coli (O157:H7)	35150	0617 ✓ #85.5,
E. coli	35218	0495
Beta lactamase producer		
E. coli	35421	0422
E. coli (O157:H7)	43888	0795
Does not produce Shiga-Like Toxin I or II		
E. coli	51446	0869
E. coli	51755	0860
Thymidine-dependent QC strain for Mueller Hinton		
E. coli	51813	0791
E. coli (O157:H7)	700728	0231
E. coli	**********	0861
Derivative of NCTC# 12900		
Eubacterium		
E. lentum	43055	0936
Refer to Eggerthella lenta		
Exiguobacterium		
E. species (Group A)	49676	0964
Formerly Corynebacterium species (Group A)		
Flavobacterium		
F. odoratum	4651	0324
Refer to Myroides odoratus		
Fluoribacter		
F. bozemanae	33217	0212
Deposited as Legionella		
Fusobacterium		
F. necrophorum	25286	0407
F. nucleatum	25586	0328
F. varium	27725	0886
Gardnerella		
G. vaginalis	14018	0410
G. vaginalis	14019	0252
G. vaginalis	49145	0643
Haemophilus		
H. aphrophilus	19415	0862
H. haemolyticus	33390	0381
H. influenzae	19418	0376
H. influenzae	33930	0829
Resistant to ampicillin, chloramphenicol and tetracycline		
H. influenzae	35056	0993
Beta lactamase producer		
H. influenzae	43065	0438
H. influenzae	43163	0476
Beta lactamase producer		
H. influenzae	49144	0644
Beta lactamase producer		
H. influenzae	49247	0647
H. influenzae	49766	0919
H. influenzae	**********	0850
Derivative of NCTC# 11931		
H. influenzae (Type a)	9006	0620
H. influenzae (Type b)	10211	0441
H. influenzae (Type b)	33533	0338
Beta lactamase producer		

MICROORGANISM	ATCC#	MBL#
H. parahaemolyticus	10014	0377
H. parainfluenzae	7901	0411
H. paraphrophilus	29241	0467
V - dependent		
H. paraphrophilus	49146	0645
H. paraphrophilus	49917	0249
H. somnus	700025	0790
Issatchenkia		
I. orientalis	6258	0227
Deposited as Candida krusei		
Klebsiella		
K. oxytoca	8724	0840
K. oxytoca	43086	0606
K. oxytoca	43165	0477
K. oxytoca	43863	0214
K. oxytoca	49131	0626
K. oxytoca	700324	0757
K. pneumoniae	4352	0683
K. pneumoniae	10031	0684
K. pneumoniae	13882	0458
K. pneumoniae	13883	0351
K. pneumoniae	27736	0685
K. pneumoniae	33495	0957
K. pneumoniae	35657	0942
K. pneumoniae	700603	0784 ✓ #85.3
NCCLS Mandated Microorganism for ESBLs		
Kocuria		
K. rosea	186	0766
Lactobacillus		
L. acidophilus	314	0885
L. acidophilus	4356	0243
L. delbrueckii	7830	0235
L. fermentum	9338	0813
L. plantarum	8014	0234
L. rhamnosus	7469	0233
L. rhamnosus	9595	0989
Lactococcus		
L. lactis	11454	0205
Leclercia		
L. adecarboxylata	23216	0837
L. adecarboxylata	700325	0758
Legionella		
L. pneumophila	33152	0211
Listeria		
L. grayi	25401	0856
L. grayi	700545	0222
L. innocua	33090	0814
L. ivanovii	19119	0815
L. monocytogenes	7644	✓ 0398 #85.24.
L. monocytogenes	15313	0727
Non-hemolytic		
L. monocytogenes	19112	0232
L. monocytogenes	19114	0686
Type 4a		
L. monocytogenes	19115	0687
Type 4b		

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MICROORGANISM	ATCC#	MBL#
L. monocytogenes	*********	0783
Derivative of NCTC# 10890, Type 7		
L. seeligeri	35967	0802
L. welshimeri	35897	0816
Mannheimia		
M. haemolyticia	33396	0664
Formerly Pasteurella haemolyticia		
Micrococcus		
M. luteus	533	0359
M. luteus	4698	0242
M. luteus	7468	0218
M. luteus	9341	0688
M. luteus	10240	0689
M. luteus	15957	0670
M. luteus	49732	0804
M. luteus	9341a	0669
M. species	700405	0740
Microsporum		
M. canis	36299	0894
M. gypseum	24102	0893
Moraxella		
M. osloensis	10973	0475
Moraxella (Branhamella)		
M. catarrhalis	8176	0622
Subgenus Branhamella		
M. catarrhalis	23246	0248
Subgenus Branhamella		
M. catarrhalis	25238	0951
Subgenus Branhamella		
M. catarrhalis	25240	√0403 #85.8.
Subgenus Branhamella		
M. catarrhalis	49143	0642
Subgenus Branhamella		
Morganella		
M. morganii	25829	0215
M. morganii	25830	0839
Mycobacterium		
M. gordonae	14470	0995
M. smegmatis	14468	0721
Myroides		
M. odoratus	4651	0324
Formerly Flavobacterium		
Neisseria		
N. gonorrhoeae	19424	0378
N. gonorrhoeae	31426	0375
Beta lactamase producer		
N. gonorrhoeae	43069	0429
N. gonorrhoeae	43070	0426
N. gonorrhoeae	49226	√0648 # 85.21.
N. gonorrhoeae	49981	0952
Penicillin resistant		
N. lactamica	23970	0405
N. lactamica	23971	0943
N. lactamica	49142	0646
N. meningitidis (Group A)	13077	0453
N. meningitidis (Group B)	13090	0454

MICROORGANISM	ATCC#	MBL#
N. meningitidis (Group C)	13102	0404
N. mucosa	19695	0653
N. sicca	9913	0406
N. sicca	29193	0464
N. subflava	14799	0456
Nocardia		
N. brasiliensis	19296	0866
Oligella		
O. ureolytica	43534	0868
O. ureolytica	43535	0970
O. urethralis	17960	0621
Paenibacillus		
P. polymyxa	842	0883
Formerly Bacillus polymyxa		
P. polymyxa	43865	0228
Pasteurella		
P. aerogenes	27883	0808
P. haemolytica	33396	0664
Refer to Mannheimia haemolytica		
P. multocida	12945	0668
Penicillium		
P. aurantiogriseum	16025	0794
P. notatum	9179	0207
Peptostreptococcus		
P. anaerobius	27337	0322
P. asaccharolyticus	29743	0849
P. magnus	29328	0409
P. micros	33270	0958
Plesiomonas		
P. shigelloides	14029	0846
P. shigelloides	51903	0835
Porphyromonas		
P. gingivalis	33277	0912
P. levii	29147	0600
Prevotella		
P. loeschell	15930	0408
Propionibacterium		
P. acnes	11827	0419
Proteus		
P. mirabilis	7002	0607
P. mirabilis	12453	0440
P. mirabilis	25933	0690
P. mirabilis	29245	0321
P. mirabilis	35659	0944
P. mirabilis	43071	0432
P. vulgaris	6380	0459
P. vulgaris	6896	0841
P. vulgaris	8427	0691
P. vulgaris	13315	0355
P. vulgaris	33420	0300
P. vulgaris	49132	√0640 #85.20.
Prototheca		
P. wickerhamii	16529	0780
Providencia		
P. alcalifaciens	9886	0692
P. alcalifaciens	51902	0834

LIST 1
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MICROORGANISM	ATCC#	MBL#
P. rettgeri	9250	0997
P. stuartii	33672	0384
P. stuartii	49809	0879
Pseudomonas		
P. aeruginosa	9027	0484
P. aeruginosa	10145	0416
P. aeruginosa	15442	0693
Pyocyanin not produced		
P. aeruginosa	25619	0695
P. aeruginosa	27853	√0353 #85,12,
P. aeruginosa	35032	0975
P. aeruginosa	**********	0830
Derivative of NCTC# 10662, same as ATCC 25668		
P. fluorescens	13525	0241
P. fluorescens	49838	0880
P. putida	49128	0627
P. stutzeri	17588	0853
Ralstonia		
R. pickettii	49129	0641
Formerly Burkholderia pickettii		
Rhodococcus		
R. equi	6939	0697
Recommended for CAMP Test for Listeria monocytogenes		
Rizopus		
R. stolonifer (-)	6227a	0208
R. stolonifer (+)	6227b	0209
Saccharomyces		
S. cerevisiae	2601	0698
S. cerevisiae	9763	0699
S. cerevisiae	**********	0736
Derivative of NCYC# 79		
Salmonella		
S. abaetetuba	35640	0817
S. abony	**********	0890
Derivative of NCTC# 6017		
S. anatum (Group E)	9270	0346
choleraesuis subsp. choleraesuis serotype Anatum		
S. arizonae	13314	0901
choleraesuis subsp. Arizonae		
S. choleraesuis	10708	0902
choleraesuis subsp. choleraesuis serotype Choleraesuis		
S. choleraesuis (Group C)	7001	0343
choleraesuis subsp. choleraesuis serotype Choleraesuis		
S. enteritidis (Group D)	13076	√0345 #85,13,
choleraesuis subsp. choleraesuis serotype Enteritidis		
S. kunzendorf	12011	0903
choleraesuis subsp. choleraesuis serotype Kunzendorf		
S. paratyphi (Group A)	9150	0341
choleraesuis subsp. choleraesuis serotype Paratyphi-A		
S. poona	**********	0851
Derivative of NCTC# 4840		
S. tallahassee	12002	0344
choleraesuis subsp. choleraesuis serotype Tallahassee		
S. typhi	6539	0904
choleraesuis subsp. choleraesuis serotype Typhi		

MICROORGANISM	ATCC#	MBL#
S. typhi (D, Vi[+])	19430	0905
choleraesuis subsp. choleraesuis serotype Typhi		
S. typhimurium	13311	0421
choleraesuis subsp. choleraesuis serotype Typhimurium		
S. typhimurium	14028	0363
choleraesuis subsp. choleraesuis serotype Typhimurium		
S. typhimurium	25241	0253
choleraesuis subsp. choleraesuis serotype Typhimurium		
S. vellore (Group B)	15611	0342
choleraesuis subsp. choleraesuis serotype Vellore		
Serratia		
S. liquefaciens	27592	0838
S. marcescens	8100	0354
Non-pigmented		
S. marcescens	13880	0247
S. marcescens	14756	0806
S. marcescens	43861	0216
S. odorifera	33077	0654
Shewanella		
S. putrefaciens	8071	0888
S. putrefaciens	49138	0638
Shigella		
S. boydii (Serotype 1)	9207	0349
S. flexneri (Serotype1a)	9199	0348
S. flexneri (Serotype 2b)	12022	√0356 #85,10,
S. sonnei	9290	0446
S. sonnei	25931	√0303 #85,11,
S. sonnei	29930	0350
Sordaria		
S. firmicola	14517	0240
Sphingobacterium		
S. multivorum	35656	0948
S. spiritivorum	33861	0760
Sphingomonas		
S. capsulata	14666	0206
Staphylococcus		
S. aureus	6538	0485
S. aureus	6538P	0827
S. aureus	11632	0462
Beta lactamase producer		
S. aureus	25923	√0360 #85,17,
S. aureus	29213	√0365 #85,18,
S. aureus	29737	0906
S. aureus	33591	0496
Methicillin resistant		
S. aureus	33592	0889
Gentamicin and Methicillin resistant		
S. aureus	33862	0352
Recommended for CAMP Test		
S. aureus	43300	0852
Methicillin resistant		
S. aureus	49444	0907
Recommended for CAMP Test for Listeria monocytogenes		
S. aureus	49476	0937
S. aureus	51153	0832

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MICROORGANISM	ATCC#	MBL#
S. aureus	**********	0831
Derivative of NCTC# 6571		
S. capitis	35661	0963
S. cohnii	35662	0962
S. epidermidis	12228	√0371 #85.16.
S. epidermidis	13518	0415
Formerly Staphylococcus species		
S. epidermidis	14990	0412
S. epidermidis	49134	0628
S. epidermidis	49461	0976
S. gallinarum	700401	0219
S. haemolyticus	29970	0246
S. lentus	700403	0739
S. lugdunensis	49576	0217
S. lugdunensis	700328	0762
S. saprophyticus	15305	0494
S. saprophyticus	49453	0945
S. saprophyticus	49907	0881
S. sciuri ssp. sciuri	29060	0460
S. sciuri ssp. sciuri	29061	0764
S. simulans	27851	0413
S. species	155	0238
S. warneri	49454	0946
S. xylosus	29971	0605
S. xylosus	35033	0797
S. xylosus	35663	0961
S. xylosus	49148	0629
S. xylosus	700404	0741
Stenotrophomonas		
S. maltophilia	13637	0369
S. maltophilia	17666	0759
S. maltophilia	51331	0742
Streptococcus		
S. agalactiae (Group B)	13813	0370 √ #85.4.
Nonhemolytic in absence of CAMP Factor		
S. agalactiae (Group B)	27956	0436
S. bovis	9809	0391
S. bovis	33317	0463
S. bovis	49133	0630
S. bovis	49147	0631
S. bovis	49475	0949
S. equi ssp. equi	9528	0656
Designated as Group C		
S. equi ssp. equi	33398	0221
S. equi ssp. zooepidemicu	700400	0743
Formerly Streptococcus zooepidemicus		
S. equisimilis (Group C)	9542	0776
S. equisimilis (Group C)	12388	0603
Formerly Streptococcus species (Group C)		
S. equisimilis (Group C)	35666	0967
S. mitis	6249	0423
S. mutans	35668	0969
S. parasanguinis	15909	0401
Formerly Streptococcus parasanguis		
S. pneumoniae	6301	0763
S. pneumoniae	6303	0380

MICROORGANISM	ATCC#	MBL#
S. pneumoniae	6305	0447
S. pneumoniae	10015	0865
S. pneumoniae	27336	0435
S. pneumoniae	49136	0632
S. pneumoniae	49150	0633
S. pneumoniae	49619	0947 √ #85.1
Low level penicillin resistance by oxacillin test		
S. pyogenes (Group A)	12384	0979
Designated Type 3		
S. pyogenes (Group A)	19615	0385 √ #85.2
S. pyogenes (Group A)	49399	0994
S. salivarius	13419	0237
S. sanguinis	10556	0858
Formerly Streptococcus sanguis		
S. species (Group B)	12386	0439
S. species (Group C)	12388	0603
Refer to Streptococcus equisimilis (Group C)		
S. species (Group F)	12392	0978
Designated Type 2		
S. species (Group G)	12394	0602
S. species (Group B)	12401	0864
Designated Type Ib		
S. uberis	9927	0765
S. uberis	700407	0744
S. vestibularis	49124	0224
S. zooepidemicus	700400	0743
equi ssp. zooepidemicus		
Streptomyces		
S. griseus	10137	0859
Thermoanaerobacterium		
T. thermosaccharolyticum	7956	0728
Formerly Clostridium		
Trichophyton		
T. mentagrophytes	9533	0442
T. rubrum	28188	0444
T. tonsurans	28942	0891
Trichosporon		
T. mucoides	201382	0771
T. mucoides	201383	0775
T. mucoides	204094	0778
Veillonella		
V. parvula	10790	0867
Vibrio		
V. alginolyticus	17749	0819
V. furnissii	********	0720
Derivative of NCTC# 11218		
V. parahaemolyticus	17802	0818
Yarrowia		
Y. lipolytica	9773	0950
Yersinia		
Y. enterocolitica	9610	0938
Y. enterocolitica	23715	√0316 # 85.14.
Y. enterocolitica	27729	0909
Y. kristensenii	33639	0974
Y. ruckeri	29473	0785
Available in DuoPak only.		

LIST 1
INDIVIDUAL MICROORGANISMS

DECLARATION N°: 104/01

MICROORGANISM	ATCC#	MBL#	MICROORGANISM	ATCC#	MBL#
Zygosaccharomyces					
Z. rouxii	**********	0255			
Derivative of NCYC# 381					
Z. rouxii	28253	0803			
Z. rouxii	34890	0960			

BD *Declaration of Conformity*

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	✓245000 - BD BBL Crystal E/NF #88.1, 245002 - BD BBL Crystal E/NF Code Book

We hereby declare that the above mentioned product(s) manufactured after 2010/06/30 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2010/06/30
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number:

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	✓245010 - BD BBL Crystal ANR #88.2. 245011 - BD BBL Crystal ANR Manual

We hereby declare that the above mentioned product(s) manufactured after 2010/06/30 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2010/06/30
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number:

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	245240 - BD BBL Crystal GP 245140 - BD BBL Crystal GP # 88.3. 245037 - BD BBL Crystal GP Code Book

We hereby declare that the above mentioned product(s) manufactured after 2010/06/30 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2010/06/30
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number:

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	245009 - NEPHELOMETER CRYSTALSPEC NEPHELOMETER √245015 - NEPHELOMETER CRYSTALSPEC NEPHELOMETER #88.4.

We hereby declare that the above mentioned product(s) manufactured after 2010/06/30 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2010/06/30
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: ER245009

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	231562 - DISC TAXO KANAMYCIN 1 EA ✓ #91.1.

We hereby declare that the above mentioned product(s) manufactured after 2011/03/31 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

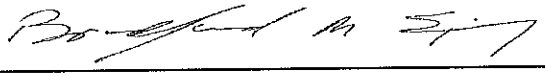
Signed In Baltimore:	2011/03/31
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: ER231562

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	230918 - BD BBL Sensi-Disc Susceptibility Test PENICILLIN 10 IU/IE/UI ✓231321 - BD BBL Sensi-Disc Susceptibility Test PENICILLIN 10 IU/IE/UI #91.2.

We hereby declare that the above mentioned product(s) manufactured after 2013/04/01 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2013/04/01
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	

Technical File Number: ER230918

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	230749 - BD BBL Sensi-Disc Colistin 10 µg ✓ 231278 - BD BBL Sensi-Disc Colistin 10 µg #91.3.

We hereby declare that the above mentioned product(s) manufactured after 2013/04/01 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2013/04/01
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: BALTER230749

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	✓ 291279 - BD BBL Sensi-Disc Metronidazole 5 µg #91.4.

We hereby declare that the above mentioned product(s) manufactured after 2013/03/28 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed in Baltimore:	2013/03/28
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: BALTER291279

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	✓ 231650 - CEFINASE 1/4 DISCS # 91.5

We hereby declare that the above mentioned product(s) manufactured after 2010/06/30 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2010/06/30
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number:

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	230886 - BD BBL Sensi-Disc Susceptibility Test NOVOBIOCIN 5 µg ✓ 231314 - BD BBL Sensi-Disc Susceptibility Test NOVOBIOCIN 5 µg # 91.6.

We hereby declare that the above mentioned product(s) manufactured after 2013/04/01 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2013/04/01
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: ER230886

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	230926 - BD BBL Sensi-Disc Susceptibility Test POLYMYXIN B 300 IU/IE/UI ✓231324 - BD BBL Sensi-Disc Susceptibility Test POLYMYXIN B 300 IU/IE/UI # 91.7.

We hereby declare that the above mentioned product(s) manufactured after 2013/04/02 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2013/04/02
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: ER230926

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	231040 - BD BBL Taxo A Discs, 50 231041 - BD BBL Taxo A Discs, 6 x 50 # 91.8.

We hereby declare that the above mentioned product(s) manufactured after 2010/06/30 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2010/06/30
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: ER231040

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	231046 - BD BBL Taxo P Discs, 50 ✓ 231047 - BD BBL Taxo P Discs, 6 x 50 #91.9.

We hereby declare that the above mentioned product(s) manufactured after 2011/03/31 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2011/03/31
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: ER231046

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 07 73936 008

#96.
#102.

Manufacturer: **Copan Italia S.p.a.**
Via F. Perotti, 10
25125 Brescia
ITALY

Facility(ies): Copan Italia S.p.a.
Via F. Perotti, 10, 25125 Brescia, ITALY

Product Category(ies): **Fiber swabs and flocked swabs for the collection of biological specimens with or without transport medium**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA262911

Valid from: 2015-09-02
Valid until: 2020-09-01

664550

Date, 2015-07-31

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

A1 / 04.11

ELITechGroup
EM
MICROBIO

CE DECLARATION OF CONFORMITY

According to Annex III of the IVD Directive 98/79/EC

MANUFACTURER
ELITech MICROBIO
Parc d'activités, allée d'Athènes
83870 SIGNES (France)

PLACE OF MANUFACTURE
ELITech MICROBIO
Parc d'activités, allée d'Athènes
83870 SIGNES (France)

PRODUCTS

MYCOFAST *Evolution* 2 (Ref. 00031)
MYCOFAST *Evolution* 3 (Ref. 00036)
MYCOFAST *US* (Ref. 00050)
MYCOFAST Screening xp (Ref. 00043)
MYCOFAST Screening *Evolution* 3 (Ref. 00042)
UMMt-UMMlyo (2 mL) (Ref. 00074)
UMMt-UMMlyo (3 mL) (Ref. 00077)
UMMt (2ml) (Ref. 00835)
UMMt (3ml) (Ref. 00836)
MYCOSCREEN PLUS (Ref. 00025)
A7 AGAR (Ref. 00090)
SEROLOGY (Ref. 00014)
MYCOPLASMA CONTROL (Ref. 00900)
URICHROM II (Ref. 22221)
URIFAST ABG V2 (Ref. 22214)
URIFAST TWIN 1C V2 (Ref. 22296)
PRESTO ABG (Ref. 22204)
ASO-BAR (Ref. 04125)
COMPLEMENT ASO-BAR (Ref. 04905)
DOR-BAR (Ref. 04135)
CANDICHROM II (Ref. 44211)
CANDICHROM II Pack (Ref. 44212)
CANDIFAST (Ref. 44030)
CANDIFAST *ES* TWIN (Ref. 44130)
FUNGIFAST (Ref. 44430) ✓ # 101.1.
FUNGIFAST AFG (Ref. 44412) ✓ # 101.2.
ELIchrom FUNGI (Ref. 44328)
ELIchrom FUNGI Codebook (Ref. 44329)

We undersigned, ELITech MICROBIO, hereby declare that the above-mentioned devices comply with all essential requirements (Annex I) and declare to fulfill the obligations imposed by Annex III – Section 2-5, of the directive 98/79/EC of the European parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices.

Signes, 26 July 2010

Bernadette QUIVIGER
Regulatory Affairs

ELITechGroup
EM
MICROBIO

CE DECLARATION OF CONFORMITY

According to Annex III of the IVD Directive 98/79/EC

MANUFACTURER
ELITech MICROBIO
Parc d'activités, allée d'Athènes
83870 SIGNES (France)

PLACE OF MANUFACTURE
ELITech MICROBIO
10, rue Gustave Eiffel
59130 LAMBERSAT (France)

PRODUCTS :

ELITex Staph (Ref. 22711, 22712)
ELITex Bicolor albi-dubli (Ref. 44500, 44501)
ELITex Bicolor *dubliniensis* (Ref. 44502)
ELITex *krusei* (Ref. 44504)
ELIchrom *glabrata* (Ref. 44506)
ELI.H.A. *Candida*, Référence 44600
ELI.H.A. *Aspergillus*, Référence 44602
ELI.H.A. *Schistosoma*, Référence 66600
ELI.H.A. Amoeba, Référence 66602
ELI.H.A. *Echinococcus*, Référence 66604
ELI.H.A. Distoma, Référence 66606
ELITex Bicolor Amoeba, Référence 66608

We undersigned, ELITech MICROBIO, hereby declare that the above-mentioned devices comply with all essential requirements (Annex I) and declare to fulfill the obligations imposed by Annex III – Section 2-5, of the directive 98/79/EC of the European parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices.

Signes,

26 July 2010

Bernadette QUIVIGER
Regulatory Affairs

ELITechGroup
EM
MICROBIO

APPENDIX LETTER TO THE CE DECLARATION OF CONFORMITY

Hereby ELITech MICROBIO (EM) declares that the devices are CE marked according to the IVD Directive 98/79/EC. The products are in the category of self declaration and the CE certification by a notified body is not applicable.

EM declares that the products comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.

EM declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

EM (SIGNES) has a Quality System in place based on ISO 9001:2008 and ISO 13485:2004; issued by AFAQ.

EM (LAMBERSAT) has a Quality System in place based on ISO 9001:2008 and ISO 13485:2004; issued by G-Med.

Signes, 26 July 2010

Bernadette QUIVIGER
Regulatory Affairs

ELITech MICROBIO
Parc d'activités du plateau – 19, allée d'Athènes – 83870 Signes
Tél : + 33(0)4 94 88 55 00 – Fax : + 33(0)4 94 88 55 05
SAS au capital de 480 864 € - RCS Toulon 503 366 239 – SIRET : 503 366 239 00021 – Code APE : 4675Z
N° d'ident. TVA : FR 13503366239

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	✓240826 - BD BBL Coagulase Plasma, Rabbit with EDTA 240661 - BD BBL Coagulase Plasma, Rabbit 10 x 15mL 240658 - BD BBL Coagulase Plasma, Rabbit 10 x 3mL 240827 - BD BBL Coagulase Plasma, Rabbit with EDTA 10 x 3mL

#110.

We hereby declare that the above mentioned product(s) manufactured after 2011/03/28 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2011/03/28
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: BALTER240826

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	✓ 261181 - BD BBL Oxidase Reagent Droppers #111.

We hereby declare that the above mentioned product(s) manufactured after 2011/03/31 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2011/03/31
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: BALTER261181

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	✓261187 - BD BBL DMACA Indole Reagent Droppers #112.

We hereby declare that the above mentioned product(s) manufactured after 2011/03/31 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2011/03/31
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: BALTER261187

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	✓ 261190 - DROPPER FERRIC CHLORIDE - # 114.

We hereby declare that the above mentioned product(s) manufactured after 2011/03/31 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2011/03/31
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: ER261190

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	✓ 261183 - DROPPER DESOXYCHOLATE REAGENT #116.

We hereby declare that the above mentioned product(s) manufactured after 2011/03/31 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2011/03/31
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bradford M Spring

Technical File Number: ER261183

BD *Declaration of Conformity*

Manufacturer	**Becton Dickinson GmbH** **Tullastrasse 8-12** **69126 Heidelberg/Germany** **Tel.: +49-62 21-30 50 Fax: +49-62 21-30 52 16**
Conformity Assessment Procedure	**IVD Directive 98/79/EC, Annex III**

Product(s):

Product Name	Cat. No.
BBL CHROMagar Candida Medium	√257480 #135
BBL CHROMagar Candida Medium	254106
BBL CHROMagar O157 Medium	254105
BBL CHROMagar Orientation Medium	257481
BBL CHROMagar Orientation Medium	254107
BBL CHROMagar Salmonella Medium	254104

We hereby declare that the above mentioned product(s) comply with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Heidelberg/Germany,	October 15, 2012
Name and Authority	Dr. Bernd Peschke Regulatory Affairs Manager G/S/A, Sicherheitsbeauftragter (Safety Officer)
Signature	

Techn. File no.: S-00006

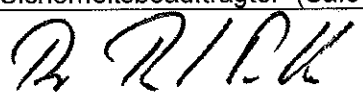
Declaration of Conformity

Manufacturer	**Becton Dickinson GmbH** **Tullastrasse 8-12** **69126 Heidelberg/Germany** **Tel.: +49-62 21-30 50 Fax: +49-62 21-30 52 16**
Conformity Assessment Procedure	**IVD Directive 98/79/EC, Annex III**

Product(s):

Product Name	Cat. No.
Brucella Blood Agar with Hemin and Vitamin K1	255509✓ #136.
BD CDC Anaerobe Agar + 5% Sheep Blood	256506
Schaedler Agar with Vitamin K1 and 5% Sheep Blood	254042
Schaedler Agar with Vitamin K1 and 5% Sheep Blood	254084

We hereby declare that the above mentioned product(s) comply with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Heidelberg/Germany,	July 21, 2014
Name and Authority	Dr. Bernd Peschke Regulatory Affairs Manager G/S/A, Sicherheitsbeauftragter (Safety Officer)
Signature	

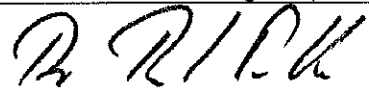
Techn. File no.: S-00015

Declaration of Conformity

Manufacturer	**Becton Dickinson GmbH** **Tullastrasse 8-12** **69126 Heidelberg/Germany** **Tel.: +49-62 21-30 50 Fax: +49-62 21-30 52 16**
Conformity Assessment Procedure	**IVD Directive 98/79/EC, Annex III**

Product(s):	**Product Name**	**Cat. No.**
	Columbia Agar with 5% Horse Blood	256006
	Columbia Agar with 5% Sheep Blood	254005
	Columbia Agar with 5% Sheep Blood	254071 ✓ #139.
	Columbia Agar with 5% Sheep Blood	257554
	Columbia III Agar with 5% Sheep Blood	254097
	Columbia III Agar with 5% Sheep Blood	254098
	Heart Infusion Agar + 5% Sheep Blood	257026
	Trypticase Soy Agar	254051
	Trypticase Soy Agar	254086
	Trypticase Soy Agar II with 5% Horse Blood	212099
	Trypticase Soy Agar II with 5% Sheep Blood	254053
	Trypticase Soy Agar II with 5% Sheep Blood	254087

We hereby declare that the above mentioned product(s) comply with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Heidelberg/Germany,	October 15, 2012
Name and Authority	Dr. Bernd Peschke Regulatory Affairs Manager G/S/A, Sicherheitsbeauftragter (Safety Officer)
Signature	

Techn. File no.: S-00018

Declaration of Conformity

Manufacturer	**Becton Dickinson GmbH** **Tullastrasse 8-12** **69126 Heidelberg/Germany** **Tel.: +49-62 21-30 50 Fax: +49-62 21-30 52 16**
Conformity Assessment Procedure	**IVD Directive 98/79/EC, Annex III**

Product(s):

Product Name	Cat. No.
Brucella Agar with 5% Horse Blood	255027
Brain Heart Infusion Agar	255003
Chocolate Agar (Blood Agar No. 2 Base)	257011
Chocolate Agar (Blood Agar No. 2 Base)	257456
Chocolate Agar (GC Agar with IsoVitaleX)	254060 ✓ #140.
Chocolate Agar (GC Agar with IsoVitaleX)	254089
Mueller Hinton Chocolate Agar	254035
Mueller Hinton Chocolate Agar	254082

We hereby declare that the above mentioned product(s) comply with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Heidelberg/Germany,	October 15, 2012
Name and Authority	Dr. Bernd Peschke Regulatory Affairs Manager G/S/A, Sicherheitsbeauftragter (Safety Officer)
Signature	

Techn. File no.: S-00014

IVD

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

CE de/en

Pandy's Reagent

Mit diesem Zertifikat erklären wir in alleiniger Verantwortung:

Die nachstehenden in-vitro Diagnostica (IVDs) sind konform mit:

Richtlinie 98/79/EG
Richtlinie des Rates über „In-vitro Diagnostica".

006698-0100	*100ml*
Pandy's Reagenz	
006698-0250	*250ml*
Pandy's Reagenz	

With this certificate we declare on our own responsibility:

The hereafter listed in-vitro diagnostic products (IVDs) are in conformity with:

Directive 98/79/EG
Directive of the council about „In-vitro Diagnostics".

006698-0100	*✓ 100mL* #242,
Pandy's Reagent	
006698-0250	*250mL*
Pandy's Reagent	

EN ISO 9001

Umkirch/Freiburg • Germany

2004-10-22

EN ISO 13485

Manfred F. Rüdinger
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Leitung Qualitätskontrolle • Manager Quality Control
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Quality since 1978 EN ISO 9001 of EN ISO 13485 bioanalytic® Richtlinie • Directive 98/79/EG Germany Fon: +49 (0)7665-5951 Fax: +49 (0)7665-5683

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IVD

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

CE de/en

Samson's Concentrate

Mit diesem Zertifikat erklären wir in alleiniger Verantwortung:

Die nachstehenden in-vitro Diagnostica (IVDs) sind konform mit:

Richtlinie 98/79/EG
Richtlinie des Rates über „In-vitro Diagnostica".

With this certificate we declare on our own responsibility:

The hereafter listed in-vitro diagnostic products (IVDs) are in conformity with:

Directive 98/79/EG
Directive of the council about „In-vitro Diagnostics".

006688-0020	*20ml*
Samson's Konzentrat	
006688-0100	*100ml*
Samson's Konzentrat	

#244.

006688-0020	*20mL*
Samson's Concentrate	
006688-0100	*100mL*
Samson's Concentrate	

#244.

Die Laufzeit des Zertifikats beträgt 5 Jahre ab Ausstellungsdatum.

The expiry date of this certificate is 5 years up from date of issue.

EN ISO 9001 certified

Umkirch/Freiburg • Germany

2009-07-01

EN ISO 13485 certified

Manfred F. Rüdinger
Ing. für biomed. Analysentechnik • Eng. for biomedical Science & Analysis Technology
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Quality since 1978 seit 1978 EN ISO 9001 of EN ISO 13485 bioanalytic® RiLi 98/79/EG Germany Fon: +49 (0)7665-5951 Fax: +49 (0)7665-5683

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Internet: www.bioanalytic.de

Individual Microorganisms

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0373L	0373K	0373P	Streptococcus dysgalactiae subsp. equisimilis NCTC 8543	2	*group C*
0221L	0221K	0221P	Streptococcus equi subsp. equi ATCC® 33398™*	2	*group C*
0656L	0656K	0656P	Streptococcus equi subsp. equi ATCC® 9528™*	2	*group C*
0101L	0101K	0101P	Streptococcus equi subsp. zooepidemicus ATCC® 43079™*	2	
0743L	0743K	0743P	Streptococcus equi subsp. zooepidemicus ATCC® 700400™*	2	
0631L	0631K	0631P	Streptococcus gallolyticus ATCC® 49147™*	1	
0391L	0391K	0391P	Streptococcus gallolyticus ATCC® 9809™*	1	
0949L	0949K	0949P	Streptococcus gallolyticus subsp. gallolyticus ATCC® 49475™*	1	
0423L	0423K	0423P	Streptococcus mitis ATCC® 6249™*	2	
0383L	0383K	0383P	Streptococcus mitis NCIMB 13770	2	
0266L	0266K	0266P	Streptococcus mutans ATCC® 25175™*	1	
0969L	0969K	0969P	Streptococcus mutans ATCC® 35668™*	1	
0401L	0401K	0401P	Streptococcus parasanguinis ATCC® 15909™*	2	
0630L	0630K	0630P	Streptococcus pasteurianus ATCC® 49133™*	1	
0865L	0865K	0865P	Streptococcus pneumoniae ATCC® 10015™*	2	
0435L	0435K	0435P	Streptococcus pneumoniae ATCC® 27336™*	2	
0632L	0632K	0632P	Streptococcus pneumoniae ATCC® 49136™*	2	
0633L	0633K	0633P	Streptococcus pneumoniae ATCC® 49150™*	2	
0947L	0947K	√0947P	Streptococcus pneumoniae ATCC® 49619™* # 85.1.	2	*low level penicillin resistance by oxacillin test*
0523L	0523K	0523P	Streptococcus pneumoniae ATCC® 51916™*	2	
0763L	0763K	0763P	Streptococcus pneumoniae ATCC® 6301™*	2	
0380L	0380K	0380P	Streptococcus pneumoniae ATCC® 6303™*	2	*mucoid colonies*
0447L	0447K	0447P	Streptococcus pneumoniae ATCC® 6305™*	2	
0267L	0267K	0267P	Streptococcus pneumoniae ATCC® 700677™*	2	
0469L	0469K	0469P	Streptococcus pneumoniae NCIMB 13286	2	
0508L	0508K	0508P	Streptococcus pyogenes ATCC® 12344™*	2	*group A; type 1*
0979L	0979K	0979P	Streptococcus pyogenes ATCC® 12384™*	2	*group A; type 3*
0385L	0385K	√0385P	Streptococcus pyogenes ATCC® 19615™* #85.2.	2	*group A*
0994L	0994K	0994P	Streptococcus pyogenes ATCC® 49399™*	2	*group A*
0314L	0314K	0314P	Streptococcus pyogenes NCIMB 13285	2	*group A*
0237L	0237K	0237P	Streptococcus salivarius ATCC® 13419™*	1	
0136L	0136K	0136P	Streptococcus salivarius subsp. thermophilus ATCC® 19258™*	1	*formerly Streptococcus thermophilus*
0858L	0858K	0858P	Streptococcus sanguinis ATCC® 10556™*	2	
0978L	0978K	0978P	Streptococcus species ATCC® 12392™*	1	*group F; type 2*
0864L	0864K	0864P	Streptococcus species ATCC® 12401™*	2	*group B; type Ib*
01096L	01096K	01096P	Streptococcus species ATCC® 9884™*	2	*group G; type 16*

Individual Microorganisms

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
01112L	01112K	01112P	Klebsiella pneumoniae NCTC 13440	2	*metallo-beta-lactamase positive*
0573L	0573K	0573P	Klebsiella pneumoniae NCTC 9633	2	
0684L	0684K	0684P	Klebsiella pneumoniae subsp. pneumoniae ATCC® 10031™*	2	
0458L	0458K	0458P	Klebsiella pneumoniae subsp. pneumoniae ATCC® 13882™*	2	
0351L	0351K	0351P	Klebsiella pneumoniae subsp. pneumoniae ATCC® 13883™*	2	
0685L	0685K	0685P	Klebsiella pneumoniae subsp. pneumoniae ATCC® 27736™*	2	
0261L	0261K	0261P	Klebsiella pneumoniae subsp. pneumoniae ATCC® 31488™*	2	
0957L	0957K	0957P	Klebsiella pneumoniae subsp. pneumoniae ATCC® 33495™*	2	
0942L	0942K	0942P	Klebsiella pneumoniae subsp. pneumoniae ATCC® 35657™*	2	
0683L	0683K	0683P	Klebsiella pneumoniae subsp. pneumoniae ATCC® 4352™*	2	
0784L	0784K	√0784P	Klebsiella pneumoniae subsp. pneumoniae ATCC® 700603™*	2	*ESBL positive* #85, 3.
0103L	0103K	0103P	Klebsiella pneumoniae subsp. pneumoniae ATCC® 8308™*	2	
0305L	0305K	0305P	Klebsiella pneumoniae subsp. pneumoniae NCIMB 8267	2	
0471L	0471K	0471P	Klebsiella pneumoniae subsp. pneumoniae NCIMB 9111	2	
0719L	0719K	0719P	Klebsiella pneumoniae subsp. pneumoniae NCTC 13368	2	
			Kloeckera		
0125L	0125K	0125P	Kloeckera apiculata var. apis ATCC® 32857™*	1	
01012L	01012K	01012P	Kloeckera japonica ATCC® 58370™*	1	
			Kocuria		
0126L	0126K	0126P	Kocuria kristinae ATCC® BAA-752™*	1	
0670L	0670K	0670P	Kocuria rhizophila ATCC® 15957™*	1	
0161L	0161K	0161P	Kocuria rhizophila ATCC® 51820™*	1	*formerly Kocuria varians*
0359L	0359K	0359P	Kocuria rhizophila ATCC® 533™*	1	
0669L	0669K	0669P	Kocuria rhizophila ATCC® 9341a™*	1	
0688L	0688K	0688P	Kocuria rhizophila ATCC® 9341™*	1	
0766L	0766K	0766P	Kocuria rosea ATCC® 186™*	1	
			Lactobacillus		
0885L	0885K	0885P	Lactobacillus acidophilus ATCC® 314™*	1	
0243L	0243K	0243P	Lactobacillus acidophilus ATCC® 4356™*	1	
0546L	0546K	0546P	Lactobacillus casei ATCC® 334™*	1	
0176L	0176K	0176P	Lactobacillus casei ATCC® 393™*	1	
0813L	0813K	0813P	Lactobacillus fermentum ATCC® 9338™*	1	
0127L	0127K	0127P	Lactobacillus gasseri ATCC® 19992™*	1	

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0238L	0238K	0238P	Staphylococcus species ATCC® 155™*	1	
01067L	01067K	01067P	Staphylococcus species ATCC® 27626™*	1	
0946L	0946K	0946P	Staphylococcus warneri ATCC® 49454™*	1	
0605L	0605K	0605P	Staphylococcus xylosus ATCC® 29971™*	2	
0797L	0797K	0797P	Staphylococcus xylosus ATCC® 35033™*	2	
0629L	0629K	0629P	Staphylococcus xylosus ATCC® 49148™*	2	
0741L	0741K	0741P	Staphylococcus xylosus ATCC® 700404™*	1	
			Stenotrophomonas		
01020L	01020K	01020P	Stenotrophomonas maltophilia ATCC® 13636™*	1	*positive control for Etest® metallo Beta-Lactamase strip*
0369L	0369K	0369P	Stenotrophomonas maltophilia ATCC® 13637™*	1	
0759L	0759K	0759P	Stenotrophomonas maltophilia ATCC® 17666™*	1	
0135L	0135K	0135P	Stenotrophomonas maltophilia ATCC® 49130™*	1	
0742L	0742K	0742P	Stenotrophomonas maltophilia ATCC® 51331™*	1	
			Streptococcus		
0439L	0439K	0439P	Streptococcus agalactiae ATCC® 12386™*	2	*group B*
0104L	0104K	0104P	Streptococcus agalactiae ATCC® 12403™*	2	*group B; type III*
0370L	0370K	√0370P	Streptococcus agalactiae ATCC® 13813™* # 85.4,	2	*group B; nonhemolytic in absence of CAMP Factor*
0436L	0436K	0436P	Streptococcus agalactiae ATCC® 27956™*	2	*group B*
0105L	0105K	0105P	Streptococcus agalactiae ATCC® BAA-611™*	2	*group B; serotype V*
0709L	0709K	0709P	Streptococcus agalactiae NCIMB 701348	2	*group B*
0480L	0480K	0480P	Streptococcus agalactiae NCTC 8017	2	*group B*
0710L	0710K	0710P	Streptococcus agalactiae NCTC 9993	2	*group B*
01077L	01077K	01077P	Streptococcus anginosus ATCC® 33397™*	2	*group G; type 1*
0389L	0389K	0389P	Streptococcus anginosus NCTC 10713	2	*group G*
0463L	0463K	0463P	Streptococcus bovis ATCC® 33317™*	1	
0307L	0307K	0307P	Streptococcus bovis NCIMB 700597	2	
0174L	0174K	0174P	Streptococcus criceti ATCC® 19642™*	1	*formerly Streptococcus cricetus*
0603L	0603K	0603P	Streptococcus dysgalactiae subsp. equisimilis ATCC® 12388™*	2	*group C*
0602L	0602K	0602P	Streptococcus dysgalactiae subsp. equisimilis ATCC® 12394™*	2	*group G*
0967L	0967K	0967P	Streptococcus dysgalactiae subsp. equisimilis ATCC® 35666™*	2	*group C*
0776L	0776K	0776P	Streptococcus dysgalactiae subsp. equisimilis ATCC® 9542™*	2	*group C*

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
			Escherichia		
01101L	01101K	01101P	Escherichia coli (O103:H11) CDC 06-3008	2	*serotype O103:H11; eae positive; stx 1 and/or stx 2 positive; export license required for shipping this product outside the United States*
01102L	01102K	01102P	Escherichia coli (O111:H8) CDC 2010C-3114	2	*serotype O111:H8; eae positive; stx 1 and/or stx 2 positive; export license required for shipping this product outside the United States*
01099L	01099K	01099P	Escherichia coli (O121:H19) CDC 02-3211	2	*serotype O121:H19; eae positive; stx 1 and/or stx 2 positive; export license required for shipping this product outside the United States*
01097L	01097K	01097P	Escherichia coli (O145:NM) CDC 99-3311	2	*serotype O145:NM; eae positive; stx 1 and/or stx 2 positive; export license required for shipping this product outside the United States.*
01100L	01100K	01100P	Escherichia coli (O26:H11) CDC 03-3014	2	*serotype O26:H11; eae positive; stx 1 and/or stx 2 positive; export license required for shipping this product outside the United States*
01098L	01098K	01098P	Escherichia coli (O45:H2) CDC 00-3039	2	*serotype O45:H2; eae positive; stx 1 and/or stx 2 positive; export license required for shipping this product outside the United States*
01104L	01104K	01104P	Escherichia coli (O104:H4) ATCC® BAA-2326™**	2	*serotype O104:H4; aggR positive; stx 2 positive; export license required for shipping this product outside the United States*
0617L	0617K	0617P	Escherichia coli (*O157:H7*) ATCC® 35150™* #85.5.	2	*serotype O157:H7; Export license required for shipping this product outside the United States*

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LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0644L	0644K	0644P	Haemophilus influenzae ATCC® 49144™*	2	*beta lactamase producer*
0647L	0647K	0647P	Haemophilus influenzae ATCC® 49247™*	2	
0919L	0919K	0919P	Haemophilus influenzae ATCC® 49766™*	2	
0620L	0620K	0620P	Haemophilus influenzae ATCC® 9006™*	2	*type a*
0185L	0185K	0185P	Haemophilus influenzae ATCC® 9007™*	2	*type c*
0850L	0850K	0850P	Haemophilus influenzae NCTC 11931	2	
0717L	0717K	0717P	Haemophilus influenzae NCTC 12699	2	
0716L	0716K	0716P	Haemophilus influenzae NCTC 13377	2	*type b*
0397L	0397K	0397P	Haemophilus influenzae NCTC 8143	2	
01024L	01024K	01024P	Haemophilus influenzae NCTC 8468 # 85,6,	2	
0377L	0377K	0377P	Haemophilus parahaemolyticus ATCC® 10014™*	2	
			Hafnia		
0165L	0165K	0165P	Hafnia alvei ATCC® 51815™*	1	
			Issatchenkia		
0227L	0227K	0227P	Issatchenkia orientalis ATCC® 6258™*	2	
			Kingella		
0148L	0148K	0148P	Kingella denitrificans ATCC® 33394™*	2	
			Klebsiella		
0530L	0530K	0530P	Klebsiella oxytoca ATCC® 13182™*	2	
0606L	0606K	0606P	Klebsiella oxytoca ATCC® 43086™*	2	
0477L	0477K	0477P	Klebsiella oxytoca ATCC® 43165™*	2	
0214L	0214K	0214P	Klebsiella oxytoca ATCC® 43863™*	2	
0626L	0626K	0626P	Klebsiella oxytoca ATCC® 49131™*	2	
0167L	0167K	0167P	Klebsiella oxytoca ATCC® 51817™*	2	
0757L	0757K	0757P	Klebsiella oxytoca ATCC® 700324™*	2	
0840L	0840K	0840P	Klebsiella oxytoca ATCC® 8724™*	2	
01019L	01019K	01019P	Klebsiella pneumoniae ATCC® BAA-1144™*	2	*control strain for the AmpC disk test; weak positive*
01005L	01005K	01005P	Klebsiella pneumoniae ATCC® BAA-1705™*	2	*Modified Hodge Test (MHT) positive control*
01006L	01006K	01006P	Klebsiella pneumoniae ATCC® BAA-1706™*	2	*Modified Hodge Test (MHT) negative control*
01060L	01060K	01060P	Klebsiella pneumoniae ATCC® BAA-2146™*	2	*New Delhi metallo-beta-lactamase (NDM-1) positive*

Individual Microorganisms

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0623L	0623K	0623P	Enterococcus durans ATCC® 11576™*	1	
0651L	0651K	0651P	Enterococcus durans ATCC® 6056™*	1	
0181L	0181K	0181P	Enterococcus faecalis ATCC® 14506™*	2	
0367L	0367K	0367P	Enterococcus faecalis ATCC® 19433™*	2	
0366L	0366K	0366P	Enterococcus faecalis ATCC® 29212™* # 85.7	2	
0197L	0197K	0197P	Enterococcus faecalis ATCC® 33186™*	2	
0941L	0941K	0941P	Enterococcus faecalis ATCC® 49452™*	2	
0753L	0753K	0753P	Enterococcus faecalis ATCC® 49532™*	2	*Gentamicin-resistant and Streptomycin-sensitive*
0752L	0752K	0752P	Enterococcus faecalis ATCC® 49533™*	2	*Gentamicin-Sensitive and Streptomycin-Resistant*
0959L	0959K	0959P	Enterococcus faecalis ATCC® 51299™*	2	*Vancomycin resistant and high level aminoglycosides, vanB*
01089L	01089K	01089P	Enterococcus faecalis ATCC® 51575™*	2	*Resistant to gentamicin, streptomycin and v ancomycin*
0497L	0497K	0497P	Enterococcus faecalis ATCC® 7080™*	2	
0336L	0336K	0336P	Enterococcus faecalis NCIMB 13280	2	
0714L	0714K	0714P	Enterococcus faecalis NCTC 13379	2	
0472L	0472K	0472P	Enterococcus faecalis NCTC 775	2	
0679L	0679K	0679P	Enterococcus faecium ATCC® 27270™*	2	
0968L	0968K	0968P	Enterococcus faecium ATCC® 35667™*	2	
01052L	01052K	01052P	Enterococcus faecium ATCC® 6057™*	2	
0677L	0677K	0677P	Enterococcus faecium ATCC® 6569™*	2	
01000L	01000K	01000P	Enterococcus faecium ATCC® 700221™*	2	*Vancomycin resistant*
0895L	0895K	0895P	Enterococcus gallinarum ATCC® 49573™*	1	
0745L	0745K	0745P	Enterococcus gallinarum ATCC® 700425™*	1	
0678L	0678K	0678P	Enterococcus hirae ATCC® 10541™*	1	
0624L	0624K	0624P	Enterococcus hirae ATCC® 49135™*	1	*formerly Enterococcus durans*
0935L	0935K	0935P	Enterococcus hirae ATCC® 49479™*	1	*formerly Enterococcus durans*
0650L	0650K	0650P	Enterococcus hirae ATCC® 8043™*	1	
0857L	0857K	0857P	Enterococcus raffinosus ATCC® 49464™*	1	
0223L	0223K	0223P	Enterococcus saccharolyticus ATCC® 43076™*	1	
			Erysipelothrix		
0661L	0661K	0661P	Erysipelothrix rhusiopathiae ATCC® 19414™*	2	

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0337L	0337K	0337P	Micrococcus luteus NCIMB 8166	1	
0740L	0740K	0740P	Micrococcus species ATCC® 700405™*	1	
			Microsporum		
0894L	0894K	0894P	Microsporum canis ATCC® 36299™*	2	*fungus*
0893L	0893K	0893P	Microsporum gypseum ATCC® 24102™*	2	*fungus*
			Moraxella		
0622L	0622K	0622P	Moraxella catarrhalis ATCC® 8176™*	1	*formerly Moraxella (Branhamella) catarrhalis*
0248L	0248K	0248P	Moraxella catarrhalis ATCC® 23246™*	1	*formerly Moraxella (Branhamella) catarrhalis*
0951L	0951K	0951P	Moraxella catarrhalis ATCC® 25238™*	1	*formerly Moraxella (Branhamella) catarrhalis*
0403L	0403K	✓0403P	Moraxella catarrhalis ATCC® 25240™* #85.8,	1	*formerly Moraxella (Branhamella) catarrhalis*
0642L	0642K	0642P	Moraxella catarrhalis ATCC® 49143™*	1	*formerly Moraxella (Branhamella) catarrhalis*
0475L	0475K	0475P	Moraxella osloensis ATCC® 10973™*	2	*formerly Moraxella (Moraxella) osloensis*
			Moraxella (Branhamella)		
0395L	0395K	0395P	Moraxella (Branhamella) catarrhalis NCTC 4103	1	
			Morganella		
0215L	0215K	0215P	Morganella morganii subsp. morganii ATCC® 25829™*	2	
0839L	0839K	0839P	Morganella morganii subsp. morganii ATCC® 25830™*	2	
			Mycobacterium		
0522L	0522K	0522P	Mycobacterium avium subsp. avium ATCC® 15769™*	2	*serotype 1*
0544L	0544K	0544P	Mycobacterium avium subsp. avium ATCC® 25291™*	2	*serotype 2*
0513L	0513K	0513P	Mycobacterium fortuitum subsp. fortuitum ATCC® 6841™*	2	
0995L	0995K	0995P	Mycobacterium gordonae ATCC® 14470™*	2	
0364L	0364K	0364P	Mycobacterium gordonae NCTC 10267	2	
01049L	01049K	01049P	Mycobacterium haemophilum ATCC® 29548™*	2	*requires hemin (x factor) for growth*
0157L	0157K	0157P	Mycobacterium intracellulare ATCC® 13950™*	2	
0545L	0545K	0545P	Mycobacterium kansasii ATCC® 12478™*	2	
0512L	0512K	0512P	Mycobacterium peregrinum ATCC® 700686™*	2	
0721L	0721K	0721P	Mycobacterium smegmatis ATCC® 14468™*	1	

Individual Microorganisms

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0120L	0120K	0120P	Bacillus subtilis subsp. subtilis ATCC® 6051™*	1	
0270L	0270K	0270P	Bacillus thuringiensis ATCC® 10792™*	1	
0539L	0539K	0539P	Bacillus thuringiensis ATCC® 33679™*	1	*serotype H3:3a,3b*
			Bacteroides		
0940L	0940K	0940P	Bacteroides fragilis ATCC® 23745™*	2	
0320L	0320K	0320P	Bacteroides fragilis ATCC® 25285™* #85, 9.	2	
0358L	0358K	0358P	Bacteroides fragilis NCTC 9343	2	
0400L	0400K	0400P	Bacteroides ovatus ATCC® 8483™*	2	
0585L	0585K	0585P	Bacteroides ovatus ATCC® BAA-1296™*	2	
0587L	0587K	0587P	Bacteroides ovatus ATCC® BAA-1304™*	2	
0319L	0319K	0319P	Bacteroides thetaiotaomicron ATCC® 29741™*	2	
0619L	0619K	0619P	Bacteroides uniformis ATCC® 8492™*	2	
0908L	0908K	0908P	Bacteroides ureolyticus ATCC® 33387™*	2	
0848L	0848K	0848P	Bacteroides vulgatus ATCC® 29327™*	2	
0445L	0445K	0445P	Bacteroides vulgatus ATCC® 8482™*	2	
			Bifidobacterium		
01092L	01092K	01092P	Bifidobacterium animalis subsp. animalis ATCC® 25527™*	1	
01025L	01025K	01025P	Bifidobacterium bifidum ATCC® 11863™*	1	
0175L	0175K	0175P	Bifidobacterium breve ATCC® 15700™*	1	
			Bordetella		
0655L	0655K	0655P	Bordetella bronchiseptica ATCC® 10580™*	2	
0671L	0671K	0671P	Bordetella bronchiseptica ATCC® 4617™*	2	
0842L	0842K	0842P	Bordetella parapertussis ATCC® 15311™*	2	
0489L	0489K	0489P	Bordetella pertussis ATCC® 8467™*	2	
0100L	0100K	0100P	Bordetella pertussis ATCC® 9340™*	2	
0843L	0843K	0843P	Bordetella pertussis ATCC® 9797™*	2	
			Brevibacillus		
0139L	0139K	0139P	Brevibacillus agri ATCC® 51663™*	1	
0798L	0798K	0798P	Brevibacillus brevis ATCC® 8246™*	1	
0144L	0144K	0144P	Brevibacillus laterosporus ATCC® 64™*	1	
			Brevundimonas		
0754L	0754K	0754P	Brevundimonas diminuta ATCC® 11568™*	1	
0805L	0805K	0805P	Brevundimonas diminuta ATCC® 19146™*	1	

Individual Microorganisms

LYFO DISK®	KWIK STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0292L	0292K	0292P	Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 49416™*	2	*highly mutable; recommended for Ames test*
0180L	0180K	0180P	Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 51812™*	2	
0301L	0301K	0301P	Salmonella enterica subsp. enterica serovar Typhimurium NCIMB 13284	2	
0340L	0340K	0340P	Salmonella enterica subsp. enterica serovar Typhimurium NCTC 74	2	
0342L	0342K	0342P	Salmonella enterica subsp. enterica serovar Vellore ATCC® 15611™*	2	*group B*
01087L	01087K	01087P	Salmonella enterica subsp. salamae serotype Tranaroa NCTC 10252	2	
			Scopulariopsis		
0171L	0171K	0171P	Scopulariopsis acremonium ATCC® 58636™*	1	*fungus*
			Serratia		
0838L	0838K	0838P	Serratia liquefaciens ATCC® 27592™*	1	
0247L	0247K	0247P	Serratia marcescens ATCC® 13880™*	1	
0506L	0506K	0506P	Serratia marcescens ATCC® 14041™*	1	*pigmented*
0806L	0806K	0806P	Serratia marcescens ATCC® 14756™*	1	*pigmented*
0216L	0216K	0216P	Serratia marcescens ATCC® 43861™*	1	
0262L	0262K	0262P	Serratia marcescens ATCC® 43862™*	1	
0354L	0354K	0354P	Serratia marcescens ATCC® 8100™*	1	
0654L	0654K	0654P	Serratia odorifera ATCC® 33077™*	2	
			Shewanella		
0638L	0638K	0638P	Shewanella haliotis ATCC® 49138™*	1	*formerly Shewanella putrefaciens*
0888L	0888K	0888P	Shewanella putrefaciens ATCC® 8071™*	1	
			Shigella		
0349L	0349K	0349P	Shigella boydii ATCC® 9207™*	2	*serotype 1*
0356L	0356K	√0356P	Shigella flexneri ATCC® 12022™* #85,10,	2	*serotype 2b*
0348L	0348K	0348P	Shigella flexneri ATCC® 9199™*	2	*serotype 1a*
0303L	0303K	√0303P	Shigella sonnei ATCC® 25931™* #85,11,	2	
0350L	0350K	0350P	Shigella sonnei ATCC® 29930™*	2	
0446L	0446K	0446P	Shigella sonnei ATCC® 9290™*	2	
0705L	0705K	0705P	Shigella sonnei NCTC 12984	2	

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LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0190L	0190K	0190P	Proteus mirabilis ATCC® 33583™*	2	
0944L	0944K	0944P	Proteus mirabilis ATCC® 35659™*	2	
0432L	0432K	0432P	Proteus mirabilis ATCC® 43071™*	2	
0607L	0607K	0607P	Proteus mirabilis ATCC® 7002™*	2	
0310L	0310K	0310P	Proteus mirabilis NCIMB 13283	2	
0300L	0300K	0300P	Proteus vulgaris ATCC® 33420™*	2	
0640L	0640K	√0640P	Proteus vulgaris ATCC® 49132™*	2	#85.20.
0459L	0459K	0459P	Proteus vulgaris ATCC® 6380™*	2	
0841L	0841K	0841P	Proteus vulgaris ATCC® 6896™*	2	
0691L	0691K	0691P	Proteus vulgaris ATCC® 8427™*	2	
0393L	0393K	0393P	Proteus vulgaris NCTC 4636	2	
			Prototheca		
0780L	0780K	0780P	Prototheca wickerhamii ATCC® 16529™*	1	
			Providencia		
0834L	0834K	0834P	Providencia alcalifaciens ATCC® 51902™*	2	
0692L	0692K	0692P	Providencia alcalifaciens ATCC® 9886™*	1	
0997L	0997K	0997P	Providencia rettgeri ATCC® 9250™*	2	
0384L	0384K	0384P	Providencia stuartii ATCC® 33672™*	1	
0879L	0879K	0879P	Providencia stuartii ATCC® 49809™*	1	
			Pseudomonas		
0416L	0416K	0416P	Pseudomonas aeruginosa ATCC® 10145™*	2	
01078L	01078K	01078P	Pseudomonas aeruginosa ATCC® 13388™*	2	
0693L	0693K	0693P	Pseudomonas aeruginosa ATCC® 15442™*	2	*Pyocyanin not produced*
0199L	0199K	0199P	Pseudomonas aeruginosa ATCC® 19429™*	2	
0695L	0695K	0695P	Pseudomonas aeruginosa ATCC® 25619™*	2	
0353L	0353K	√0353P	Pseudomonas aeruginosa ATCC® 27853™* #85,12,	2	
0975L	0975K	0975P	Pseudomonas aeruginosa ATCC® 35032™*	2	
0182L	0182K	0182P	Pseudomonas aeruginosa ATCC® 35554™*	2	
0484L	0484K	0484P	Pseudomonas aeruginosa ATCC® 9027™*	2	
01009L	01009K	01009P	Pseudomonas aeruginosa ATCC® 9721™*	2	
01010L	01010K	01010P	Pseudomonas aeruginosa ATCC® BAA-1744™*	2	
0297L	0297K	0297P	Pseudomonas aeruginosa ATCC® BAA-427™*	2	
0598L	0598K	0598P	Pseudomonas aeruginosa NCIMB 12469	2	
0304L	0304K	0304P	Pseudomonas aeruginosa NCIMB 8295	2	
0576L	0576K	0576P	Pseudomonas aeruginosa NCIMB 8626	2	
0830L	0830K	0830P	Pseudomonas aeruginosa NCTC 10662	2	
0241L	0241K	0241P	Pseudomonas fluorescens ATCC® 13525™*	1	

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LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0901L	0901K	0901P	Salmonella enterica subsp. arizonae ATCC® 13314™*	2	
01054L	01054K	01054P	Salmonella enterica subsp. diarizonae ATCC® 12325™*	2	*lactose broth positive; H_2S positive*
01045L	01045K	01045P	Salmonella enterica subsp. diarizonae ATCC® 29934™*	2	*lactose broth positive; H_2S negative*
0501L	0501K	0501P	Salmonella enterica subsp. enterica ATCC® 51741™*	2	*H_2S negative; formerly Salmonella enterica subsp. enterica serovar Infantis*
0817L	0817K	0817P	Salmonella enterica subsp. enterica serovar Abaetetuba ATCC® 35640™*	2	
0826L	0826K	0826P	Salmonella enterica subsp. enterica serovar Abaetetuba Silliker® SLR156	2	
0890L	0890K	0890P	Salmonella enterica subsp. enterica serovar Abony NCTC 6017	2	
01056L	01056K	01056P	Salmonella enterica subsp. enterica serovar Abortusequi ATCC® 9842™*	2	*H_2S negative*
0346L	0346K	0346P	Salmonella enterica subsp. enterica serovar Anatum ATCC® 9270™*	2	*group E*
0902L	0902K	0902P	Salmonella enterica subsp. enterica serovar Choleraesuis ATCC® 10708™*	2	*H_2S negative*
0343L	0343K	0343P	Salmonella enterica subsp. enterica serovar Choleraesuis ATCC® 7001™*	2	*group C; H_2S negative*
0903L	0903K	0903P	Salmonella enterica subsp. enterica serovar Choleraesuis var Kunzendorf ATCC® 12011™*	2	
0345L	0345K	✓0345P	Salmonella enterica subsp. enterica serovar Enteritidis ATCC® 13076™*	2	*group D* #85, 13,
01095L	01095K	01095P	Salmonella enterica subsp. enterica serovar Newport ATCC® 6962™*	2	
0341L	0341K	0341P	Salmonella enterica subsp. enterica serovar Paratyphi ATCC® 9150™*	2	*group A; H_2S negative*
0851L	0851K	0851P	Salmonella enterica subsp. enterica serovar Poona NCTC 4840	2	
0604L	0604K	0604P	Salmonella enterica subsp. enterica serovar Pullorum ATCC® 13036™*	2	*H_2S negative*
0344L	0344K	0344P	Salmonella enterica subsp. enterica serovar Tallahassee ATCC® 12002™*	2	
0421L	0421K	0421P	Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 13311™*	2	
0363L	0363K	0363P	Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 14028™*	2	
0253L	0253K	0253P	Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 25241™*	2	
0541L	0541K	0541P	Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 29629™*	2	*H_2S negative*

Individual Microorganisms

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
			Yarrowia		
0950L	0950K	0950P	Yarrowia lipolytica ATCC® 9773™*	1	
			Yersinia		
0316L	0316K	0316P	Yersinia enterocolitica subsp. enterocolitica ATCC® 23715™*	2	*biotype 1; serotype 8*
0909L	0909K	0909P	Yersinia enterocolitica subsp. enterocolitica ATCC® 27729™*	2	*biotype 1; serotype 8*
0938L	0938K	0938P	Yersinia enterocolitica subsp. enterocolitica ATCC® 9610™*	2	*biovar 1; serogroup O:8*
0974L	0974K	0974P	Yersinia kristensenii ATCC® 33639™*	2	
0785L	0785K	0785P	Yersinia ruckeri ATCC® 29473™*	1	
			Zygosaccharomyces		
01011L	01011K	01011P	Zygosaccharomyces bailii ATCC® MYA-4549™*	1	
0960L	0960K	0960P	Zygosaccharomyces bisporus ATCC® 34890™*	1	*formerly Zygosaccharomyces rouxii*
0803L	0803K	0803P	Zygosaccharomyces rouxii ATCC® 28253™*	1	
0255L	0255K	0255P	Zygosaccharomyces rouxii NCYC 381	1	

Specialty Items

CAT #	Product Description	BSL	Comment
	Products for Cepheid® Instruments		
0360MSSA	Staphylococcus aureus subsp. aureus ATCC® 25923™*	2	*Two KWIK-STIK™ Units at E4; for use with Cepheid® GeneXpert Systems only*
0158MRSA	Staphylococcus aureus subsp. aureus ATCC® 700699™*	2	*Two KWIK-STIK™ units at E4; for use with Cepheid® GeneXpert System only; Methicillin resistant*
0371MSSE	Staphylococcus epidermidis ATCC® 12228™*	1	*Two KWIK-STIK™ units at E4; For use with Cepheid® GeneXpert System only*

Note: Additional Cepheid® Sets located are located on pages 36-37.

	Products for Roche Molecular Diagnostics Instruments		
0158ROCHE	Staphylococcus aureus subsp. aureus ATCC® 700699™*	2	*Two KWIK-STIK™ units at E4; for use with the LightCycler® MRSA Advanced Test from Roche Molecular Diagnostics only*

Note: BD GeneOhm™ sets are located on page 35. Cepheid® Smart GBS™ and Xpert™ sets are located on pages 36-37.

Individual Microorganisms

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0795L	0795K	0795P	Escherichia coli ATCC® 43888™*	2	*serotype O157:H7; does not produce Shiga-Like Toxin I or II*
0231L	0231K	0231P	Escherichia coli ATCC® 700728™*	1	*serotype O157:H7; for USA shipment only; nontoxigenic*
01069L	01069K	01069P	Escherichia coli NCTC 10279	2	*serovar 0145:K(B):H-; for USA shipment only*
01074L	01074K	01074P	Escherichia coli NCTC 10677	2	*serovar 0146:K:H21; for USA shipment only*
0861L	0861K	0861P	Escherichia coli NCTC 12900	1	*serotype O157:H7; non toxigenic; for USA shipment only*
01072L	01072K	01072P	Escherichia coli NCTC 8009	2	*serovar 0111:K58(B4):H2; for USA shipment only*
01071L	01071K	01071P	Escherichia coli NCTC 8620	2	*serovar 026:K60(B6):H-; for USA shipment only*
01062L	01062K	01062P	Escherichia coli NCTC 8622	2	*serovar 0126:K7(B16):H2; for USA shipment only*
01073L	01073K	01073P	Escherichia coli NCTC 9091	2	*serovar 091:H-; for USA shipment only*
01070L	01070K	01070P	Escherichia coli NCTC 9103	2	*serovar 0103:H8; for USA shipment only*
0204L	0204K	0204P	Escherichia coli (JM101) ATCC® 33876™*	1	
0680L	0680K	0680P	Escherichia coli ATCC® 10536™*	1	
01050L	01050K	01050P	Escherichia coli ATCC® 10799™*	1	
0681L	0681K	0681P	Escherichia coli ATCC® 11229™*	1	
0502L	0502K	0502P	Escherichia coli ATCC® 11303™*	1	
0465L	0465K	0465P	Escherichia coli ATCC® 11775™*	1	*serovar O1:K1:H7*
0747L	0747K	0747P	Escherichia coli ATCC® 13706™*	1	
0682L	0682K	0682P	Escherichia coli ATCC® 13762™*	1	
0543L	0543K	0543P	Escherichia coli ATCC® 14169™*	1	
0202L	0202K	0202P	Escherichia coli ATCC® 14948™*	1	
01037L	01037K	01037P	Escherichia coli ATCC® 15597™*	1	*Host for MS2 Bacteriophage (ATCC® 15597™*-B1)*
0203L	0203K	0203P	Escherichia coli ATCC® 23848™*	1	*Genotype B*
0335L	0335K	✓0335P	Escherichia coli ATCC® 25922™* #85,15.	1	
0887L	0887K	0887P	Escherichia coli ATCC® 33605™*	1	
01064L	01064K	01064P	Escherichia coli ATCC® 33849™*	1	*DH1; transformation host*

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Individual Microorganisms

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0113L	0113K	0113P	Staphylococcus aureus subsp. aureus ATCC® 9144™*	2	
01055L	01055K	01055P	Staphylococcus aureus subsp. aureus ATCC® BAA-44™*	2	*Methicillin resistant*
0146L	0146K	0146P	Staphylococcus aureus subsp. aureus ATCC® BAA-976™*	2	*Clindamycin sensitive; D-zone test negative*
0147L	0147K	0147P	Staphylococcus aureus subsp. aureus ATCC® BAA-977™*	2	*Clindamycin resistant; D-zone test positive*
0312L	0312K	0312P	Staphylococcus aureus subsp. aureus NCIMB 12702	2	
0579L	0579K	0579P	Staphylococcus aureus subsp. aureus NCIMB 9518	2	
0713L	0713K	0713P	Staphylococcus aureus subsp. aureus NCTC 12973	2	
0533L	0533K	0533P	Staphylococcus capitis ATCC® 146™*	1	*formerly Staphylococcus epidermidis*
0963L	0963K	0963P	Staphylococcus capitis subsp. capitis ATCC® 35661™*	1	
0371L	0371K	✓0371P	Staphylococcus epidermidis ATCC® 12228™*	1	#85, 16,
0412L	0412K	0412P	Staphylococcus epidermidis ATCC® 14990™*	1	
0628L	0628K	0628P	Staphylococcus epidermidis ATCC® 49134™*	2	
0976L	0976K	0976P	Staphylococcus epidermidis ATCC® 49461™*	2	
01068L	01068K	01068P	Staphylococcus epidermidis ATCC® 51625™*	2	*Methicillin resistant*
0155L	0155K	0155P	Staphylococcus epidermidis ATCC® 700296™*	1	
0571L	0571K	0571P	Staphylococcus epidermidis NCIMB 8853	1	
0219L	0219K	0219P	Staphylococcus gallinarum ATCC® 700401™*	1	
0246L	0246K	0246P	Staphylococcus haemolyticus ATCC® 29970™*	2	
0739L	0739K	0739P	Staphylococcus lentus ATCC® 700403™*	1	
0217L	0217K	0217P	Staphylococcus lugdunensis ATCC® 49576™*	1	
0762L	0762K	0762P	Staphylococcus lugdunensis ATCC® 700328™*	2	
0907L	0907K	0907P	Staphylococcus pseudintermedius ATCC® 49444™*	2	*formerly Staphylococcus aureus subsp. aureus; recommended for CAMP test for Listeria monocytogenes*
0494L	0494K	0494P	Staphylococcus saprophyticus ATCC® 15305™*	1	
01035L	01035K	01035P	Staphylococcus saprophyticus ATCC® 35552™*	1	
0529L	0529K	0529P	Staphylococcus saprophyticus ATCC® 43867™*	1	
0945L	0945K	0945P	Staphylococcus saprophyticus ATCC® 49453™*	1	
0881L	0881K	0881P	Staphylococcus saprophyticus ATCC® 49907™*	1	
0134L	0134K	0134P	Staphylococcus saprophyticus ATCC® BAA-750™*	1	
0470L	0470K	0470P	Staphylococcus saprophyticus subsp. saprophyticus NCIMB 8711	2	
0460L	0460K	0460P	Staphylococcus sciuri subsp. sciuri ATCC® 29060™*	1	
0764L	0764K	0764P	Staphylococcus sciuri subsp. sciuri ATCC® 29061™*	1	
0413L	0413K	0413P	Staphylococcus simulans ATCC® 27851™*	2	

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LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
			Sphingobacterium		
0948L	0948K	0948P	Sphingobacterium multivorum ATCC® 35656™*	2	
			Sphingomonas		
0274L	0274K	0274P	Sphingomonas paucimobilis ATCC® 29837™*	2	
			Sporidiobolus		
01013L	01013K	01013P	Sporidiobolus salmonicolor ATCC® MYA-4550™*	1	
			Staphylococcus		
0179L	0179K	0179P	Staphylococcus aureus ATCC® BAA-1026™*	2	
01007L	01007K	01007P	Staphylococcus aureus ATCC® BAA-1708™*	2	*mupA positive by PCR*
01065L	01065K	01065P	Staphylococcus aureus NCTC 12493 #85.23.	2	*EUCAST Strain; methicillin resistant*
0831L	0831K	0831P	Staphylococcus aureus NCTC 6571	2	
0462L	0462K	0462P	Staphylococcus aureus subsp. aureus ATCC® 11632™*	2	*beta lactamase producer*
0173L	0173K	0173P	Staphylococcus aureus subsp. aureus ATCC® 12600™*	2	
01093L	01093K	01093P	Staphylococcus aureus subsp. aureus ATCC® 14775™*	2	#85.17.
0360L	0360K	0360P	Staphylococcus aureus subsp. aureus ATCC® 25923™*	2	*recommended for CAMP Test*
0700L	0700K	0700P	Staphylococcus aureus subsp. aureus ATCC® 27734™*	2	
0365L	0365K	0365P	Staphylococcus aureus subsp. aureus ATCC® 29213™*	2	#85.18.
0906L	0906K	0906P	Staphylococcus aureus subsp. aureus ATCC® 29737™*	2	
0496L	0496K	0496P	Staphylococcus aureus subsp. aureus ATCC® 33591™*	2	*Methicillin resistant*
0889L	0889K	0889P	Staphylococcus aureus subsp. aureus ATCC® 33592™*	2	*Gentamicin and Methicillin resistant*
0352L	0352K	0352P	Staphylococcus aureus subsp. aureus ATCC® 33862™*	2	*recommended for CAMP Test*
0852L	0852K	0852P	Staphylococcus aureus subsp. aureus ATCC® 43300™*	2	*Methicillin resistant; mec A positive*
0937L	0937K	0937P	Staphylococcus aureus subsp. aureus ATCC® 49476™*	2	
0832L	0832K	0832P	Staphylococcus aureus subsp. aureus ATCC® 51153™*	2	
0159L	0159K	0159P	Staphylococcus aureus subsp. aureus ATCC® 51740™*	2	
0827L	0827K	0827P	Staphylococcus aureus subsp. aureus ATCC® 6538P™*	2	
0485L	0485K	0485P	Staphylococcus aureus subsp. aureus ATCC® 6538™*	2	
01022L	01022K	01022P	Staphylococcus aureus subsp. aureus ATCC® 700698™*	2	*Methicillin resistant; GRD Etest® control*
0158L	0158K	0158P	Staphylococcus aureus subsp. aureus ATCC® 700699™*	2	*Methicillin resistant; Mu50; reduced Vancomycin susceptibility*

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
			Brochothrix		
0150L	0150K	0150P	Brochothrix thermosphacta ATCC® 11509™*	1	
			Burkholderia		
0488L	0488K	0488P	Burkholderia cepacia ATCC® 25416™*	2	
0836L	0836K	0836P	Burkholderia cepacia ATCC® 25608™*	2	
			Campylobacter		
01023L	01023K	01023P	Campylobacter coli ATCC® 33559™*	2	
0121L	0121K	0121P	Campylobacter coli ATCC® 43478™*	2	
0325L	0325K	0325P	Campylobacter jejuni subsp. jejuni ATCC® 29428™*	2	
0481L	0481K	0481P	Campylobacter jejuni subsp. jejuni ATCC® 33291™*	2	
0111L	0111K	√0111P	Campylobacter jejuni subsp. jejuni ATCC® 33560™*	2	#85.22.
0525L	0525K	0525P	Campylobacter jejuni subsp. jejuni ATCC® 43430™*	2	*serotype O:2*
0251L	0251K	0251P	Campylobacter jejuni subsp. jejuni ATCC® 49943™*	2	
0188L	0188K	0188P	Campylobacter jejuni subsp. jejuni ATCC® BAA-1153™*	2	
0718L	0718K	0718P	Campylobacter jejuni subsp. jejuni NCTC 11322	2	
0339L	0339K	0339P	Campylobacter jejuni subsp. jejuni NCTC 11351	2	*serotype 23*
0712L	0712K	0712P	Campylobacter jejuni subsp. jejuni NCTC 13367	2	
			Candida		
0443L	0443K	0443P	Candida albicans ATCC® 10231™*	1	
0332L	0332K	0332P	Candida albicans ATCC® 14053™*	1	
0896L	0896K	0896P	Candida albicans ATCC® 2091™*	1	
0800L	0800K	0800P	Candida albicans ATCC® 24433™*	1	
0672L	0672K	0672P	Candida albicans ATCC® 26790™*	1	
0425L	0425K	0425P	Candida albicans ATCC® 60193™*	1	
0538L	0538K	0538P	Candida albicans ATCC® 62376™*	1	
0981L	0981K	0981P	Candida albicans ATCC® 66027™*	1	
0264L	0264K	0264P	Candida albicans ATCC® 90028™*	1	
0250L	0250K	√0250P	Candida albicans ATCC® 90029™*	1	#85.19.
0379L	0379K	0379P	Candida albicans NCYC 1363	1	
0187L	0187K	0187P	Candida catenulata ATCC® 10565™*	1	
0520L	0520K	0520P	Candida geochares ATCC® 36852™*	1	
0737L	0737K	0737P	Candida glabrata ATCC® 15126™*	1	
0992L	0992K	0992P	Candida glabrata ATCC® 2001™*	1	
0226L	0226K	0226P	Candida glabrata ATCC® 64677™*	1	
0986L	0986K	0986P	Candida glabrata ATCC® 66032™*	1	
0122L	0122K	0122P	Candida glabrata ATCC® MYA-2950™*	1	

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Individual Microorganisms

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0514L	0514K	0514P	Mycobacterium smegmatis ATCC® 19420™*	1	
0114L	0114K	0114P	Mycobacterium smegmatis ATCC® 607™*	1	
0272L	0272K	0272P	Mycobacterium terrae ATCC® 15755™*	1	
0112L	0112K	0112P	Mycobacterium tuberculosis ATCC® 25177™*	2	*attenuated*
			Mycoplasma		
0156L	0156K	0156P	Mycoplasma hominis ATCC® 15488™*	2	
01053L	01053K	01053P	Mycoplasma bovis ATCC® 25025™*	2	
0156L	0156K	0156P	Mycoplasma hominis ATCC® 15488™*	2	
0504L	0504K	0504P	Mycoplasma orale ATCC® 23714™*	2	
0503L	0503K	0503P	Mycoplasma pneumoniae ATCC® 15531™*	2	
			Myroides		
0324L	0324K	0324P	Myroides odoratus ATCC® 4651™*	1	
			Neisseria		
0378L	0378K	0378P	Neisseria gonorrhoeae ATCC® 19424™*	2	
0375L	0375K	0375P	Neisseria gonorrhoeae ATCC® 31426™*	2	*beta lactamase producer*
0429L	0429K	0429P	Neisseria gonorrhoeae ATCC® 43069™*	2	
0426L	0426K	0426P	Neisseria gonorrhoeae ATCC® 43070™*	2	
0648L	0648K	0648P	Neisseria gonorrhoeae ATCC® 49226™*	2	# 85.21.
0552L	0552K	0552P	Neisseria gonorrhoeae ATCC® 49498™*	2	
0952L	0952K	0952P	Neisseria gonorrhoeae ATCC® 49981™*	2	*Penicillin resistant*
0368L	0368K	0368P	Neisseria gonorrhoeae NCTC 8375	2	
0405L	0405K	0405P	Neisseria lactamica ATCC® 23970™*	2	
0943L	0943K	0943P	Neisseria lactamica ATCC® 23971™*	2	
0646L	0646K	0646P	Neisseria lactamica ATCC® 49142™*	2	
0453L	0453K	0453P	Neisseria meningitidis ATCC® 13077™*	2	*serogroup A*
0454L	0454K	0454P	Neisseria meningitidis ATCC® 13090™*	2	*serogroup B*
0404L	0404K	0404P	Neisseria meningitidis ATCC® 13102™*	2	*serogroup C*
01004L	01004K	01004P	Neisseria meningitidis ATCC® 13113™*	2	*serogroup D*
0268L	0268K	0268P	Neisseria meningitidis ATCC® 35561™*	2	*serogroup Y*
0649L	0649K	0649P	Neisseria meningitidis NCTC 10026	2	*serogroup B*
0653L	0653K	0653P	Neisseria mucosa ATCC® 19695™*	2	
0131L	0131K	0131P	Neisseria mucosa ATCC® 49233™*	2	
0390L	0390K	0390P	Neisseria mucosa NCTC 10774	2	
0456L	0456K	0456P	Neisseria perflava ATCC® 14799™*	1	
0464L	0464K	0464P	Neisseria sicca ATCC® 29193™*	1	
0406L	0406K	0406P	Neisseria sicca ATCC® 9913™*	1	

Individual Microorganisms

LYFO DISK®	KWIK-STIK™ 6PK	KWIK-STIK™ 2PK	Microorganism Description	BSL	Comment
0687L	0687K	0687P	Listeria monocytogenes ATCC® 19115™*	2	*serotype 4b*
0154L	0154K	0154P	Listeria monocytogenes ATCC® 19118™*	2	*serotype 4e*
0398L	0398K	0398P	Listeria monocytogenes ATCC® 7644™*	2	#85.24.
0130L	0130K	0130P	Listeria monocytogenes ATCC® BAA-751™*	2	
0254L	0254K	0254P	Listeria monocytogenes Cornell University SLR2249	2	*Act A gene removed*
0783L	0783K	0783P	Listeria monocytogenes NCTC 10890	2	*serotype 7*
0802L	0802K	0802P	Listeria seeligeri ATCC® 35967™*	1	
0816L	0816K	0816P	Listeria welshimeri ATCC® 35897™*	1	
			Lysinibacillus		
0810L	0810K	0810P	Lysinibacillus sphaericus ATCC® 4525™*	1	*formerly Bacillus sphaericus*
			Macrococcus		
0415L	0415K	0415P	Macrococcus caseolyticus ATCC® 13518™*	1	*formerly Staphylococcus epidermidis*
0962L	0962K	0962P	Macrococcus caseolyticus ATCC® 35662™*	2	
			Malassezia		
0701L	0701K	0701P	Malassezia furfur ATCC® 14521™*	2	*fungus*
			Mannheimia		
0664L	0664K	0664P	Mannheimia haemolytica ATCC® 33396™*	2	
			Methylobacterium		
01110L	01110K	01110P	Methylobacterium extorquens ATCC® BAA-2500™*	1	
0280L	0280K	0280P	Methylobacterium mesophilicum ATCC® 29983™*	1	
			Microbacterium		
0163L	0163K	0163P	Microbacterium esteraromaticum ATCC® 51822™*	1	
01042L	01042K	01042P	Microbacterium liquefaciens ATCC® BAA-1819™*	1	
01041L	01041K	01041P	Microbacterium paraoxydans ATCC® BAA-1818™*	1	
0295L	0295K	0295P	Microbacterium testaceum ATCC® 15829™*	1	
			Micrococcus		
0689L	0689K	0689P	Micrococcus luteus ATCC® 10240™*	1	
0242L	0242K	0242P	Micrococcus luteus ATCC® 4698™*	1	
0804L	0804K	0804P	Micrococcus luteus ATCC® 49732™*	1	
0218L	0218K	0218P	Micrococcus luteus ATCC® 7468™*	1	

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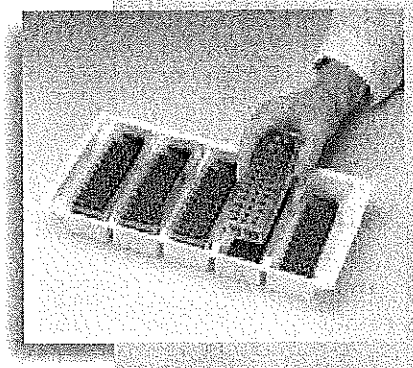
BD Crystal™ Manual Identification

BD Crystal™ Test Kits



The Crystal™ Kits are a miniaturised identification method. Many of the tests used are modifications of classical methods. These include tests for fermentation, oxidation, degradation and hydrolysis of various substrates. In addition, there are chromogen linked substrates to detect enzymes that microbes use to metabolise various substrates.
One-step inoculation with no pipetting for dramatically reduced hands-on time and virtually no repetitive movements. Reagents are pre-dispensed in the wells so no reagent additions or oil overlay are needed. All components are included in every test kit. After inoculation, the snap-on lid ensures a closed system for integrity, safety and no spillage. Each panel IDs many organisms so fewer kits are needed.

CAT. NO.	SIZE	DESCRIPTION
245000	20 tests/kit	BD Crystal™ - Enteric/Nonfermenter ID Kit

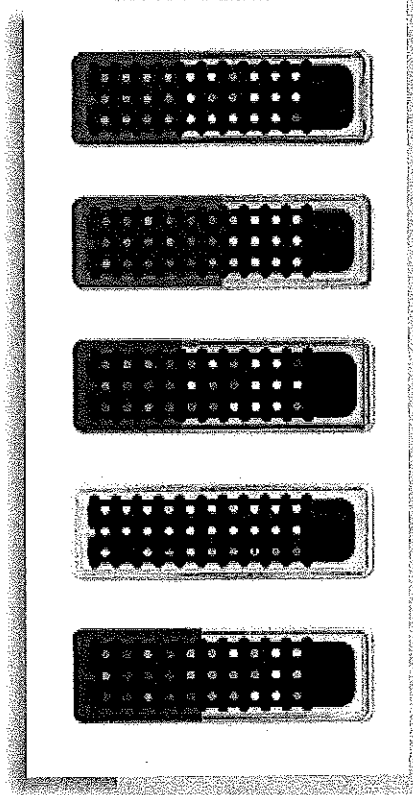
#88.1.

For the identification of aerobic Gram-negative bacteria that belong to the family Enterobacteriaceae as well as some of the more frequently isolated glucose fermenting and non-fermenting Gram-negative bacilli.
The kit contains:
- 20 panel lids
- 20 panel bases
- 20 inoculum tubes
- 2 incubation trays
- 1 result pad

245010	20 tests/kit	BD Crystal™ - Anaerobe ID Kit

#88.2.

Intended for the identification of clinically significant anaerobic bacteria in 4 hours. Separate databases for Schaedler Blood Agar, CDC Anaerobe Blood Agar and Alternate Blood Agars are included for improved specificity.
The kit contains:
- 20 panel lids
- 20 panel bases
- 20 inoculum tubes
- 2 incubation trays
- 1 result pad



245130	20 tests/kit	BD Crystal™ - Neisseria/Haemophilus ID Kit

Intended for the identification of frequently isolated *Neisseria* and *Haemophilus* species as well as several other fastidious bacteria. The kit identifies 35 organisms from multiple media.
The kit contains:
- 20 panel lids
- 20 panel bases
- 20 inoculum tubes
- 2 incubation trays
- 1 result pad

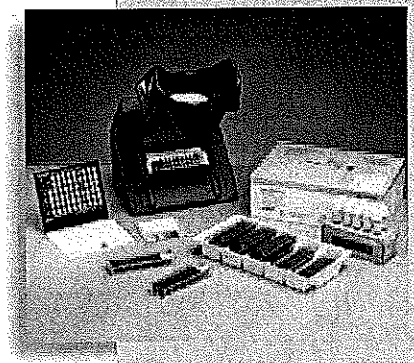
245140	20 tests/kit	BD Crystal™ - Gram-Positive ID Kit

#88.3.

Intended for the identification of frequently isolated aerobic Gram-positive bacteria.
The kit contains:
- 20 panel lids
- 20 panel bases
- 20 inoculum tubes
- 2 incubation trays
- 1 result pad

245150	20 tests/kit	BD Crystal™ - Rapid Gram-Positive ID Kit

For the identification of frequently isolated aerobic Gram-positive bacteria. The kit identifies 88 Gram-positive organisms from multiple media.
The kit congains:
- 20 panel lids
- 20 panel bases
- 20 inoculum tubes
- 2 incubation trays
- 1 result pad



BD CrystalSpec™ Nephelometer User's Guide

CE 8809791 2004/07

#88.4.

See symbol glossary at end of insert. / Viz popis symbolů na konci příbalového letáku. / Se symbolglossaret i slutningen af indlægssedlen. / Zie lijst met symbolen aan het einde van de bijsluiter. / Vaadake sümbolite seletust infolehe lõpus. / Katso pakkausselosteen lopussa olevaa kuvamerkkien sanastoa. / Voir le glossaire des symboles à la fin de la notice. / Siehe Symbol-Erklärungen am Ende der Packungsbeilage. / Δείτε το γλωσσάριο των συμβόλων στο τέλος του ένθετου. / A jelmagyarázat a használati utasítás végén található. / Vedere il glossario dei simboli alla fine del foglio illustrativo. / Žr. informacinio lapelio pabaigoje pateiktamą simbolių glosarijų. / Se i symbolforklaringen på slutten av produktvedlegget. / Zobacz objaśnienie symboli na końcu ulotki. / Consulte o glossário de símbolos no fim do folheto informativo. / Pozri slovník symbolov na konci letáka. / Consulte el glosario de símbolos al final del prospecto. / Se symbolförteckningen vid slutet av bipacksedeln.

Pokyny vám poskytne místní zástupce společnosti BD. / Kontakt den lokale BD repræsentant for at få instruktioner. / Kasutusjuhiste suhtes kontakteeruge oma kohaliku BD esindajaga. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για οδηγίες. / A használati utasítást kérje a BD helyi képviseletétől. / Naudojimo instrukcijų teiraukitės vietos BD įgaliotojo atstovo. / Aby uzyskać instrukcje użytkowania, skontaktuj się z lokalnym przedstawicielstwem BD. / Contacte o seu representante local da BD para obter instruções. / Inštrukcie získate u miestneho zástupcu spoločnosti BD. / Kontakta lokal Becton Dickinson-representant för anvisningar.

INTENDED USE

The CrystalSpec™ Nephelometer is a battery-powered, portable device designed to measure the turbidity of microbial suspensions equivalent to McFarland standards 0.5 through 4.0. The instrument can be used for any laboratory procedure that requires inoculum density adjustments within this range.

SUMMARY AND EXPLANATION

The visual comparison of organism suspensions to turbidity standards is an accepted method of estimating organism densities. The most widely accepted standard is the McFarland standard.[1] A McFarland standard is prepared by adding barium chloride to aqueous sulfuric acid. The density of the resulting barium sulfate precipitate can be used to approximate the colony count of a prepared suspension; e.g., McFarland 1 is the equivalent of approximately 3×10^8 CFU/mL. Other standards have been used for density measurements, including titanium dioxide[2] and latex particle suspensions.[3]

The instrumented measurement of turbidity relies on the ability of particles to scatter light while in suspension. The measurement of this scattered light is referred to as nephelometry.[4] In order to obtain an accurate density measurement, a reliable method of calibration must be used.

PRINCIPLES OF THE PROCEDURE

The CrystalSpec Nephelometer measures scattered light at a 90° angle of incidence. It is a solid state instrument that uses a light-emitting diode as a light source and a photodiode detector. The instrument was developed using bacterial suspensions at known concentrations (CFU/mL). Colony counts were correlated with McFarland units and the CrystalSpec Instrument was programmed to display the measurement in McFarland units. The calibration standards supplied with the instrument have been developed to assure an accurate calibration.

Before making a measurement on the CrystalSpec Nephelometer, the instrument is calibrated using the supplied standards. To determine the McFarland equivalent of a microbial suspension, a tube is placed in the reading chamber and the test button is pressed. The results are then displayed on the LCD screen in McFarland units.

SPECIFICATIONS:

Range	McFarland 0.5 – 4.0	Instrument Ambient Operating Conditions	20 to 30°C
Accuracy	± 0.2 McFarland Unit	Storage Temperature Range (Instrument and calibration tube)	20 to 30°C
Reproducibility	± 0.1 McFarland Unit	Sample Tube Size	16 – 17 mm dia., flat bottomed glass tube
Battery	9 V Alkaline		
Battery Life	1 Year (typically)		

Precautions: *in vitro* Diagnostic

Read all instructions before use and follow precisely.

PROCEDURE

Materials Provided: CrystalSpec Nephelometer, including a CrystalSpec Calibration Blank (B), CrystalSpec Calibration Standard (S), Low Volume Sample Adapter, and 9-volt battery.

Materials Not Provided: Ancillary culture media and equipment required to prepare a bacterial suspension.

Instructions:

BATTERY INSTALLATION AND REPLACEMENT – Unpack the CrystalSpec Nephelometer and the 9 V battery. Invert the instrument and remove the battery cover plate. Connect the battery and replace the cover.

If replacing a discharged battery, press one of the buttons (either "Calibration" or "Test") for 3 sec after discharged battery has been removed.

When a battery is initially installed, *"T"* will be displayed in the readout window while the internal evaluation is in progress. This *"T"* will also appear when a discharged battery is replaced with a new battery.

When installing a new battery, interrupting the contact before the battery clip is secure may cause the *"T"* display to not continue to show. The unit should be functioning properly, but if in doubt, reinstall the battery per above.

The CrystalSpec instrument has an internal battery charge indicator. Along with sample readouts, a reading from *"B0"* to *"B5"* is displayed at the far right edge of the window to indicate the level of battery charge. A fully charged battery will display *"B5"*, a battery needing replacement will display *"B0"*.

When the battery charge is so low that the integrity of the readings is compromised, *"X"* will be displayed and the battery will be completely discharged by the instrument. The meter will not operate until the battery is replaced.

NOTE: *Anytime a battery is replaced or the battery is disconnected from the unit, the instrument must be re-calibrated.*

CALIBRATION PROCEDURES – The CrystalSpec instrument requires no warm-up period and is ready for calibration and immediate use. A CrystalSpec Calibration Blank (B) and CrystalSpec Calibration Standard (S) are supplied with the instrument; *use only these calibration standards for calibration.* Internal error checking is in place to assure proper calibration of the instrument.

The nephelometer has internal features that minimize the need for frequent calibrations. Calibration needs to be performed only under the following conditions: (a) Any time the battery is replaced or disconnected, (b) If the *"E"* message is displayed when taking a reading and (c) Whenever the daily reading using the Calibration Standard (S) fails to read 1.9, 2.0 or 2.1.

Refer to Calibration Procedure, Table 2, page 10

1. If the sample volume to be measured is between 2.0 mL and 4.0 mL, insert the Low Volume Sample Adapter provided prior to calibration. If the volume is greater than 4.0 mL, the Low Volume Sample Adapter is *not* needed.

2. For ease of calibrating, press the Calibration Button using a finger of your left hand and press the Test Button using a finger of your right hand.
3. The sequence of button press and release is important for the proper calibration and accurate functioning of the CrystalSpec.
4. If during calibration the expected displays do not show, after the display clears, re-start the calibration procedure with step 1.
5. If a calibration reading (step 8) of other than "2.0" is returned, remove the Calibration Standard and wipe the outside of the tube with a Kimwipe or clean cloth to remove any smudges, finger prints, etc. and re-calibrate.
6. Calibration between sample readings is not necessary; however, the CrystalSpec Calibration Standard (S) should be read as a sample on a daily basis. If the standard reads 1.9, 2.0 or 2.1, the instrument is calibrated and *does not need re-calibration.*
7. The calibration should be stable if ambient conditions of temperature and light remain relatively constant. If these conditions change, re-calibration is recommended.
8. Do not press the Test Button until the calibration procedure has been successfully completed (steps 1 - 8 are completed successfully) or the CrystalSpec will not be properly calibrated and readings will not be valid.

TESTING PROCEDURES – *Clear, flat bottomed glass tubes, 16 – 17 mm diameter must be used for samples.* Organisms may be suspended in water, saline or clear growth medium of yellow to pale brown color (e.g., Mueller-Hinton Broth, TSB, or BHI Broth). Use of other colored liquids as a suspending medium is not recommended. A minimum of 2.0 mL of liquid is required.

1. If the sample volume is between 2.0 mL and 4.0 mL, insert the Low Volume Sample Adapter. If the volume is greater than 4.0 mL, the Low Volume Sample Adapter is not needed.
2. Vortex the test sample and set aside briefly if bubbles are present. Gently tapping on the tube may aid in eliminating bubbles. Insert the test tube sample tube into the nephelometer. Make sure the tube is inserted as far as possible into the instrument.
3. Depress and release the test button [test tube graphic]. The result will be displayed along with the battery status readout.

   EXAMPLE: For a sample of McFarland 1.0 and a battery that requires changing, the display will read:

   "1.0 MCFARLAND B0".
4. Adjust the sample preparation with more organisms if the readout is lower than expected, or with sterile diluent if the reading is higher than expected. Vortex the sample and reread.
5. Repeat step 4 until the desired turbidity is achieved.
6. Repeat steps 2 – 5 (above) for additional samples.

RESULTS

The CrystalSpec Nephelometer displays the measurement in McFarland units. These readings represent the density of the suspension and can be used to estimate the CFU/mL of the suspension tested.

LIMITATIONS OF THE PROCEDURE

The meter must be calibrated with the supplied CrystalSpec Calibration Blank (B) and CrystalSpec Calibration Standard (S). The use of other standards will result in miscalibration of the instrument.

The CrystalSpec Standard is to be used only for calibration of this instrument and not as a visual, i.e. manual approximation to a barium sulfate McFarland standard.

Do not use the CrystalSpec Nephelometer for measurements outside the range of McFarland standards 0.5 – 4.0.

Volumes below 2.0 mL cannot be measured in the instrument.

Clear, flat bottomed glass tubes, 16 – 17 mm diameter must be used for samples.

For best results we recommend 9 V Alkaline batteries.

Do not use in direct sunlight.

PERFORMANCE CHARACTERISTICS

The reproducibility of the instrument was measured over time with standards at concentrations equivalent to McFarland 0.5, 1, 2, 3, and 4 turbidity standards. The error for any estimate was determined to be ± 0.1 McFarland unit.

To determine the accuracy of the CrystalSpec Nephelometer, colony counts were performed on suspensions of *E. coli* ATCC™ 25922 prepared in saline. Each test was performed in replicates of five and the average of the plate counts is given in Table 1.

Table 1

McFarland	Expected CFU/mL x 10^8	Adjusted* CFU/mL x 10^8	%CV
0.5	1.5	1.7	11.6
1.0	3.0	3.3	10.7
2.0	6.0	6.5	14.8
3.0	9.0	10.4	8.2
4**0	12.0	13.0	9.9

* Because of difficulty in achieving the exact target McFarland density, these results were obtained by using the CrystalSpec readings and adjusting the observed CFU/mL as if each dilution had been the target McFarland.

**Four replicators were used to calculate the adjusted CFU/mL and % CV.

WARRANTY: The CrystalSpec Nephelometer is warranted to be free from defects for one year from the date of purchase.

MAINTENANCE AND TROUBLESHOOTING: No maintenance is required except for battery replacement when the battery indicator reads *"B0"*, or *"E"* is displayed, indicating a low battery.

If the *"E"* is displayed, the internal error checking has detected a problem due to improper use, discharged battery, or an electronic failure. If calibration and/or replacement of the battery does not correct the problem, (In the United States) contact Becton Dickinson, Technical Services, toll free (800) 638-8663.

AVAILABILITY

Cat. No.	Description
245009	CrystalSpec™ Nephelometer, including a CrystalSpec™ Calibration Blank and CrystalSpec™ Calibration Standard, Low Volume Sample Adapter, and battery.
245015	CrystalSpec™ Calibration Blank and CrystalSpec™ Calibration Standard, carton of one each.

#88,4.

REFERENCES

1. McFarland, J. 1907. The nephelometer: an instrument for estimating the number of bacteria in suspensions used for calculating the opsonic index for vaccines. JAMA 49:1176-1178.
2. Roessler, W.G., and C.R. Brewer. 1967. Permanent turbidity standards. Appl. Microbiol. 15:1114-1121.
3. Pugh, T.L., and W. Heller. 1957. Density of polystyrene and polyvinyl toluene latex particles. J. Colloid Sci. 12:173-180.
4. Mallette, M.F. 1969. XV. Evaluation of growth by physical and chemical means, p. 521-566. *In* J.R. Norris and D.W. Ribbons (ed.). Methods in microbiology, vol. 1. Academic Press Inc., New York.

BD BBL™ Taxo™ Discs for Presumptive Identification of Gram-Negative Anaerobic Bacilli

CE 8840221JAA(02) 2015-04

#91.1.

Contact your local BD representative for instructions. / Свържете се с местния представител на BD за инструкции. / Pokyny vám poskytne místní zástupce společnosti BD. / Kontakt den lokale BD repræsentant for at få instruktioner. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για οδηγίες. / Kasutusjuhiste suhtes kontakteeruge oma kohaliku BD esindajaga. / Ota yhteys lähimpään BD:n edustajaan ohjeiden saamiseksi. / Kontaktiraj lokalnog predstavnika BD za upute. / A használati utasítást kérje a BD helyi képviseletétől. / Нұсқаулар үшін жергілікті BD өкілімен хабарласыңыз. / Lai saņemtu norādījumus, sazinieties ar vietējo BD pārstāvi. / Naudojimo instrukcijų teiraukitės vietos BD įgaliotojo atstovo. / Neem contact op met uw plaatselijke BD-vertegenwoordiger voor instructies. / Kontakt din lokale BD-representant for mer informasjon. / Aby uzyskać instrukcje użytkowania, skontaktuj się z lokalnym przedstawicielstwem BD. / Contacte o representante local da BD para instruções. / Pentru instrucțiuni, contactați reprezentantul local BD. / Для получения указаний обратитесь к местному представителю компании BD. / Inštrukcie získate u miestneho zástupcu spoločnosti BD. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Kontakta närmaste BD-representant för anvisningar. / Talimatlar için yerel BD temsilcinizle temasa geçin. / За інструкціями зверніться до місцевого представника компанії BD.

INTENDED USE

These discs are recommended for use in the presumptive identification of gram-negative anaerobic bacilli based on differences in susceptibility to antimicrobial agents. *This procedure is not for use for therapeutic purposes.*

SUMMARY AND EXPLANATION

Sutter and Finegold reported on the value of special-potency antibiotic discs in differentiating *Bacteroides* and *Fusobacterium* spp. on the basis of antibiotic inhibition patterns.[1] The patterns, along with colonial and microscopic observations and a limited number of biochemical tests, permitted the rapid presumptive identification of anaerobic bacilli. A similar differentiation protocol was adopted by the Centers for Disease Control (CDC).[2]

Sutter et al. recommend the use of kanamycin 1 mg, vancomycin 5 µg and colistin 10 µg discs with pure cultures streaked on Brucella Blood Agar with Hemin and Vitamin K_1, with a 10 mm zone size breakpoint for reporting susceptibility or resistance.[3] The CDC protocol utilizes penicillin 2 units, rifampin 15 µg and kanamycin 1 mg discs on CDC Anaerobe Blood Agar, an enriched medium supplemented with hemin and Vitamin K_1, with larger zone size criteria.[2] The BBL test protocol utilizes these five discs on either medium and the 10 mm zone size breakpoint.

PRINCIPLES OF THE PROCEDURE

These discs are used for the differentiation of gram-negative anaerobic bacilli on the basis of *in vitro* testing of pure cultures against selected antimicrobial agents using the agar diffusion method. Growth of the microorganisms may be inhibited by the antimicrobial agent diffusing out from the disc, resulting in a zone of inhibition around the disc. Differentiation is based on the presence of zones of inhibition of equal to or greater than 10 mm (susceptible) or less than 10 mm (resistant).

PRODUCT DESCRIPTION

These 1/4" discs are made from high quality absorbent paper impregnated with accurately determined amounts of antimicrobial agents. They are furnished in cartridges containing 50 discs each. The last disc in each cartridge is marked "X" and contains the drug as coded. Cartridges are for use in BBL single disc dispensers.

Warnings and Precautions:

For *in vitro* Diagnostic Use.

The Taxo Kanamycin 1 mg and Taxo Rifampin 15 µg discs are not for use in susceptibility testing for therapeutic purposes.

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. After use, test plates and other contaminated materials must be sterilized by autoclaving.

Storage Instructions:

1. On receipt, store containers of discs at -20 to +8 °C. If the laboratory refrigerator is frequently opened and closed, and a suitable temperature is not maintained, place there a supply sufficient only for use within a week.
2. Allow containers to come to room temperature before opening. Return unused discs to the refrigerator when application of discs has been completed.
3. Use the oldest discs first.
4. Discard expired discs. Also discard cartridges from which discs have been frequently removed during a week. Discard discs left out overnight in the laboratory, or test the discs for performance.
5. If the discs form incorrect zones with the recommended control organism, the entire procedure should be checked; a faulty zone may be due to the disc, the inoculation, the preparation or depth of the medium or other factors.

The expiration date applies to discs in the intact container, stored as directed.

SPECIMENS

These discs are not for use directly with clinical specimens or other sources containing mixed flora. The organism to be presumptively identified first must be isolated as separate colonies by streaking the specimen onto appropriate culture media.

PROCEDURE

Material Provided: In this package are discs for the differentiation of gram-negative anaerobic bacilli as labeled.

Materials Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

Test Procedure:

1. Preparation of inoculum with test and control cultures
   a. Prior to inoculation, loosen the cap of a tube of inoculum broth (e.g., Schaedler Broth with Vitamin K_1 or suitable alternative medium) and heat in a boiling water bath to drive off oxygen, retighten the cap and cool to room temperature, or reduce the inoculum broth overnight in an anaerobic jar.
   b. Perform a Gram stain. Use only pure cultures.
   c. Select three or four similar colonies and inoculate the inoculum broth.
   d. Incubate anaerobically at 35 °C for 18 to 24 h or until heavy turbidity is observed; adjust the turbidity to be comparable to a McFarland No. 1 barium sulfate standard.
2. Inoculation
   a. Pre-warm to room temperature plates of CDC Anaerobe Blood Agar or Brucella Blood Agar with Hemin and Vitamin K_1. Agar surfaces should be smooth and moist.
   b. Within 15 min of adjusting the turbidity of the inoculum, dip a sterile swab into the properly diluted inoculum and rotate it firmly several times against the upper inside wall of the tube to express the excess fluid.
   c. Inoculate the entire agar surface three times, turning the plate 60° between streakings to obtain even inoculation.
   d. Replace the lid of the plate and hold for 3 to 5 min at room temperature to allow absorption of the moisture from the inoculum.
   e. Apply the discs evenly spaced to the inoculated agar surface with sterile forceps or single disc dispenser and lamp with a sterile needle or forceps to make complete contact with the medium surface.
   f. Incubate immediately at 35 °C under anaerobic conditions.
   g. Examine the plates after 48 h. Measure and record each zone of inhibition to the nearest millimeter: less than 10 mm as resistant; equal to or greater than 10 mm as susceptible.

User Quality Control: Control tests using known cultures should be included each time a susceptibility test is performed. The following organisms are recommended:

	Antimicrobial Agent and Code				
Organism	**Kanamycin K**	**Rifampin RA**	**Penicillin P-2**	**Vancomycin Va-5**	**Colistin CL-10**
Bacteroides fragilis ATCC® 25285	R	S	R	R	R
Fusobacterium mortiferum ATCC 9817	S	R	S	R	S

S = Susceptible (zones ≥ 10 mm) R = Resistant (zones < 10 mm)

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

RESULTS

Compare reactivity patterns with those in the table.

Inhibition of *Bacteroides* and *Fusobacterium* Species with Antibiotic Discs†

Organism	Antimicrobial Agent and Code				
	Kanamycin K	Rifampin RA	Penicillin P-2	Vancomycin Va-5	Colistin CL-10
B. fragilis group*	R	S	R	R	R
P. melaninogenica	R^S	S	S	R^S	S^r
P. buccalis and *P. veroralis*	R	S	S	R^S	S^r
B. ureolyticus	S	S	S	R	S
F. mortiferum	S	R	S^r	R	S
F. varium	S	R	S^r	R	S
F. necrophorum	S	S	S	R	S
F. nucleatum	S	S	S	R	S

S = Susceptible (zones ≥ 10 mm); S^r = majority of strains susceptible.
R = Resistant (zones < 10 mm); R^S = majority of strains resistant.
† Data were obtained on CDC Anaerobe Blood Agar and Brucella Blood Agar with Hemin and Vitamin K_1.
* The *B. fragilis* group includes *B. fragilis*, *B. distesonis*, *B. ovatus*, *B. thetaiotaomicron*, *B. vulgatus* and *B. uniformis*.

LIMITATIONS OF THE PROCEDURE

The references should be consulted for the complete schema of morphological and biochemical characteristics that, along with these antibiotic inhibition patterns, enable a presumptive identification to be made.[1–4] Following presumptive identification, definitive identification procedures should be performed to establish the validity of the presumptive identification. Appropriate references should be consulted for additional information.[2–8]

PERFORMANCE CHARACTERISTICS

Prior to release, all lots of BBL Taxo Anaerobe Differentiation Discs are tested to verify specific product characteristics. Samples are assayed for the potency of each of the antimicrobial agents contained in the kit.

Additionally, plates of CDC Anaerobe 5% Sheep Blood Agar and Brucella Blood Agar with Hemin and Vitamin K_1 are swab-inoculated with cultures of *Bacteroides fragilis* (ATCC 25285) and *Fusobacterium mortiferum* (ATCC 9817). Samples are placed on the inoculated plates and incubated at 35 ± 2 °C under anaerobic conditions. After 48 h incubation, the plates are then read for zones of inhibition around each disc. *B. fragilis* is resistant (< 10 mm) to kanamycin, penicillin, vancomycin and colistin and susceptible (≥ 10 mm) to rifampin. *F. mortiferum* is resistant (< 10 mm) to rifampin and vancomycin and susceptible (≥ 10 mm) to kanamycin, penicillin and colistin.

AVAILABILITY

Cat. No.	Description
231651	BD BBL™ Taxo™ Anaerobe Differentiation Discs Set, 50 tests Set components – one cartridge of 50 discs of each of the following antimicrobial agents: BBL™ Taxo™ Kanamycin, 1 mg BBL™ Taxo™ Rifampin, 15 µg Sensi-Disc™ Penicillin, 2 units Sensi-Disc™ Vancomycin, 5 µg Sensi-Disc™ Colistin, 10 µg
V231562	BD BBL™ Taxo™ Kanamycin, 1 mg Discs, Single cartridge of 50 discs #91.1.

REFERENCES

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3. Sutter, V.L., D.M. Citron, M.A.C. Edelstein, and S.M. Finegold. 1985. Wadsworth anaerobic bacteriology manual, 4th ed. Star Publishing Co., Belmont, Ca.
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8. Summanen, P., E.J. Baron, D.M. Citron, C. Strong, H.M. Wexler, S.M. Finegold. 1993. Wadworth anaerobic bacteriology manual, 5th ed. Star Publishing Co., Belmont, Ca.

Technical Information: In the United States, contact BD Technical Service and Support at 800-638-8663 or www.bd.com/ds.

BD BBL Taxo Discs pour l'identification présomptive des bacilles anaérobies à Gram négatif

Français

APPLICATION

Ces disques sont recommandés pour l'identification présomptive des bacilles anaérobies à Gram négatif d'après les différences de sensibilité aux agents antimicrobiens. *Ne pas employer cette méthode à des fins thérapeutiques.*

RESUME ET EXPLICATION

Les travaux de Sutter et Finegold ont démontré l'intérêt des disques imprégnés d'antibiotiques d'activité donnée pour différencier *Bacteroides* et *Fusobacterium* spp. d'après les profils d'inhibition par les antibiotiques.[1] Les profils de sensibilité, l'observation de la morphologie des colonies et l'observation microscopique associés à un petit nombre de tests biochimiques suffisent à l'identification présomptive rapide des bacilles anaérobies. Un protocole de différenciation similaire a été retenu par le Centers for Disease Control (CDC).[2]

Sutter et al. ont préconisé l'utilisation de disques imprégnés de kanamycine (1 mg), vancomycine (5 µg) ou colistine (10 µg) sur une gélose au sang pour *Brucella*, complémentée d'hémine et de vitamine K_1, ensemencée en stries avec des cultures pures, et d'un diamètre de transition résistant/sensible de 10 mm pour la zone d'inhibition.[3] Le protocole du CDC utilise des disques imprégnés de pénicilline (2 unités), rifampine (15 µg) ou kanamycine (1 mg) sur une gélose au sang anaérobie du CDC, un milieu enrichi complémenté d'hémine et de vitamine K_1 sur lequel les diamètres de transition des zones d'inhibition sont plus grands.[2] Le protocole du test **BBL** utilise ces cinq disques sur chaque milieu et un diamètre de transition de 10 mm pour la zone d'inhibition.

PRINCIPES DE LA METHODE

Ces disques servent à différencier des bacilles anaérobies à Gram négatif d'après des tests de sensibilité à des agents antimicrobiens spécifiques, réalisés *in vitro* par la méthode de diffusion en gélose sur des cultures pures. La croissance des microorganismes peut être inhibée par l'agent antimicrobien diffusant à partir du disque, d'où la présence d'une zone d'inhibition autour du disque. La différenciation repose sur la présence d'une zone d'inhibition de diamètre supérieur ou égal à 10 mm (sensible) ou inférieur à 10 mm (résistant).

DESCRIPTION

Ces disques de 6 mm de diamètre sont constitués de papier absorbant de haute qualité, imprégné de quantités précisément dosées d'agents antimicrobiens. Ils sont fournis en cartouches de 50 disques chacune. Un << X >> sur le dernier disque de chaque cartouche indique que celui-ci contient le médicament codé. Les cartouches s'utilisent avec les distributeurs de disque unique BBL.

Avertissements et précautions :

Réservé au diagnostic *in vitro*.

Ne pas utiliser les disques Taxo Kanamycin (1 mg) et Taxo Rifampin (15 µg) pour réaliser des tests de sensibilité à des fins thérapeutiques.

Respecter les techniques d'asepsie et prendre les précautions en vigueur contre les dangers microbiologiques. Après utilisation, stériliser à l'autoclave les boîtes de test et les autres matériaux contaminés.

Instructions pour la conservation :

1. Dès réception, conserver les cartouches de disques entre -20 et +8 °C. Si le réfrigérateur du laboratoire est fréquemment ouvert et que la température préconisée n'est pas assurée, n'y placer que la quantité de disques suffisante pour une semaine.
2. Laisser les cartouches se réchauffer jusqu'à la température ambiante avant de les ouvrir. Remettre les disques inutilisés au réfrigérateur une fois que les disques ont été appliqués.

BD BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Discs

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Français:	pages	4 – 7	Italiano:	pagine	9 – 11	Português:	páginas	13 – 16	2011/07

Pokyny vám poskytne místní zástupce společnosti BD. / *Kontakt den lokale BD repræsentant for at få instruktioner.* / Kasutusjuhiste suhtes kontakteeruge oma kohaliku BD esindajaga. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για οδηγίες. / A használati utasítást kérje a BD helyi képviseletétől. / *Naudojimo instrukcijų teiraukitės vietos BD įgaliotojo atstovo.* / *Kontakt din lokale BD representant for mer informasjon.* / Aby uzyskać instrukcje użytkowania, skontaktuj się z lokalnym przedstawicielstwem BD. / Instrukcie získate u miestneho zástupcu spoločnosti BD. / *Kontakta lokal Becton Dickinson representant för anvisningar.* / Свържете се с местния представител на BD за инструкции. / Contactaţi reprezentantul dumneavoastră local BD pentru instrucţiuni. / Talimatlar için yerel BD temsilcinize danışın. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Для получения инструкций свяжитесь с местным представителем компании BD. / Gaiņjaļaļ apgriniami BD [illegible] / Kontaktirajte lokalnog predstavnika BD za upute.

Refer to product label for CE mark availability. / Informace o dostupnosti značky CE najdete na etiketě na výrobku. / *Produktet er tilgængeligt, hvis CE-mærkningen findes på etiketten.* / Toote saadavuse teadasaamiseks kontrollige CE-märgi olemasolu etiketil. / *Pour vérifier le marquage CE du produit, se référer à l'étiquette.* / *Siehe Produktetikett für die Verfügbarkeit CE-markierter Produkte.* / Το προϊόν είναι διαθέσιμο όταν η ετικέτα φέρει τη σήμανση CE. / Lásd a termék címkéjén levő CE jel meglétét. / *Prodotto disponibile se l'etichetta reca il marchio CE.* / CE ženklo [illegible] produkto etiketės. / *Se på produktmerkingen om det har CE-merket.* / O dostępności produktu informuje znak CE na etykiecie. / *Verificar a disponibilidade do produto pela marca CE no rótulo.* / Pre kontrolu prítomnosti CE značky nahliadnite do etikety výrobku. / *"Ver disponibilidad del marcado CE en la etiqueta del producto".* / *Produkten finns tillgänglig om dess etikett är CE-märkt.* / Вижте за продукта за наличие на знак CE. / Verificaţi prezenţa marcajului CE pe eticheta produsului. / CE işaretiyle ilgili olarak ürün etiketine başvurun. / Potražite oznaku CE na nalepnici proizvoda. / Проверьте наличие знака CE на этикетке продукта. / Potražite CE oznaku na naljepnici proizvoda. / Samo proizvodi sa CE oznakom dostupni su u Europi.

INTENDED USE – These discs are used for semi-quantitative *in vitro* susceptibility testing by the agar disc diffusion test procedure of common, rapidly growing and certain fastidious bacterial pathogens. These include the *Enterobacteriaceae*, *Staphylococcus* spp., *Pseudomonas* spp., *Acinetobacter* spp., *Enterococcus* spp., *Vibrio cholerae* and, by modified procedures, *Haemophilus influenzae*, *Neisseria gonorrhoeae*, *Streptococcus pneumoniae* and other streptococci. NOTE: Special procedures are required for testing pneumococci, enterococci and methicillin/oxacillin-resistant staphylococci, for performing β-lactamase tests and for screening and confirmatory tests for ESBLs; see the "RESULTS" section.

For zone diameter interpretive criteria adopted in France, refer to the instructions in the french language section of this insert.

SUMMARY AND EXPLANATION – Agar diffusion methods employing dried filter paper discs impregnated with specific concentrations of antimicrobial agents were developed in the 1940s. In order to eliminate or minimize variability in this testing, Bauer et al. developed a standardized procedure in which Mueller Hinton Agar was selected as the test medium.[1,2]

Various regulatory agencies and standards-writing organizations subsequently published standardized reference procedures based on the Bauer-Kirby method. Among the earliest and most widely accepted of these standardized procedures were those published by the U.S. Food and Drug Administration (FDA)[3] and the World Health Organization (WHO).[4,5] The procedure was adopted as a consensus standard by the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) and is periodically updated.[6,7] *The latest CLSI documents should be consulted for current recommendations.*

PRINCIPLES OF THE PROCEDURE – Discs containing a wide variety of antimicrobial agents are applied to the surface of Mueller Hinton Agar plates (or Haemophilus Test Medium Agar for *H. influenzae*, GC II Agar with *IsoVitaleX*™ Enrichment for *N. gonorrhoeae* or Mueller Hinton Agar with 5% Sheep Blood for *S. pneumoniae*, β-hemolytic and viridans group streptococci) that have been inoculated with pure cultures of clinical isolates. Following incubation, the plates are examined and the zones of inhibition surrounding the discs are measured and compared with established zone size ranges for individual antimicrobial agents in order to determine the agent(s) most suitable for use in antimicrobial therapy.

REAGENTS – *Sensi-Disc*™ brand discs are 6-mm discs prepared by impregnating high quality absorbent paper with accurately determined amounts of antibiotic or other chemotherapeutic agents. Discs are clearly marked on both sides with letters and numbers designating the agent and the drug content. (See chart giving concentrations of reactive ingredients.) The drug content of discs is assayed by the methods established by the FDA or by methods similar or comparable to those published in the United States *Federal Register*.

Sensi-Disc agents are furnished in cartridges containing 50 discs each. The last disc in each cartridge is marked "X" and contains the drug as coded. Cartridges are for use in *BBL™ Sensi-Disc*™ Dispensers; these include a Single Disc Dispenser, an 8-Place Dispenser for 100 mm-style Petri dishes, 6- and 8-Place Self-Tamping Dispensers for 100 mm-style dishes and a Self-Tamping 12-Place Dispenser for 150 mm-style plates.

Warnings and Precautions: For *in vitro* Diagnostic Use.

Follow directions for use; disc performance depends not only on disc potency, but on use of proper inoculum and control cultures, functional prepared plates, proper storage temperature and other factors.

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. Sterilize cultures, containers and other contaminated materials after use.

Storage Instructions:

1. On receipt, store discs at -20 – +8°C. If the laboratory refrigerator is frequently opened and closed, and a suitable temperature is not maintained, place there a supply sufficient only for use within a week. Some discs (e.g., β-lactams) should preferably be kept frozen at -20°C.
2. Allow containers to come to room temperature before opening. Return unused discs to the refrigerator when application of discs has been completed. Once opened, discs should be placed in a tightly sealed, desiccated container for storage.
3. Use the oldest discs first.
4. Discard expired discs. Also, cartridges from which discs have been frequently removed during a week and discs left out overnight in the laboratory should be discarded, or else the discs should be tested for acceptable performance prior to continued use.
5. If the discs form incorrect zones with the recommended control organisms, the entire procedure should be checked; faulty zone size may be due to the disc, the inoculation, the preparation or depth (about 4 mm) of medium, or other factors.

The expiration date applies only to discs in intact containers, stored as directed.

SPECIMENS – Specimens should not ordinarily be employed in this test. See Directions, which include preparation of inoculum. If possible, cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy.

PROCEDURE

Material Provided: *Sensi-Disc*™ susceptibility test discs as labeled.

Materials Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment required to perform disc diffusion susceptibility testing by the standardized procedure. Prepare a 0.5 McFarland turbidity standard by adding 0.5 mL of 0.048 M $BaCl_2$ (1.175% (w/vol) $BaCl_2 \cdot 2H_2O$) to 99.5 mL of 0.18 M (0.36N) H_2SO_4 (1% (vol/vol)). Verify by using a spectrophotometer with a 1-cm light path and matched cuvette; absorbance at 625 nm should be 0.08 – 0.13.

Directions, Including User Controls:[6]

1. Preparation of inoculum with test and control cultures.
   a. Perform a Gram stain. Use only pure cultures.
   b. Select three to five similar colonies and transfer with inoculation needle or loop into 4 – 5 mL of a suitable broth such as *Trypticase*™ *Soy Broth* (or Mueller Hinton Broth for fastidious organisms).
   c. Incubate the broth cultures at 35°C for 2 – 6 h, if necessary, to develop a turbidity equivalent to the 0.5 McFarland turbidity standard (approximately 1 to 2 x 10^8 CFU/mL). Alternatively, make a direct broth or saline suspension of colonies selected from an agar plate incubated overnight (a nonselective medium such as blood agar, or chocolate agar for *H. influenzae* and *N. gonorrhoeae*, should be used). *The direct colony suspension method is preferred for Staphylococcus spp., S. pneumoniae and other streptococci, Haemophilus spp. and N. gonorrhoeae.*[6]
   d. Dilute, if required, to obtain turbidity equivalent to the 0.5 McFarland turbidity standard. For diluent, use sterile broth or saline. Alternatively, standardize the inoculum photometrically, to facilitate inoculum adjustment of rapidly growing organisms, the *Prompt*™ Inoculation System (volumetric inoculum preparation device) may be used.[8]

   Overnight broth cultures should not be used as inoculum.
2. Inoculation.
   a. Within 15 min, dip a sterile cotton swab into the properly adjusted inoculum and rotate it firmly several times against the upper inside wall of the tube to express excess fluid.
   b. Streak the entire agar surface of a Mueller Hinton Agar (or other appropriate agar) plate three times, turning the plate 60° between streakings to obtain even inoculation.
   c. The lid may be left ajar for 3 – 5 min, but no more than 15 min, to allow for any surface moisture to be absorbed before applying the drug-impregnated discs.
3. Select appropriate discs (such as recommended in reference 7, Tables 1A and 1B of M100 (M2)).
4. Apply the discs by means of a *BBL*™ dispenser, using aseptic precautions. Deposit discs so that the centers are at least 24 mm apart. It is preferable to deposit penicillin and cephalosporin discs so that they are no less than 10 mm from the edge of the Petri dish, and their centers are at least 30 mm apart. Avoid placing such discs adjacent to one another. With *H. influenzae*, *N. gonorrhoeae* and *S. pneumoniae*, use no more than nine discs per 150 mm plate or four discs per 100 mm plate. If discs have been placed on the agar with other than the Self-Tamping Dispensers, press them down with a sterile needle or forceps to make contact with the surface.
5. Within 15 min, place the plates agar side up in a 35 ± 2°C incubator (for *Staphylococcus* spp., testing at temperatures above 35°C may not detect methicillin-resistant staphylococci (MRS); for *N. gonorrhoeae*, incubate at 36 ± 1°C (do not exceed 37°C)). *Haemophilus* spp., *N. gonorrhoeae*, *S. pneumoniae* and other streptococci should be incubated in an atmosphere enriched with 5% CO_2.
6. Examine the plates after 16 – 18 h of incubation (20 – 24 h for *N. gonorrhoeae*, *S. pneumoniae* and other streptococci). A full 24 h of incubation is recommended for *Staphylococcus* spp. to detect methicillin/nafcillin/oxacillin/vancomycin resistant staphylococci and *Enterococcus* spp. for vancomycin resistance. The diameters of the zones of complete inhibition are measured, as determined by gross visual inspection. Zones are measured to the nearest whole millimeter. For further details in measuring zones of inhibition, consult the reference.[6] If only isolated colonies grow, the inoculum is too light and the test should be repeated. Zones around discs containing different drugs are not comparable for the purpose of comparing activity of drugs. See the Zone Diameter Interpretive Chart, which gives expected values from testing common aerobes. Zone measurement may be simplified by using a *BBL™ Sensi-Disc*™ Zone Interpretation Set.
7. Control tests using prescribed cultures should be included each day susceptibility testing is performed or weekly if satisfactory performance can be documented according to the CLSI standard.[6] Typical zone sizes of *E. coli* ATCC™ 25922, *S. aureus* ATCC 25923, *P. aeruginosa* ATCC 27853, *H. influenzae* ATCC 49247, *H. influenzae* ATCC 49766, *N. gonorrhoeae* ATCC 49226, *S. pneumoniae* ATCC 49619, *E. coli* ATCC 35218 (β-lactamase-producing strain), *E. faecalis* ATCC 29212 (for quality control testing of gentamicin 120 µg and streptomycin 300 µg discs) and *Klebsiella pneumoniae* ATCC 700603 (for screening and confirmatory tests for ESBLs) are given in the chart (or footnotes) and indicate the correct performance of the entire procedure. *E. faecalis* ATCC 29212 (or 33186) is also recommended for evaluating new lots of Mueller Hinton Agar for low thymine and thymidine content (see footnote ff). *H. influenzae* ATCC 10211 is recommended as a useful additional quality control strain to verify the growth promotion properties of Haemophilus Test Medium Agar.[7]

RESULTS[6,7] – NOTE: Recommended interpretive criteria are based on usual dosage regimens and routes of administration in the U.S.

Beginning in 2006, CLSI established zone diameter interpretive ranges for *Neisseria meningitidis*, *Burkholderia cepacia* and *Stenotrophomonas maltophilia*. For these ranges, consult CLSI M100-S21[7] or the latest M100 supplement available. In addition, CLSI guideline M45 – *Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria* – can be consulted to obtain information for testing a variety of organisms including *Campylobacter*, *Corynebacterium* spp., *Bacillus* spp., etc.[9] For organisms not found in the accompanying table, or the references mentioned, studies are not yet adequate to develop reproducible definitive standards for interpretation of results. If necessary, a dilution method usually will be the most appropriate testing method, which may require submitting the organism to a reference laboratory.

In some instances, CLSI has implemented new zone diameter ranges for interpretive or quality control criteria. When this has occurred, footnote "aa" has been added indicating that the FDA-approved zone diameters provided differ from the current CLSI recommendations.

Compare recorded zone diameters with those in the chart; results with a specific organism may be reported as Resistant, Intermediate or Susceptible. For some organism/antimicrobial agent combinations, the absence or rare occurrence of resistant strains precludes defining any results categories other than "Susceptible." For strains yielding results suggestive of a "nonsusceptible" category, organism identification and antimicrobial susceptibility test results should be confirmed. Subsequently, the isolates should be saved and submitted to a reference laboratory that will confirm results using a CLSI reference dilution method.[6]

A rapid β-lactamase test (e.g., using *Cefinase*™ discs) may yield clinically relevant information earlier than results of a disc diffusion test with *Haemophilus* spp., *N. gonorrhoeae* and *Moraxella catarrhalis*; it is the only reliable test for detecting β-lactamase-producing *Enterococcus* spp. A positive β-lactamase test predicts resistance to penicillin, ampicillin and amoxicillin among *Haemophilus* spp., *N. gonorrhoeae* and *M. catarrhalis* and resistance to penicillin, including amino-, carboxy- and ureido-penicillins among staphylococci and enterococci. A negative β-lactamase test does not rule out resistance due to other mechanisms. Do not test members of the *Enterobacteriaceae*, *Pseudomonas* spp. and other aerobic gram-negative bacilli because the results may not be predictive of susceptibility to the β-lactams most often used for therapy. Accurate detection of β-lactamase in staphylococci may require induction of the enzyme and incubation of a nitrocefin-based test for up to 1 h. Induction can be easily accomplished by testing the growth from the zone margin surrounding an oxacillin disc test. Care must be exercised to ensure accurate results, including testing of known positive and negative control strains at the time clinical isolates are examined.[6]

Enterobacteriaceae: When fecal isolates of *Salmonella* and *Shigella* spp. are tested, only ampicillin, a quinolone and trimethoprim/sulfamethoxazole should be reported routinely. In addition, chloramphenicol and a third generation cephalosporin should be tested and reported for extraintestinal isolates of *Salmonella* spp. For *Salmonella* and *Shigella* spp., aminoglycosides and first and second generation cephalosporins and cephamycins may appear active *in vitro* but are not effective clinically and should not be reported as susceptible.[7]

Enterobacter, *Citrobacter*, and *Serratia* may develop resistance during prolonged therapy with third generation cephalosporins. Therefore, isolates that are initially susceptible may become resistant within 3 to 4 days after initiation of therapy. Testing of repeat isolates may be warranted.[7]

Extended-spectrum β-lactamases (ESBLs) are enzymes produced by gram-negative bacilli that arise by mutation in genes for common plasmid-mediated β-lactamases. Strains of *Klebsiella* spp. and *E. coli* that produce ESBLs may be clinically resistant to therapy with penicillins, cephalosporins, or aztreonam, despite apparent *in vitro* susceptibility to some of these agents. Some of these strains will show zones of inhibition below the normal susceptible population but above the standard breakpoints for certain extended spectrum cephalosporins or aztreonam; such strains should be screened for potential ESBL production by using the ESBL screening breakpoints before reporting results for penicillins, extended-spectrum cephalosporins or aztreonam. Other strains may test intermediate or resistant by standard breakpoints to one or more of these agents. In all strains with ESBLs the zone diameters for one or more of the extended spectrum cephalosporins or aztreonam should increase in the presence of clavulanic acid as determined in phenotypic confirmatory testing. For all confirmed ESBL-producing strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam. See footnote t for ESBL screening and confirmatory tests. The decision to perform ESBL screening tests on all urine isolates should be made on an institutional basis, considering prevalence, therapy and infection control issues.[7] To screen *Proteus mirabilis* for ESBL production, see M100.[7]

Non-Enterobacteriaceae: Non-*Enterobacteriaceae* other than *P. aeruginosa*, *Acinetobacter* spp., *B. cepacia* and *S. maltophilia* should be tested by the dilution method (see M7[10]). For *B. cepacia* and *S. maltophilia*, consult CLSI M100-S21 for zone diameter interpretative standards and quality control.

P. aeruginosa may develop resistance during prolonged therapy with all antibiotics. Isolates that are initially susceptible may become resistant within 3 to 4 days after initiation of therapy and testing of repeat isolates may be warranted.[7]

The susceptibility of *Pseudomonas aeruginosa* isolated from patients with cystic fibrosis can be reliably determined by the disc method, but may require extended incubation up to 24 h before reporting as susceptible.[7]

Staphylococcus spp.: *Staphylococcus* spp. may develop resistance during prolonged therapy with quinolones. Therefore, isolates that are initially susceptible may become resistant within 3 to 4 days after initiation of therapy. Testing of repeat isolates may be warranted.[7]

Methods for the detection of methicillin-resistant staphylococci include the oxacillin disc test, the cefoxitin disc test and tests for *mecA* or the protein encoded by *mecA*, the penicillin-binding protein 2a (PBP 2a, also called PBP 2'). In the past, the presence of resistance to other classes of agents was an indication of methicillin (oxacillin) resistance. However, some methicillin-resistant *S. aureus* (MRSA), such as those found in community-associated infections, are not multiply-resistant.[7]

MRSA and methicillin-resistant, coagulase-negative staphylococci should be reported as resistant (or not reported) to all other penicillins, carbapenems, cephems, and β-lactam/β-lactamase inhibitor combinations, regardless of *in vitro* test results with those agents. This is because most cases of documented methicillin-resistant infections have responded poorly to β-lactam therapy, and convincing clinical data have yet to be presented that document clinical efficacy for β-lactams versus MRS. For oxacillin-susceptible *S. aureus* and coagulase-negative staphylococci, results for parenteral and oral cephems, β-lactam/β-lactamase inhibitor combinations, and carbapenems, if tested, should be reported according to the results generated using routine interpretive criteria. For oxacillin-resistant *S. aureus* and coagulase-negative staphylococci (MRS), other β-lactam agents, i.e., penicillins, β-lactam/β-lactamase inhibitor combinations, cephems, and carbapenems, may appear active *in vitro*, but are not effective clinically. Results for these drugs should be reported as resistant or should not be reported. This is because most cases of documented MRS infections have responded poorly to β-lactam therapy, or because convincing clinical data have yet to be presented that document clinical efficacy for those agents. Routine testing of urine isolates of *S. saprophyticus* is not advised, because infections respond to concentrations achieved in urine of antimicrobial agents commonly used to treat acute, uncomplicated urinary tract infections (e.g., nitrofurantoin, trimethoprim/sulfamethoxazole or a fluoroquinolone).[6,7]

To obtain information on predicting *mecA*-mediated resistance in *Staphylococcus* spp. using cefoxitin (30 µg), consult CLSI M100-S21.

Similarly, to obtain information on testing *Staphylococcus* spp. for inducible clindamycin resistance consult M100-S21.

Enterococcus spp.: Enterococci may be resistant to penicillin and ampicillin because of the production of low affinity penicillin binding proteins (PBPs), or the production of β-lactamase. The disc diffusion test can accurately detect isolates with altered PBPs, but it will not reliably detect β-lactamase producing strains. The latter strains are best detected by using a direct β-lactamase test,[6] e.g., with *Cefinase* nitrocefin discs or chromogenic cephalosporin discs.

For *Enterococcus* spp., cephalosporins, aminoglycosides (except for high level resistance screening), clindamycin and trimethoprim/sulfamethoxazole may appear active *in vitro* but are not effective clinically and isolates should not be reported as susceptible.

Haemophilus spp.: Only results of tests with ampicillin, one of the third generation cephalosporins, chloramphenicol and meropenem should be reported routinely with cerebrospinal fluid isolates of *H. influenzae*.

Amoxicillin/clavulanic acid, azithromycin, clarithromycin, cefaclor, cefprozil, loracarbef, cefdinir, cefixime, cefpodoxime, cefuroxime axetil and telithromycin are oral agents that may be used as empiric therapy for respiratory tract infections due to *Haemophilus* spp. The results of susceptibility tests with these antimicrobial agents are often not useful for management of individual patients. However, susceptibility testing of *Haemophilus* spp. with these compounds may be appropriate for surveillance or epidemiologic studies.

Streptococcus spp. other than S. pneumoniae: Susceptibility testing of penicillins and other β-lactams approved by the U.S. Food and Drug Administration for treatment of *S. pyogenes* or *S. agalactiae* is not necessary for clinical purposes and need not be done routinely, since as with vancomycin, resistant strains have not been recognized. Interpretive criteria are provided for pharmaceutical development, epidemiology or monitoring for emerging resistance. Any strain found to be intermediate or resistant should be referred to a reference laboratory for confirmation.

To obtain information on testing β-hemolytic streptococci for inducible clindamycin resistance consult M100-S21.[7]

LIMITATIONS OF THE PROCEDURE

1. The test as herein described applies primarily to rapidly growing aerobic pathogens. For fastidious bacteria other than *H. influenzae*, *N. gonorrhoeae*, *S. pneumoniae* and other streptococci, consult M100 (*N. meningitidis*) or M45.[7,9] Otherwise, test by the dilution method. Testing of anaerobes requires special procedures.[11]
2. The classifications of Resistant, Intermediate and Susceptible vary only by one millimeter, which is within normal laboratory error. Some cultures may give a borderline zone that varies from day to day or from laboratory to laboratory; such cultures are relatively uncommon.
3. For detecting pneumococcal and enterococcal resistance, strictly adhere to CLSI recommended methods.[6]
4. Antimicrobial agents other than those listed in the Chart may be in current use. Susceptibility tests employing these agents should be interpreted on the basis of presence or absence of a definite zone of inhibition and should be considered as only qualitative until such time as interpretive zones have been established. All zone diameters should be recorded.
5. ESBL confirmatory testing is only valid when the four discs (cefotaxime, cefotaxime/clavulanic acid, ceftazidime, ceftazidime/clavulanic acid) are used simultaneously. Individual usage of these discs is not recommended by CLSI.[6,7]
6. Accurate results are a function of the correct storage and maintenance of quality control organisms. This is especially true for *E. coli* ATCC 35218 and *K. pneumoniae* ATCC 700603, because spontaneous loss of the plasmid encoding the β-lactamase has been documented. Refer to CLSI standard M2 for recommendations on the correct storage and maintenance of quality control organisms.[6]
7. The ability to detect vancomycin-resistant *Staphylococcus aureus* (VRSA) with this product is unknown. Additional testing methods as recommended by the Centers for Disease Control and Prevention (CDC) should be used when performing susceptibility testing on *S. aureus* isolates, particularly methicillin-resistant *S. aureus* (MRSA). These tests include nonautomated MIC methods (e.g., broth microdilution or agar dilution) and a vancomycin agar screen test (Brain Heart Infusion Agar with 6 µg/mL of vancomycin). These methods require a full 24 h of incubation to detect VRSA. For additional information, refer to the CDC web site.[12]

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#91.2, 91.3, 91.4, 91.6, 91.7,

Zone Diameter Interpretive Chart 1

Antimicrobial Agent	Code	Disc Potency	Zone Diameter Interpretive Standards (mm): Resistant	Intermediate	Susceptible	Control Zone Diameter Limits (mm): E. coli ATCC 25922	S. aureus ATCC 25923	P. aeruginosa ATCC 27853	H. influenzae ATCC 49247	H. influenzae ATCC 49766	N. gonorrhoeae ATCC 49226	S. pneumoniae ATCC 49619
Amdinocillin	AMD-10	10 µg				23 – 29	—	—				
Enterobacteriaceae			≤15	—	≥16							
Amikacin	AN-30	30 µg				19 – 26	20 – 26	18 – 26				
Enterobacteriaceae, P. aeruginosa, Acinetobacter and staphylococci			≤14	15 – 16	≥17							
Amoxicillin/Clavulanic Acid	AmC-30	20/10 µg				18 – 24	28 – 36	—				
Enterobacteriaceae			≤13	14 – 17	≥18							
Staphylococcus spp.			≤19	—	≥20							
Haemophilus spp.			≤19	—	≥20				15 – 23	—		
Ampicillin	AM-10	10 µg				16 – 22	27 – 35	—				
Enterobacteriaceae and *V. cholerae*			≤13	14 – 16	≥17							
Staphylococci			≤28	—	≥29							
Enterococcus spp.			≤16	—	≥17							
Listeria monocytogenes			≤19	—	≥20							
Haemophilus spp.			≤18	19 – 21	≥22				13 – 21	—		
Streptococci (non-*S. pneumoniae*, β-hemolytic only)			—	—	≥24							30 – 36
Ampicillin/Sulbactam	SAM-20	10/10 µg				19 – 24	29 – 37	—				
Enterobacteriaceae, P. aeruginosa, Acinetobacter and staphylococci			≤11	12 – 14	≥15							
Haemophilus spp.			≤19	—	≥20				14 – 22	—		
Azithromycin	AZM-15	15 µg				—	21 – 26	—				
Staphylococcus spp.			≤13	14 – 17	≥18							
Haemophilus spp.			—	—	≥12				13 – 21	—		
S. pneumoniae and other streptococci			≤13	14 – 17	≥18							19 – 25
Azlocillin	AZ-75	75 µg				—	—	24 – 30				
P. aeruginosa			≤17	—	≥18							
Aztreonam	ATM-30	30 µg				28 – 36	—	23 – 29				
Enterobacteriaceae, P. aeruginosa & Acinetobacter			≤15	16 – 21	≥22							
Haemophilus spp.			—	—	≥26				30 – 38	—		
Bacitracin	B-10	10 U	≤8	9 – 12	≥13	—	12 – 22	—				
Carbenicillin	CB-100	100 µg				23 – 29	—	18 – 24				
Enterobacteriaceae and *Acinetobacter*			≤19	20 – 22	≥23							
P. aeruginosa			≤13	14 – 16	≥17							
Cefaclor	CEC-30	30 µg				23 – 27	27 – 31	—				
Enterobacteriaceae and staphylococci			≤14	15 – 17	≥18							
Haemophilus spp.			≤16	17 – 19	≥20				—	25 – 31		
Cefamandole	MA-30	30 µg				26 – 32	26 – 34	—				
Enterobacteriaceae and staphylococci			≤14	15 – 17	≥18							
Cefazolin	CZ-30	30 µg				21 – 27	29 – 35	—				
Enterobacteriaceae and staphylococci			≤14	15 – 17	≥18							
Cefdinir	CDR-5	5 µg				24 – 28	25 – 32	—				
Enterobacteriaceae and methicillin-susceptible staphylococci			≤16	17 – 19	≥20							
Haemophilus spp.			—	—	≥20				—	24 – 31		
Cefepime	FEP-30	30 µg				31 – 37	23 – 29	24 – 30				
Enterobacteriaceae, P. aeruginosa, Acinetobacter and staphylococci			≤14	15 – 17	≥18							
Haemophilus spp.			—	—	≥26				25 – 31	—		
N. gonorrhoeae			—	—	≥31						37 – 46	
Viridans Streptococci (non-*S. pneumoniae*)			≤21	22 – 23	≥24							28 – 35
Streptococci (non-*S. pneumoniae*, β-hemolytic only)			—	—	≥24							
Cefixime	CFM-5	5 µg				23 – 27	—	—				
Enterobacteriaceae			≤15	16 – 18	≥19							
Haemophilus spp.			—	—	≥21				25 – 33	—		
N. gonorrhoeae			—	—	≥31						37 – 45	
Cefmetazole	CMZ-30	30 µg				26 – 32	25 – 34	—				
Enterobacteriaceae and staphylococci			≤12	13 – 15	≥16							
N. gonorrhoeae			≤27	28 – 32	≥33						31 – 36	
Cefonicid	CID-30	30 µg				25 – 29	22 – 28	—				
Enterobacteriaceae and staphylococci			≤14	15 – 17	≥18							
Haemophilus spp.			≤16	17 – 19	≥20				—	30 – 38		
Cefoperazone	CFP-75	75 µg				28 – 34	24 – 33	23 – 29				
Enterobacteriaceae, P. aeruginosa, Acinetobacter and staphylococci			≤15	16 – 20	≥21							
Cefotaxime	CTX-30	30 µg				29 – 35	25 – 31	18 – 22				
Enterobacteriaceae, P. aeruginosa, Acinetobacter and staphylococci			≤14	15 – 22	≥23							
Haemophilus spp.			—	—	≥26				31 – 39	—		
N. gonorrhoeae			—	—	≥31						38 – 48	
Viridans Streptococci (non-*S. pneumoniae*)			≤25	26 – 27	≥28							31 – 39
Streptococci (non-*S. pneumoniae*, β-hemolytic only)			—	—	≥24							
Cefotaxime/Clavulanic Acid	CTX/CLA	30/10 µg										
Cefotetan	CTT-30	30 µg				28 – 34	17 – 23	—				
Enterobacteriaceae and staphylococci			≤12	13 – 15	≥16							
N. gonorrhoeae			≤19	20 – 25	≥26						30 – 36	
Cefoxitin	FOX-30	30 µg				23 – 29	23 – 29	—				
Enterobacteriaceae and staphylococci			≤14	15 – 17	≥18							
N. gonorrhoeae			≤23	24 – 27	≥28						33 – 41	
Cefpodoxime	CPD-10	10 µg				23 – 28	19 – 25	—				
Enterobacteriaceae and staphylococci			≤17	18 – 20	≥21							
Haemophilus spp.			—	—	≥21				25 – 31	—		
N. gonorrhoeae			—	—	≥29						35 – 43	
Cefprozil	CPR-30	30 µg				21 – 27	27 – 33	—				
Enterobacteriaceae and staphylococci			≤14	15 – 17	≥18							
Haemophilus spp.			≤14	15 – 17	≥18				—	20 – 27		
Ceftazidime	CAZ-30	30 µg				25 – 32	16 – 20	22 – 29				
Enterobacteriaceae, P. aeruginosa, Acinetobacter and staphylococci			≤14	15 – 17	≥18							
Haemophilus spp.			—	—	≥26				27 – 35	—		
N. gonorrhoeae			—	—	≥31						35 – 43	
Ceftazidime/Clavulanic Acid	CAZ/CLA	30/10 µg										
Ceftibuten	CTB-30	30 µg				27 – 35	—	—				
Enterobacteriaceae			≤17	18 – 20	≥21							
Haemophilus spp.			—	—	≥28				29 – 36	—		
Ceftizoxime	ZOX-30	30 µg				30 – 36	27 – 35	12 – 17				
Enterobacteriaceae, P. aeruginosa, Acinetobacter and staphylococci			≤14	15 – 19	≥20							
Haemophilus spp.			—	—	≥26				29 – 35	—		
N. gonorrhoeae			—	—	≥38						42 – 51	
Ceftriaxone	CRO-30	30 µg				29 – 35	22 – 28	17 – 23				
Enterobacteriaceae, P. aeruginosa, Acinetobacter and staphylococci			≤13	14 – 20	≥21							
Haemophilus spp.			—	—	≥26				31 – 39	—		
N. gonorrhoeae			—	—	≥35						39 – 51	
Viridans Streptococci (non-*S. pneumoniae*)			≤24	25 – 26	≥27							30 – 35
Streptococci (non-*S. pneumoniae*, β-hemolytic only)			—	—	≥24							
Cefuroxime (sodium)	CXM-30	30 µg				20 – 26	27 – 35	—				
Enterobacteriaceae and staphylococci (parenteral)			≤14	15 – 17	≥18							
Haemophilus spp.			≤16	17 – 19	≥20				—	28 – 36		
N. gonorrhoeae			≤25	26 – 30	≥31						33 – 41	
Cephalothin	CF-30	30 µg				15 – 21	29 – 37	—				
Enterobacteriaceae and staphylococci			≤14	15 – 17	≥18							
Chloramphenicol	C-30	30 µg				21 – 27	19 – 26	—				
Enterobacteriaceae, P. aeruginosa, Acinetobacter, staphylococci, enterococci and *V. cholerae*			≤12	13 – 17	≥18							
Haemophilus spp.			≤25	26 – 28	≥29				31 – 40	—		
S. pneumoniae			≤20	—	≥21							23 – 27
Streptococci (non-*S. pneumoniae*)			≤17	18 – 20	≥21							
Cinoxacin	CIN-100	100 µg				26 – 32	—	—				
Enterobacteriaceae			≤14	15 – 18	≥19							
Ciprofloxacin	CIP-5	5 µg				30 – 40	22 – 30	25 – 33				
Enterobacteriaceae, P. aeruginosa, Acinetobacter, staphylococci and enterococci			≤15	16 – 20	≥21							
Haemophilus spp.			—	—	≥21				34 – 42	—		
N. gonorrhoeae			≤27	28 – 40	≥41						48 – 58	
Clarithromycin	CLR-15	15 µg				—	26 – 32	—				
Staphylococcus spp.			≤13	14 – 17	≥18							
Haemophilus spp.			≤10	11 – 12	≥13				11 – 17	—		
S. pneumoniae and other streptococci			≤16	17 – 20	≥21							25 – 31
Clindamycin	CC-2	2 µg				—	24 – 30	—				
Staphylococcus spp.			≤14	15 – 20	≥21							
S. pneumoniae and other streptococci			≤15	16 – 18	≥19							19 – 25
Colistin	CL-10	10 µg	≤8	9 – 10	≥11	11 – 15	—	—				
Doripenem	DOR-10	10 µg				28 – 35	33 – 42	28 – 35	21 – 31	—	—	30 – 38
Enterobacteriaceae			—	—	≥23							
Pseudomonas aeruginosa			—	—	≥24							
Acinetobacter baumannii			—	—	≥17							
Streptococcus anginosus group (*S. constellatus* and *S. intermedius*)			—	—	≥24							
Doxycycline	D-30	30 µg				18 – 24	23 – 29	—				
Enterobacteriaceae, P. aeruginosa, Acinetobacter, staphylococci and enterococci			≤12	13 – 15	≥16							
Enoxacin	ENX-10	10 µg				28 – 36	22 – 28	22 – 28				
Enterobacteriaceae and staphylococci			≤14	15 – 17	≥18							
N. gonorrhoeae			≤31	32 – 35	≥36						43 – 51	

Zone Diameter Interpretive Chart †

Antimicrobial Agent	Code	Disc Potency	Zone Diameter Interpretive Standards (mm): Resistant	Intermediate	Susceptible	Control Zone Diameter Limits (mm): E. coli ATCC 25922	S. aureus ATCC 25923	P. aeruginosa ATCC 27853	H. influenzae ATCC 49247	H. influenzae ATCC 49766	N. gonorrhoeae ATCC 49226	S. pneumoniae ATCC 49619
Ertapenem[h,l]	ETP-10	10 µg				28 – 36	24 – 31	13 – 21				28 – 35
Enterobacteriaceae and *Staphylococcus* spp.[j]			≤15	16 – 18	≥19							
Haemophilus spp.[c]			—	—	≥19				20 – 28	27 – 33		
Erythromycin	E-15	15 µg				—	22 – 30	—				
Staphylococcus spp.[r] and enterococci[r,yy]			≤13	14 – 22[ii]	≥23[ii]							
S. pneumoniae and other streptococci[e,uu]			≤15	16 – 20	≥21							25 – 30[e]
Fosfomycin[z]	FOS-200	200 µg				22 – 30[N]	25 – 33	—				
E. coli and *E. faecalis* only			≤12	13 – 15	≥16							
Gatifloxacin	GAT-5	5 µg				30 – 37	27 – 33	20 – 28[mm]				
Enterobacteriaceae[ddd] and *Staphylococcus* spp.[aa]			≤14	15 – 17	≥18							
P. aeruginosa, Acinetobacter spp. and enterococci[a]			≤14[a]	15 – 17[a]	≥18[a]							
H. influenzae[c] and *H. parainfluenzae*[c]			—	—	≥18				33 – 41[c]	—		
N. gonorrhoeae[d]			≤33	34 – 37	≥38						45 – 56[d]	
S. pneumoniae and other streptococci (non-*S. pneumoniae*, β-hemolytic only)[e]			≤17[a]	18 – 20[a]	≥21[a]							24 – 31[e]
Gemifloxacin	GEM-5	5 µg				29 – 36	27 – 33[jj]	19 – 25[mm,jj]				
Enterobacteriaceae[ii,ddd]			≤15	16 – 19	≥20							
H. influenzae[c] and *H. parainfluenzae*[c]			—	—	≥18				30 – 37	—		
S. pneumoniae[e]			≤19	20 – 22	≥23							28 – 34
Gentamicin												
Testing enterococci for high-level resistance[o,p,gg]	GM-120	120 µg	6	7 – 9[hh]	≥10	—	—	—				
Enterobacteriaceae, *P. aeruginosa, Acinetobacter* and staphylococci	GM-10	10 µg	≤12	13 – 14	≥15	19 – 26	19 – 27	16 – 21				
Imipenem[h,l]	IPM-10	10 µg				26 – 32	—	20 – 28				
Enterobacteriaceae, *P. aeruginosa, Acinetobacter* and staphylococci[j]			≤13	14 – 15	≥16							
Haemophilus spp.[c]			—	—	≥16				21 – 29[c]	—		
Kanamycin	K-30	30 µg				17 – 25	19 – 26	—				
Enterobacteriaceae and staphylococci			≤13	14 – 17	≥18							
Levofloxacin	LVX-5	5 µg				29 – 37	25 – 30	19 – 26				
Enterobacteriaceae[ddd], *P. aeruginosa, Acinetobacter*, staphylococci[aa] and enterococci			≤13	14 – 16	≥17							
Haemophilus spp.[c]			—	—	≥17				32 – 40[c]	—		
S. pneumoniae and other streptococci (non-*S. pneumoniae*, β-hemolytic only)[e]			≤13	14 – 16	≥17							20 – 25[e]
Linezolid	LZD-30	30 µg				—	25 – 32[a]	—				
Staphylococcus spp.			—	—	≥21							
Enterococcus spp.			≤20	21 – 22	≥23							
S. pneumoniae and other streptococci[e]			—	—	≥21							25 – 34[e,ii]
Lomefloxacin	LOM-10	10 µg				27 – 33	23 – 29	22 – 28				
Enterobacteriaceae[ddd], *P. aeruginosa, Acinetobacter* and staphylococci			≤18	19 – 21	≥22							
Haemophilus spp.[c]			—	—	≥22				33 – 41[c]	—		
N. gonorrhoeae[d]			≤26	27 – 37	≥38						45 – 54[d]	
Loracarbef[h,l]	LOR-30	30 µg				23 – 29	23 – 31	—				
Enterobacteriaceae[u,kk] and staphylococci[j]			≤14	15 – 17	≥18							
Haemophilus spp.[c,k]			≤15	16 – 18	≥19				—	26 – 32[c]		
Meropenem[h,l]	MEM-10	10 µg				28 – 34	29 – 37[a]	27 – 33				
Enterobacteriaceae, *P. aeruginosa, Acinetobacter* and staphylococci[j]			≤13	14 – 15	≥16							
Haemophilus spp.[c]			—	—	≥20				20 – 28[c]	—		
Mezlocillin[n]	MZ-75	75 µg				23 – 29	—	19 – 25				
Enterobacteriaceae and *Acinetobacter*			≤17	18 – 20	≥21							
P. aeruginosa			≤15	—	≥16							
Minocycline[ee]	MI-30	30 µg				19 – 25	25 – 30	—				
Enterobacteriaceae[ff], *P. aeruginosa, Acinetobacter*[ff], staphylococci and enterococci[ff]			≤14	15 – 18	≥19							
Moxalactam	MOX-30	30 µg				28 – 35	18 – 24	17 – 25				
Enterobacteriaceae, *P. aeruginosa, Acinetobacter* and staphylococci[j]			≤14	15 – 22	≥23							
Moxifloxacin	MXF-5	5 µg				28 – 35	28 – 35	—[ii]				
Enterobacteriaceae[ii,ddd] and *Staphylococcus* spp.[ii]			≤15	16 – 18	≥19							
H. influenzae[c] and *H. parainfluenzae*[c]			—	—	≥18				31 – 39[c]	—		
S. pneumoniae[e]			≤14	15 – 17	≥18							25 – 31[e]
Nafcillin	NF-1	1 µg				—	16 – 22	—				
Staphylococcus aureus[j,nn]			≤10	11 – 12	≥13							
Nalidixic Acid	NA-30	30 µg				22 – 28	—	—				
Enterobacteriaceae[z]			≤13	14 – 18	≥19							
Neomycin[l]	N-30	30 µg	≤12	13 – 16	≥17	17 – 23	18 – 26	—				
Netilmicin	NET-30	30 µg				22 – 30	22 – 31	17 – 23				
Enterobacteriaceae, *P. aeruginosa, Acinetobacter* and staphylococci			≤12	13 – 14	≥15							
Nitrofurantoin	FM-300	300 µg				20 – 25	18 – 22	—				
Enterobacteriaceae, staphylococci and enterococci			≤14	15 – 16	≥17							
Norfloxacin[z]	NOR-10	10 µg				28 – 35	17 – 28	22 – 29				
Enterobacteriaceae[ddd], *P. aeruginosa, Acinetobacter*, staphylococci and enterococci			≤12	13 – 16	≥17							
Novobiocin[f]	NB-30	30 µg	≤17	18 – 21	≥22	—	22 – 31	—				
(Mueller Hinton agar with sheep blood for veterinary use)			≤14	15 – 16	≥17							
Ofloxacin	OFX-5	5 µg				29 – 33	24 – 28	17 – 21				
Enterobacteriaceae[ddd], *P. aeruginosa, Acinetobacter* and staphylococci[aa]			≤12	13 – 15	≥16							
Haemophilus spp.[c]			—	—	≥16				31 – 40[c]	—		
N. gonorrhoeae[d]			≤24	25 – 30[w]	≥31						43 – 51[d]	
S. pneumoniae[e] and other streptococci (non-*S. pneumoniae*, β-hemolytic only)[e]			≤12	13 – 15	≥16							16 – 21[e]
Oxacillin	OX-1	1 µg				—	18 – 24	—				
Staphylococcus aureus[j,nn,oo]			≤10	11 – 12	≥13							
Staphylococci, coagulase-negative[j,nn]			≤17	—	≥18							
S. pneumoniae (for penicillin G susceptibility)[e,h]			—	—	≥20							≤12[e,hh]
Oxolinic Acid[l]	OA-2	2 µg	≤10	—	≥11	20 – 24	14 – 18	—				
Penicillin[b]	P-10	10 U				—	26 – 37	—				
Staphylococcus spp.[j,pp]			≤28	—	≥29							
Enterococcus spp.[r,o]			≤14	—	≥15							
L. monocytogenes[l]			≤19	20 – 27	≥28							
N. gonorrhoeae[d,qq,ii]			≤26	27 – 46[w]	≥47						26 – 34[d]	
Streptococci (non-*S. pneumoniae*, β-hemolytic only)[e,l,rr,uuu]			—	—	≥24							24 – 30[e]
Piperacillin	PIP-100	100 µg				24 – 30[g]	—	25 – 33				
Enterobacteriaceae and *Acinetobacter*			≤17	18 – 20	≥21							
P. aeruginosa			≤17	—	≥18							
Piperacillin/Tazobactam[g]	TZP-110	100/10 µg				24 – 30[g]	27 – 36	25 – 33[ii]				
Enterobacteriaceae and *Acinetobacter*[ii]			≤17	18 – 20	≥21							
Staphylococcus spp.[j,ii] and *P. aeruginosa*[ii]			≤17	—	≥18							
Polymyxin B[ii,dd]	PB-300	300 U	≤8	9 – 11	≥12	12 – 16	—	—				
Quinupristin/Dalfopristin	SYN-15	4.5/10.5 µg				—	21 – 28[jj]	—				
Staphylococcus spp., *Enterococcus faecium* and *S. pyogenes*[e] only			≤15	16 – 18	≥19							19 – 24[e,ii,cc]
Rifampin	RA-5	5 µg				8 – 10	26 – 34	—				
Staphylococcus spp. and *Enterococcus* spp.[yy]			≤16	17 – 19	≥20							
Haemophilus spp.[c]			≤16	17 – 19	≥20				22 – 30[c]	—		
S. pneumoniae[e]			≤16	17 – 18	≥19							25 – 30[e]
Sparfloxacin	SPX-5	5 µg				30 – 38	27 – 33	21 – 29[ii]				
Staphylococcus spp.			≤15	16 – 18	≥19							
S. pneumoniae[e]			≤15[ii]	16 – 18[ii]	≥19							21 – 27[e]
Spectinomycin	SPT-100	100 µg				—	—	—				
N. gonorrhoeae[d]			≤14	15 – 17[w]	≥18						23 – 29[d]	
Streptomycin												
Testing enterococci for high-level resistance[o,p,gg]	S-300	300 µg	6	7 – 9[hh]	≥10	—	—	—				
Enterobacteriaceae	S-10	10 µg	≤11	12 – 14	≥15	12 – 20	14 – 22	—				
Sulfisoxazole[tt]	G-.25	250 µg				15 – 23	24 – 34	—				
Enterobacteriaceae, *P. aeruginosa, Acinetobacter*, staphylococci and *V. cholerae*[m]			≤12	13 – 16	≥17							
Telavancin	TLV-30	30 µg				—	16 – 20	—				17 – 24
Staphylococcus aureus (including methicillin-resistant isolates)[j]			—	—	≥15							
Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus group (*S. anginosus, S. constellatus* and *S. intermedius*)[e,l]			—	—	≥15							
Enterococcus faecalis (vancomycin-susceptible isolates only)[f]			—	—	≥13							
Telithromycin	TEL-15	15 µg				—	24 – 30	—				
S. aureus			—[ii]	—[ii]	≥22							
Haemophilus spp.[c]			≤11	12 – 14	≥15				17 – 23	—		
S. pneumoniae[e]			≤15	16 – 18	≥19							27 – 33
Tetracycline[ee]	TE-30	30 µg				18 – 25	24 – 30	—				
Enterobacteriaceae[ff], *P. aeruginosa, Acinetobacter*[ff], staphylococci, enterococci[ff] and *V. cholerae*[m]			≤14	15 – 18	≥19							
Haemophilus spp.[c]			≤25	26 – 28	≥29				14 – 22[c]	—		
N. gonorrhoeae[d,uu]			≤30	31 – 37[w]	≥38						30 – 42[d]	
S. pneumoniae and other streptococci[e]			≤18	19 – 22	≥23							27 – 31[e]
Ticarcillin	TIC-75	75 µg				24 – 30	—	21 – 27[g]				
Enterobacteriaceae and *Acinetobacter*			≤14	15 – 19	≥20							
P. aeruginosa			≤14	—	≥15							
Ticarcillin/Clavulanic Acid[g]	TIM-85	75/10 µg				24 – 30[g,N]	29 – 37	20 – 28				
Enterobacteriaceae and *Acinetobacter*			≤14	15 – 19	≥20							
P. aeruginosa			≤14	—	≥15							
Staphylococcus spp.[j]			≤22	—	≥23							
Tigecycline	TGC-15	15 µg				20 – 27	20 – 25	9 – 13[ss,mm]	23 – 31[jj]	—	30 – 40[kk]	
Enterobacteriaceae[l,ss]			≤14	15 – 18	≥19							
S. aureus (including MRSA)[l]			—	—	≥19							
E. faecalis (vancomycin-susceptible isolates only)[l]			—	—	≥19							
Streptococcus spp. (other than *S. pneumoniae*)[e,l]			—	—	≥19							23 – 29[cc]
Tobramycin	NN-10	10 µg				18 – 26	19 – 29	19 – 25				
Enterobacteriaceae, *P. aeruginosa, Acinetobacter* and staphylococci			≤12	13 – 14	≥15							
Trimethoprim	TMP-5	5 µg				21 – 28	19 – 26	—				
Enterobacteriaceae and staphylococci			≤10	11 – 15	≥16							
Trimethoprim/Sulfamethoxazole[tt]	SXT	1.25/23.75 µg				23 – 29[x]	24 – 32	—				
Enterobacteriaceae, *P. aeruginosa, Acinetobacter*, staphylococci and *V. cholerae*[m]			≤10	11 – 15	≥16							
Haemophilus spp.[c]			≤10	11 – 15	≥16				24 – 32[c]	—		
S. pneumoniae[e]			≤15	16 – 18	≥19							20 – 28[e]
Vancomycin	VA-30	30 µg				—	17 – 21	—				
Staphylococcus spp.[vv,ii]			—	—	≥15							
Enterococcus spp.[r,o,ww]			≤14	15 – 16	≥17							
S. pneumoniae[xx] and other streptococci[e]			—	—	≥17							20 – 27[e]

† Adapted in part from CLSI Document M100-S21 (M2): Disk Diffusion Supplemental Tables, *Performance Standards for Antimicrobial Susceptibility Testing*, with permission. The complete standard may be obtained from the Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA. Values not in M100-S21 are explained in other footnotes. For appropriate MIC correlates, refer to M100-S21.[5,11]

a The "intermediate" category includes isolates with antimicrobial agent MICs that approach usually attainable blood and tissue levels and for which response rates may be lower than for susceptible isolates. The "intermediate" category implies clinical applicability in body sites where the drugs are physiologically concentrated (e.g., quinolones and β-lactams in urine), or when a higher than normal dosage of a drug can be used (e.g., β-lactams). The "intermediate" category also includes "buffer zone" which should prevent small uncontrolled technical factors from causing major discrepancies in interpretation, especially for drugs with narrow pharmacotoxicity margins.

b Policies regarding generation of cumulative antibiograms should be developed in concert with the infectious disease service, infection control personnel, and the pharmacy and therapeutics committee. Under most circumstances, the percentage of susceptible and intermediate results should not be combined into the same statistic.

c These zone diameter standards and quality control limits apply only to tests with *Haemophilus* spp. using Haemophilus Test Medium (HTM) incubated in 5% CO_2 (16-18 h). *H. influenzae* ATCC 10211 is recommended as a useful additional quality control strain to verify the growth promotion properties of HTM. The zone margin should be considered as the area showing no obvious growth visible with the unaided eye. Faint growth of tiny colonies that may appear to fade from the more obvious zone should be ignored in the measurement. When testing *Haemophilus* with amoxicillin/clavulanic acid on HTM, include *E. coli* ATCC 35218 as the control strain. The acceptable limits for *E. coli* ATCC 35218 are 17-22 mm for amoxicillin/clavulanic acid when incubated in ambient air.

d These zone diameter standards and quality control limits are applicable only to tests performed using GC agar base and 1% defined growth supplement (e.g., BBL™ GC II Agar with IsoVitaleX™ Enrichment) incubated in 5% CO_2 (20 – 24 h).

e These zone diameter standards and quality control limits are applicable only to tests performed using Mueller Hinton agar supplemented with 5% defibrinated sheep blood incubated in 5% CO_2 (20 – 24 h). Interpretive standards apply to *S. pneumoniae* and other streptococci as indicated. Results may be inaccurate if specified criteria are applied to organisms other than those listed. Interpretive criteria for streptococci other than *S. pneumoniae* are proposed based on population distributions of various species, pharmacokinetics of the antimicrobial agents, previously published literature and the clinical experience of certain members of the CLSI subcommittee. Systematically collected clinical data were not available for review with many of the compounds in the group.[7] Despite the lack of reliable disc diffusion interpretive criteria for *S. pneumoniae* with certain β-lactams, *S. pneumoniae* ATCC 49619 is the strain designated for quality control of all disc diffusion tests with all *Streptococcus* spp.

f FDA-approved zone size recommendations from drug manufacturers not included in CLSI M100-S21 (M2-A10).[4]

g Another *E. coli* (ATCC 35218) has been designated for quality control of discs containing combinations of β-lactams and β-lactamase inhibitors. This strain produces a β-lactamase which should be inactivated by the inhibitor. When used in conjunction with ATCC 25922, both components of the combination disc can be monitored. Control limits with this strain for amoxicillin/clavulanic acid are 17-22 mm, for ampicillin is 6 mm (i.e., no zone), for ampicillin/sulbactam are 13-19 mm, for piperacillin are 12-18 mm, for piperacillin/tazobactam are 24-30 mm, for ticarcillin is 6 mm (i.e., no zone) and for ticarcillin/clavulanic acid are 21-25 mm. The *E. coli* ATCC 35218 control strain contains a plasmid-encoded β-lactamase (non-ESBL); therefore, the organism is resistant to many penicillinase-labile drugs, but susceptible to β-lactam/β-lactamase inhibitor combinations. The plasmid must be present in the control strain for the quality control test to be valid; however, the plasmid may be lost during storage at refrigerator or freezer temperatures. See "Limitations of the Procedure" and M2 for additional details.

h Isolates of pneumococci with oxacillin zone sizes of ≥ 20 mm are susceptible (MIC ≤ 0.06 µg/mL) to penicillin and can be considered susceptible to ampicillin, amoxicillin, amoxicillin/clavulanic acid, ampicillin/sulbactam, cefaclor, cefdinir, cefepime, cefetamet, cefixime, cefotaxime, cefprozil, ceftibuten, ceftriaxone, cefuroxime, cefpodoxime, ceftizoxime, ertapenem, imipenem, loracarbef, and meropenem for approved indications, and these agents need not be tested. Penicillin and cefotaxime or ceftriaxone or meropenem MICs should be determined for those isolates with oxacillin zone sizes ≤ 19 mm because zones of ≤ 19 mm occur with penicillin-resistant, intermediate, or certain susceptible strains. Isolates should not be reported as penicillin resistant or intermediate based solely on an oxacillin zone ≤ 19 mm. Amoxicillin, ampicillin, cefepime, cefotaxime, ceftriaxone, cefuroxime, ertapenem, imipenem, and meropenem may be used to treat pneumococcal infections; however, reliable disc diffusion susceptibility tests with these agents do not yet exist. Their in vitro activity is best determined using an MIC method. Penicillin and cefotaxime or ceftriaxone or meropenem should be tested by a reliable MIC method (such as that described in CLSI document M7[9]) and reported routinely with CSF isolates of *S. pneumoniae*. Such isolates should also be tested against vancomycin using the MIC or disc method. With isolates from other sites, the oxacillin disc screening test may be used. If the oxacillin zone size is ≤ 19 mm, penicillin and cefotaxime or ceftriaxone MICs should be determined. To determine susceptibility of streptococci other than *S. pneumoniae* to cefdinir, use the 10-unit penicillin disc; isolates with penicillin zone sizes ≥ 28 mm are susceptible to penicillin and can be considered susceptible to cefdinir.

i A streptococcal isolate that is susceptible to penicillin can be considered susceptible to ampicillin, amoxicillin, amoxicillin/clavulanic acid, ampicillin/sulbactam, cefaclor, cefazolin, cefdinir, cefepime, cefprozil, cefotaxime, ceftibuten (group A streptococci only), ceftriaxone, cefuroxime, cefpodoxime, ceftizoxime, cephalothin, cephapirin, cephradine, imipenem, loracarbef, and meropenem for approved indications, and need not be tested against those agents. Viridans streptococci isolated from blood and normally sterile body sites (e.g., cerebrospinal fluid, blood, bone, etc.), should be tested for penicillin or ampicillin susceptibility using an MIC method.

j Penicillin-susceptible staphylococci are also susceptible to other penicillins, β-lactam/β-lactamase inhibitor combinations, cephems, and carbapenems approved for use by the FDA for staphylococcal infections. Penicillin-resistant, oxacillin-susceptible strains are resistant to penicillinase-labile penicillins but susceptible to other penicillinase-stable penicillins, β-lactam/β-lactamase inhibitor combinations, relevant cephems, and carbapenems. Oxacillin-resistant staphylococci are resistant to all currently available β-lactam antibiotics. Thus, susceptibility or resistance to a wide array of β-lactam antibiotics may be deduced from testing only penicillin and oxacillin. Routine testing of other penicillins, β-lactam/β-lactamase inhibitor combinations, cephems, and carbapenems is not advised.[7] For oxacillin-resistant staphylococci, report as resistant or do not report.

k Rare, β-lactamase negative, ampicillin-resistant (BLNAR) strains of *Haemophilus influenzae* should be considered resistant to amoxicillin/clavulanic acid, ampicillin/sulbactam, cefaclor, cefetamet, cefonicid, cefprozil, cefuroxime, and loracarbef despite apparent in vitro susceptibility of some BLNAR strains to these agents.

l Class representative for ampicillin and amoxicillin.

m For *V. cholerae*, the results of disc diffusion tests for ampicillin, tetracycline, trimethoprim/sulfamethoxazole and sulfonamides (i.e., percentage of susceptible, intermediate, and resistant) correlate well with results determined by broth microdilution. Tetracycline results can be used to predict the likely susceptibility of isolates to doxycycline; do not use disc test for doxycycline or erythromycin because there is poor correlation with MIC results.

n Ampicillin is the class representative for ampicillin and amoxicillin. Ampicillin results may be used to predict susceptibility to amoxicillin/clavulanic acid, ampicillin/sulbactam, piperacillin and piperacillin/tazobactam among non-β-lactamase-producing enterococci. Enterococci susceptible to penicillin are predictably susceptible to ampicillin, amoxicillin, ampicillin/sulbactam, amoxicillin/clavulanic acid, piperacillin, and piperacillin/tazobactam for non-β-lactamase-producing enterococci. However, enterococci susceptible to ampicillin cannot be assumed to be susceptible to penicillin. If penicillin results are needed, testing of penicillin is required. Because ampicillin or penicillin resistance among enterococci due to β-lactamase production is not reliably detected using routine disc or dilution methods, a direct, nitrocefin-based β-lactamase test is recommended for blood and cerebrospinal fluid isolates. A positive β-lactamase test predicts resistance to penicillin, as well as amino-, carboxy- and ureido-penicillins. Certain penicillin- or ampicillin-resistant enterococci may possess high level resistance (i.e., penicillin MICs ≥ 128 µg/mL or ampicillin [illegible]

o [illegible]

p [illegible]

q [illegible]

r [illegible]

s [illegible]

t [illegible]

u Cephalothin can be used to predict activity of cephalothin, cephapirin, cephradine, cephalexin, cefaclor and cefadroxil. Cefazolin, cefuroxime, cefpodoxime, cefprozil, and loracarbef (urinary isolates only) may be tested individually because some isolates may be susceptible to these agents when resistant to cephalothin.

v Not applicable for testing *Morganella* spp.

w For *N. gonorrhoeae*, an intermediate result for an antimicrobial agent indicates either a technical problem that should be resolved by repeat testing or a lack of clinical experience in treating organisms with these zones. The latter seems to be the case for cefmetazole, cefotetan, cefoxitin, and spectinomycin. Strains with intermediate zones with the other agents have a documented lower clinical cure rate (85 - 95%) compared to >95% for susceptible strains.

x Cefotaxime, ceftizoxime or ceftriaxone should be tested and reported on isolates from CSF in place of cephalothin and cefazolin.

y Because certain strains of *Providencia* spp. have been reported to give false-susceptible results with cefprozil discs, strains of this genus should not be tested and reported with this disc.

z Indicated for urine isolates only. In addition to testing urine isolates, nalidixic acid may be used to test for reduced fluoroquinolone susceptibility in isolates from patients with extraintestinal *Salmonella* infections. See footnote ddd.

aa FDA-approved zone diameters for interpretive and/or quality control criteria that differ from CLSI recommendations.

bb For *V. cholerae*, use with caution as the disc diffusion test may misclassify many organisms (higher minor error rate).

cc No criteria have been established to support testing of this drug with *Streptococcus pneumoniae*. The control range is listed for quality control purposes only.

dd Colistin and polymyxin B diffuse poorly in agar and the accuracy of the diffusion method is thus less than with other antibiotics. Resistance is always significant, but when treatment of systemic infections due to susceptible strains is considered, it is wise to confirm the results of a diffusion test with a dilution method.

ee Organisms that are susceptible to tetracycline are also considered susceptible to doxycycline and minocycline. However, some organisms that are intermediate or resistant to tetracycline may be susceptible to doxycycline or minocycline or both.

ff FDA-approved for *S. saprophyticus* and *S. epidermidis* (not *S. aureus*).

gg For control limits of gentamicin 120 µg and streptomycin 300 µg discs, use *E. faecalis* ATCC 29212 (gentamicin: 16 - 23[f] mm; streptomycin: 14 - 20[f] mm).

hh If the zone is 7 - 9 mm, the test is inconclusive and an agar dilution or broth microdilution screen test should be performed to confirm resistance.

ii CLSI-recommended zone sizes that differ from FDA-approved zone size recommendations.

jj No criteria have been established to support testing of this drug with *H. influenzae*. The control range is listed for quality control purposes only.

kk Because certain strains of *Citrobacter*, *Providencia*, and *Enterobacter* spp. have been reported to give false susceptible results with cefdinir and loracarbef discs, strains of these genera should not be tested and reported with these discs.

ll FDA-approved for *K. pneumoniae*.

mm No criteria have been established to support testing of this drug with *Pseudomonas aeruginosa*. The control range is listed for quality control purposes only.

nn If a penicillinase-stable penicillin is tested, oxacillin is the preferred agent and results can be applied to the other penicillinase-stable penicillins, cloxacillin, dicloxacillin, flucloxacillin, methicillin and nafcillin. Oxacillin is preferred because it is more resistant to degradation in storage, and because it is more likely to detect heteroresistant staphylococcal strains. Cloxacillin discs should not be used because they may not detect oxacillin-resistant *S. aureus*. Cefoxitin may be tested instead of oxacillin (see M100-S21). After incubation for a full 24 h, examine for light growth within the zone of inhibition of the oxacillin disc using transmitted light (plate held up to light). Any discernable growth within the zone of inhibition is indicative of oxacillin resistance.

oo If oxacillin intermediate results are obtained for *S. aureus*, perform testing for *mecA* or PBP 2a, the cefoxitin disc test, an oxacillin MIC test or the oxacillin-salt agar screening test. Report the result of the alternative test rather than the intermediate result.

pp Penicillin-resistant, oxacillin-susceptible strains of *Staphylococcus aureus* produce β-lactamase and the testing of the 10-unit penicillin disc instead of the ampicillin disc is preferred. Penicillin should be used to test the susceptibility of all β-lactamase-labile penicillins, such as ampicillin, amoxicillin, azlocillin, carbenicillin, mezlocillin, piperacillin, and ticarcillin. Likewise, a positive β-lactamase test predicts resistance to these agents.[4] For oxacillin-resistant staphylococci, report as resistant or do not report.

qq A positive β-lactamase test predicts resistance to penicillin, ampicillin, and amoxicillin. A β-lactamase test will detect one form of penicillin resistance in *N. gonorrhoeae* and also may be used to provide epidemiologic information. Strains with chromosomally-mediated resistance can be detected only by additional susceptibility testing, such as the disc diffusion method or the agar dilution MIC method. Gonococci with 10-unit penicillin disc zone diameters of ≤19 mm are likely to be β-lactamase-producing strains. However, the β-lactamase test remains preferable to other susceptibility methods for rapid, accurate recognition of this plasmid-mediated penicillin resistance.

rr Susceptibility tests on *S. pyogenes* to penicillin are seldom necessary since this microorganism has continued to be universally susceptible to penicillin. However, some strains of *S. agalactiae* may give penicillin-intermediate results.[7]

ss Tigecycline has decreased in vitro activity against *Morganella* spp., *Proteus* spp. and *Providencia* spp.

tt The sulfisoxazole disc can be used to represent any of the currently available sulfonamides. Blood-containing media (except for lysed horse blood) are generally not suitable for testing sulfonamides or trimethoprim. Mueller Hinton agar should be as thymidine-free as possible for sulfonamide and/or trimethoprim testing. To determine whether the Mueller Hinton agar has sufficiently low levels of thymine and thymidine, *Enterococcus faecalis* ATCC 29212 or ATCC 33186 may be tested with the trimethoprim/sulfamethoxazole disc (see ref. 13). An inhibition zone of ≥ 20 mm that is essentially free of fine colonies indicates a sufficiently low level of thymine and thymidine.[4]

uu Gonococci with 30-µg tetracycline disc zone diameters of ≤ 19 mm usually indicate a plasmid-mediated tetracycline-resistant *N. gonorrhoeae* (TRNG) isolate. These strains should be confirmed by a dilution test (MIC ≥ 16 µg/mL) and/or referred to a public health laboratory for epidemiological investigation.

vv All staphylococcal isolates with vancomycin zone diameters of 14 mm or less should be tested by a reference MIC method. The disc diffusion procedure will not differentiate strains with reduced susceptibility to vancomycin (MICs 4 to 8 µg/mL) from susceptible strains (MICs 0.5 to 2 µg/mL) even when incubated 24 h. Additionally, vancomycin-resistant *S. aureus* (VRSA) strains (MICs ≥ 16 µg/mL) may produce only subtle growth around a vancomycin disc. The vancomycin agar screen test described for enterococci (Brain Heart Infusion Agar with 6 µg/mL Vancomycin) may be used to enhance the sensitivity of detecting vancomycin-intermediate and vancomycin-resistant strains of *S. aureus* incubating the plates for a full 24 h at 35°C. Use of a susceptible quality control strain, such as *E. faecalis* ATCC 29212 is critical to ensure specificity. *E. faecalis* ATCC 51299 may be used as a positive (i.e., resistant) control. Until further data on the prevalence or clinical significance of these isolates is known, laboratories may choose to examine MRSA strains more carefully for elevated MICs to vancomycin.[7] Currently, there are insufficient data to recommend using this agar screen test for coagulase-negative staphylococci. Send any staphylococci determined to have an elevated MIC to vancomycin (≥ 4 µg/mL) to a reference laboratory.

ww [illegible]

xx [illegible]

yy [illegible]

zz [illegible]

aaa [illegible]

bbb [illegible]

ccc [illegible]

ddd [illegible]

eee [illegible]

BD BBL Sensi-Disc Antimicrobial Susceptibility Test Discs

(Disques Sensi-Disc BBL pour antibiogramme)

Français

APPLICATION – Ces disques sont utilisés pour une évaluation semi-quantitative in vitro de la sensibilité aux antibiotiques des agents pathogènes bactériens courants à croissance rapide [illegible]

[illegible]

BD BBL™ Paper Discs for the Detection of β-Lactamase Enzymes

Cefinase Discs

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INTENDED USE

Cefinase™ discs are intended for use in rapid testing of isolated colonies of *Neisseria gonorrhoeae*, *Staphylococcus* species, *Haemophilus influenzae*, enterococci and anaerobic bacteria for the production of β-lactamase.

SUMMARY AND EXPLANATION

The ability of certain bacteria to produce enzymes that inactivate β-lactam antibiotics, i.e., penicillins and cephalosporins, has long been recognized. Abraham and Chain in 1940 first recognized an enzymatic activity in extracts of *Escherichia coli* that inactivated penicillin.[1] Since then a large number of similar enzymes have been isolated from a number of bacterial species with somewhat different substrate specificities. Some selectively hydrolyze penicillin-class antimicrobics (i.e., penicillin G, ampicillin, carbenicillin) and have been described as penicillinases. Others selectively hydrolyze the cephalosporin-class antimicrobics (i.e., cephalothin, cephalexin, cephradine) and have been described as cephalosporinases. Still other enzymes hydrolyze both cephalosporins and penicillins.[2]

A large number of β-lactamase-resistant penicillin and cephalosporin class antimicrobics have been developed by various pharmaceutical companies. One group includes the semisynthetic penicillins; methicillin, oxacillin, nafcillin and others, which are resistant to the penicillinase enzymes produced by staphylococci.[3] A large number of cephalosporins have also been developed which have varying degrees of resistance to β-lactamases. These include the second-generation cephalosporins (cefoxitin, cefamandole and cefuroxime) and third-generation cephalosporins (cefotaxime, moxalactam, cefoperazone and others).[4]

Several clinical tests have been developed for the detection of β-lactamases. These tests provide rapid information predictive of the development of resistance. Interpretation of β-lactamase test results must consider: the sensitivity of the test for different classes of β-lactamase enzymes, the types of β-lactamases produced by different taxonomic groups of organisms and the substrate specificities of the different β-lactamases.

The most commonly used clinical procedures include the iodometric method, the acidometric method, and a variety of chromogenic substrates.[5] The iodometric and acidometric tests are generally performed using penicillin as a substrate and, therefore, can only detect enzymes which hydrolyze penicillin. One of the chromogenic cephalosporins, PADAC (Calbiochem-Behring) has been found effective in detecting most of the known β-lactamases except for some of the penicillinases produced by staphylococci, and some β-lactamases produced by anaerobic bacteria.[6] Another chromogenic cephalosporin, nitrocefin (Glaxo Research), has been found effective in detecting all known β-lactamases including the staphylococcal penicillinases.[7–9]

For many taxonomic groups of organisms, e.g. *Enterobacteriaceae*, the β-lactamase test is of little value because a diversity of β-lactamase enzymes with different substrate specificities may be produced within the group, or even within a single strain.[10]

In other bacteria, for example, penicillin-resistant *Neisseria gonorrhoeae*,[11] *Staphylococcus aureus*,[12,13] *Moraxella catarrhalis*,[14] and ampicillin-resistant *Haemophilus influenzae*,[5,9,15] only one class of enzyme is produced by resistant strains. The β-lactamase test performed with these organisms enables a prediction of resistance to be made immediately after primary isolation, 18-24 h prior to the time that growth-dependent susceptibility results would be available.

While the prevalence of β-lacatmase-producing enterococci appears to be small, a low inoculum may result in strains going undetected by susceptibility-testing procedures, and routine screening by the nitrocefin disc procedure is recommended.[16]

With anaerobic bacteria, the relationship between the production of β-lactamase and resistance to β-lactam antimicrobics is complicated and somewhat similar to *Enterobacteriaceae*. β-lactamases are most commonly found within the *Bacteroides* species,[17] however, β-lactamase-producing strains of *Clostridium butyricum*, *C. perfringens* and *Fusobacterium* sp. have been reported.[18,19] Among the *Bacteroides* group, a variety of enzymes may be produced with different substrate specificities. The β-lactamases frequently found in strains of *Prevotella melaninogenica* and *P. oralis* are usually specific for penicillins (penicillinase),[20] whereas the β-lactamases frequently found in the *B. fragilis* group are cephalosporinases.[21,22] A variety of cephalosporinases have been reported in the *B. fragilis* group and they include some very active enzymes which can hydrolyze some of the reportedly β-lactamase-resistant cephalosporins such as cefotaxime.[23,24] Rare strains have been reported which hydrolyze at high rates all known β-lactams including cefoxitin.[24,25]

Even though the β-lactamases produced by the *B. fragilis* group are most active against cephalosporins, most strains are found to be resistant to penicillin, carbenicillin and ampicillin in growth-dependent susceptibility tests.[17,26] This finding suggests that the *B. fragilis* group may be intrinsically resistant to penicillins through factors such as permeability barriers,[22] or that the β-lactamase is produced in quantities sufficient to overcome the relatively slow hydrolysis rate of the enzyme with penicillins. Evidence which tends to support a contributory role for β-lactamase in the resistance to penicillins is found in reports that the combination of clavulanic acid (a β-lactamase inhibitor) and penicillins is many times more active against *B. fragilis* than is the penicillin alone.[27]

Whatever the cause or causes of penicillin resistance in *B. fragilis*, all strains should probably be considered resistant.[28] The other gram-negative anaerobic strains are probably susceptible to penicillin so long as they are β-lactamase negative.[28]

PRINCIPLES OF THE PROCEDURE

The Cefinase disc is impregnated with the chromogenic cephalosporin, nitrocefin. This compound exhibits a very rapid color change from yellow to red as the amide bond in the β-lactam ring is hydrolyzed by a β-lactamase. When a bacterium produces this enzyme in significant quantities, the yellow-colored disc turns red in the area where the isolate is smeared.

Although other penicillins and cephalosporins may be used as substrates for specific enzymes, nitrocefin has the wide spectrum of susceptibility and sensitivity of the commercially available β-lactams. It is not known to react with other microbial enzymes.[29]

Each disc is used to test one bacterial strain for the presence of β-lactamase.

REAGENTS

Cefinase discs impregnated with nitrocefin.

Warnings and Precautions:

For *in vitro* Diagnostic Use.

These discs are not for use in susceptibility testing.

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. After use, prepared plates and other contaminated materials must be sterilized by autoclaving before discarding.

Nitrocefin induces mutations in certain strains of bacteria (Ames test) and may be sensitizing. Ingestion, inhalation or contact with the skin or eyes should be avoided.

Storage Instructions: Upon receipt, store unopened package at -20 to +8°C. After use, the Cefinase cartridge should be stored in any glass, air tight container containing desiccant and stored at -20 to +8°C. Discard remaining Cefinase discs 60 days after opening blister packaging. The expiration date on the cartridge applies only to discs intact in unopened blister packaging.

Indications of Deterioration: Do not use the cartridge if the discs appear orange or red in color.

SPECIMEN COLLECTION AND HANDLING

This procedure is not to be used directly with clinical specimens or other sources containing mixed microbial flora. The bacteria to be tested must first be isolated as separate colonies by streaking the specimen onto appropriate culture media plates.

PROCEDURE

Material Provided: Cefinase discs, 50 discs per cartridge.

Materials Required But Not Provided: Ancillary reagents, quality control organisms and laboratory equipment as required for the procedure.

Test Procedure:

1. Using a single disc dispenser, dispense the required number of discs from the cartridge into an empty Petri dish or onto a microscope slide.
2. Moisten each disc with one drop of purified water.
3. With a sterilized loop or applicator stick remove several well-isolated similar colonies and smear onto a disc surface.
4. Observe disc for color change.
5. Alternate procedure: Using forceps moisten disc with one drop of purified water and then wipe across colony.

User Quality Control: Control reference cultures should be run with each group of unknowns. The following organisms are recommended for use as test strains.

Test Strain	Expected Results
Staphylococcus aureus ATCC® 29213	Positive
Haemophilus influenzae ATCC 10211	Negative

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

RESULTS AND INTERPRETATION

A positive reaction will show a yellow to red color change on the area where the culture was applied. Note: color change does not usually develop over the entire disc. A negative result will show no color change on the disc.

For most bacterial strains a positive result will develop within 5 min. However, positive reactions for some staphylococci may take up to 1 h to develop.

Organism	Result	Approx. Reaction Time	Interpretation
Staphylococcus aureus	Positive	1 h	Resistant to penicillin, ampicillin, carbenicillin and ticarcillin. Probably susceptible to cephalothin, methicillin, oxacillin, nafcillin and other penicillinase-resistant penicillins.*
Haemophilus influenzae	Positive	1 min	Resistant to ampicillin. Susceptibile to cephalosporins.*
Neisseria gonorrhoeae and *Moraxella catarrhalis*	Positive	1 min	Resistant to penicillin.
Enterococcus faecalis	Positive	5 min	Resistant to penicillin and ampicillin
Anaerobic bacteria	Positive	30 min	Probable identification is *Bacteroides* species. Probably resistant to penicillin and may be resistant to cephalosporins including cefotaxime and rarely cefoxitin.

* Susceptibility should be confirmed by growth-dependent susceptibility tests.
Negative results imply but do not guarantee susceptibility.

LIMITATIONS OF THE PROCEDURE

The efficacy of this test in predicting the β-lactam resistance of microorganisms other than *Neisseria gonorrhoeae, Haemophilus influenzae, Moraxella catarrhalis,* staphylococci, enterococci and certain anaerobic bacteria is unproven.

Resistance to β-lactam antibiotics has been on rare occasions reported in some of the above organisms without the production of β-lactamases.[30,31] In these cases, resistance mechanisms such as permeability barriers have been postulated. Therefore, the β-lactamase test should be used as a rapid supplement and not a replacement for conventional susceptibility testing.

For some strains of staphylococci,[13] particularly *S. epidermidis*, an inducible β-lactamase has been described that might result in a false-negative β-lactamase reaction with a strain which is resistant to penicillin or ampicillin.

SPECIFIC PERFORMANCE CHARACTERISTICS

In a comparative study of four methods for detecting β-lactamase activity in anaerobic bacteria, the following percentages of agreement with a "standard" employing nitrocefin-saturated filter paper were obtained: Cefinase, 100%; pyridine-2-azo-p-dimethylaniline cephalosporin, 96%; a penicillinase disc using bromcresol purple pH indicator, 72%; the slide iodometric technique, 78%.[32]

AVAILABILITY

Cat. No.	Description
231650	**BD BBL™ Cefinase™**, 50

#91.5.

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Technical Information: In the United States, contact BD Technical Service and Support at 800-638-8663 or www.bd.com/ds.

BD BBL™ Taxo™ A Discs for Differentiation of Group A Streptococci

CE

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INTENDED USE

Taxo™ A discs are for the presumptive identification of group A beta-hemolytic streptococci based on susceptibility to a low level of bacitracin. Discs are intended for use with pure cultures, with the exception noted under "Specimens."

SUMMARY AND EXPLANATION

Taxo A discs are impregnated with a low level of bacitracin. According to the work of Maxted, of Levinson and Frank, and others, the group A streptococci may be differentiated from the other Lancefield groups of hemolytic streptococci by the formation of a zone of inhibition around the disc.[1-6]

PRINCIPLES OF PROCEDURE

Group A beta-hemolytic streptococci are sensitive to small amounts of bacitracin, while beta-hemolytic streptococci of other serologic groups are more resistant. The **Taxo** A disc on a blood agar plate can be used for presumptive identification of group A beta-hemolytic streptococci after overnight incubation.

REAGENTS

Taxo A discs are impregnated with approximately 0.04 unit of bacitracin per disc.

Warnings and Precautions:

For *in vitro* Diagnostic Use.

Taxo A discs *are not for susceptibility testing.*

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. After use, test plates and other contaminated materials must be sterilized by autoclaving before discarding. Directions for use should be read and followed carefully.

Storage Instructions: On receipt, store at -20 to +8 °C. After use, store vial or cartridge to protect product integrity at 2 to 8 °C.

Use oldest discs first and discard expired discs. Allow containers to come to room temperature before opening. Return unused discs to the refrigerator when application of discs has been completed. Vials and cartridges from which discs have been frequently removed during one week and discs left out overnight in the laboratory should be discarded, or the discs should be tested for performance with control organisms prior to continued use.

SPECIMENS

Taxo A discs are not for use directly with clinical specimens or other sources containing mixed flora. The organism to be presumptively identified must first be isolated as separate colonies by streaking the specimen onto appropriate culture media; e.g., **Trypticase™** Soy Agar with 5% Sheep Blood (TSA II). However, the **BBL™** Group A Selective Strep Agar with 5% Sheep Blood (**ssA™**) plate, which may be used for the primary isolation of group A streptococci from throat specimens, was designed specifically for use with the **Taxo** A disc.[7]

PROCEDURE

Material Provided: Taxo A Discs.

Materials Required But Not Provided: Ancillary culture media, quality control organisms and laboratory equipment as required for this procedure.

Test Procedure

1. Inoculate a **Trypticase** Soy Agar with 5% Sheep Blood plate with the test organism exhibiting beta-hemolysis on the primary isolation plate. If the plate is inoculated with a suspension, it should be adjusted to provide just confluent growth over the surface of the plate. With sterile forceps or single disc dispenser place the **Taxo** A disc in the center of the inoculated area. If the organism is streak-inoculated, the disc should be placed in the primary streak area or at the junction of the primary and secondary streak area. For further information regarding the use of the **Taxo** A disc with **ssA**, consult **ssA** product literature.
2. Incubate plate(s) in ambient air (or in an atmosphere enriched with 5 to 10% CO_2) at 35 to 37 °C for 18 to 24 hours.
3. Observe plate for presence of a zone of growth inhibition around the bacitracin disc.

User Quality Control: At the time of use, check performance with pure cultures of stable control organisms producing known, desired reactions. The use of *Streptococcus pyogenes* ATCC® 12384 is recommended to demonstrate zone formation. One or more beta-hemolytic streptococcal species belonging to groups B, C, D and/or G may be employed to demonstrate lack of zone formation.

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

RESULTS

A zone of inhibition is formed around the **Taxo** A disc if the organism is a group A streptococcus. It is recommended that any zone of inhibition, regardless of diameter, be reported as "beta-hemolytic *Streptococcus*, presumptively group A by bacitracin."[8]

No zone of inhibition (growth up to the edge of the disc) is reported as "beta-hemolytic *Streptococcus*, presumptively not group A by bacitracin."[8]

LIMITATIONS OF THE PROCEDURE

The **Taxo** A disc test is presumptive, and a positive result should be followed with more specific physiological and/or serological tests.[9]

It should be noted that an excessive inoculum concentration may result in the absence of a zone of inhibition (false-negative) with some group A streptococci. It has been reported that 6% of group B and 7.5% of groups C and G streptococci may produce zones of inhibition (false-positive result).[10] Also, some streptococci may fail to grow in the absence of CO_2.

PERFORMANCE CHARACTERISTICS

Prior to release, all lots of **Taxo** A Discs are tested for performance characteristics. Representative samples of the lot are assayed for bacitracin content using a microbiological assay procedure. The acceptable minimal concentration of bacitracin per disc is determined.

Additionally, plates of **Trypticase** Soy Agar with 5% Sheep Blood are swab-inoculated with cultures of *Streptococcus pyogenes* group A (A451), *S. pyogenes* group A (ATCC 12384), *S. pyogenes* group A (ATCC 10389), *S. pyogenes* group A (ATCC 19615), *Streptococcus* group B (ATCC 12400), *Streptococcus* group B (ATCC 12386), *Streptococcus* group C (152), *Streptococcus* group D (1305) and *Streptococcus* group G (R58/2336) diluted to 10^{-1}. Representative samples of the lot are placed on the inoculated plates and incubated at 35 ± 2 °C for 18 to 24 h. The plates are then read for zone size around the **Taxo** A disc. All strains of *S. pyogenes* group A show zones of inhibition around the disc. No zones are observed around the **Taxo** A disc with *Streptococcus* groups B, C, D and G.

AVAILABILITY

Cat No.	Description
231040	BD BBL Taxo™ A, 50
231041	BD BBL Taxo™ A, 6 x 50
231042	BD BBL Taxo™ A, 50
231552	BD BBL Taxo™ A, 10 x 50

#91.8.

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Technical Information: In the United States contact BD Technical Service and Support at 800-638-8663 or www.bd.com/ds.

BD BBL Taxo A Discs pour la différenciation des Streptococques du Groupe A

Français

APPLICATION

Les **Taxo** A discs (disques **Taxo** A) sont destinés à l'identification présomptive des streptocoques hémolytiques bêta du groupe A en fonction de leur sensibilité à la bacitracine en faible concentration. Les disques sont prévus pour être utilisés avec des cultures pures, à l'exception du cas envisagé dans la rubrique "Echantillons".

RESUME ET EXPLICATION

Les **Taxo** A discs sont imprégnés de bacitracine à faible concentration. D'après les travaux de Maxted, et de Levinson et Frank, ainsi que d'autres chercheurs, les streptocoques du groupe A peuvent être différenciés des autres groupes Lancefield de streptocoques hémolytiques par la formation d'une zone d'inhibition autour du disque.[1-6]

BD BBL™ Taxo™ P Discs
for Differentiation of Pneumococci

CE

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2015-04

#919

Contact your local BD representative for instructions. / Свържете се с местния представител на BD за инструкции. / Pokyny vám poskytne místní zástupce společnosti BD. / Kontakt den lokale BD repræsentant for at få instruktioner. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για οδηγίες. / Kasutusjuhiste suhtes kontakteeruge oma kohaliku BD esindajaga. / Ota yhteys lähimpään BD:n edustajaan ohjeiden saamiseksi. / Kontaktiraj lokalnog predstavnika BD za upute. / A használati utasítást kérje a BD helyi képviseletétől. / Нұсқаулар үшін жергілікті BD өкілімен хабарласыңыз. / Lai saņemtu norādījumus, sazinieties ar vietējo BD pārstāvi. / Naudojimo instrukcijų teiraukitės vietos BD įgaliotojo atstovo. / Neem contact op met uw plaatselijke BD-vertegenwoordiger voor instructies. / Kontakt din lokale BD-representant for mer informasjon. / Aby uzyskać instrukcje użytkowania, skontaktuj się z lokalnym przedstawicielstwem BD. / Contacte o representante local da BD para instruções. / Pentru instrucțiuni, contactați reprezentantul local BD. / Для получения указаний обратитесь к местному представителю компании BD. / Inštrukcie získate u miestneho zástupcu spoločnosti BD. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Kontakta närmaste BD-representant för anvisningar. / Talimatlar için yerel BD temsilcinizle temasa geçin. / За інструкціями зверніться до місцевого представника компанії BD.

INTENDED USE

Taxo™ P Discs are recommended for use in the presumptive identification of pneumococci, and are intended for use with pure cultures.

SUMMARY AND EXPLANATION

Taxo P Discs are impregnated with ethylhydrocupreine hydrochloride (optochin), a drug used for pneumonia therapy before sulfonamides became available. The growth of pneumococci, but not of other streptococci, is markedly inhibited by this chemical.[1,2] Pneumococci may, therefore, be differentiated from other alpha-hemolytic streptococci by the formation of a zone of inhibition around a Taxo P disc placed on a blood agar plate heavily inoculated with a pure culture suspected to be *Streptococcus pneumoniae*.[2]

PRINCIPLES OF THE PROCEDURE

Taxo paper discs are impregnated with various chemicals as an aid in the rapid differentiation and presumptive identification of microoganisms. Evidence may be obtained from the reactions or responses to the impregnated agents to indicate the taxonomy of the organism under test.

The Taxo P Disc on a blood agar plate can be used for the rapid presumptive identification of pneumococci by observing zones of inhibition and hemolytic reactions.

REAGENTS

Taxo P Discs are 6 mm discs made from high quality absorbent paper impregnated with approximately 5.0 µg of ethylhydrocupreine hydrochloride per disc. The last disc in each cartridge is marked "X" and contains the agent as coded.

Warnings and Precautions:

For *in vitro* Diagnostic Use.

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. After use, test plates and other contaminated materials must be sterilized by autoclaving before discarding.

Storage Instructions: On receipt, store at -20 to +8 °C. After use, store vial or cartridge at 2 to 8 °C to protect product integrity. The expiration date applies to unopened containers stored as directed. Do not open until ready to use.

Use oldest discs first and discard expired discs. Allow containers to come to room temperature before opening. Return unused discs to the refrigerator. Discard containers which have been left out overnight.

SPECIMENS

These discs are not for use directly with clinical specimens or other sources containing mixed flora. The organism to be presumptively identified must first be isolated as separate colonies by streaking the specimen onto appropriate culture media; e.g., Trypticase™ Soy Agar with 5% Sheep Blood (TSA II).

PROCEDURE

Material Provided: Taxo P Discs.

Materials Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

Test Procedure:

1. With sterile forceps or Single Disc Dispenser, place a Taxo P disc onto a Trypticase Soy Agar with 5% Sheep Blood (TSA II) subculture plate which has been heavily inoculated with a pure culture of the test organism exhibiting alpha hemolysis on the primary isolation plate.
2. Incubate plate(s) aerobically at 35 ± 2 °C for 24 h, or as needed to obtain good growth; incubation in a CO_2-enriched atmosphere will enhance growth but reduce zone size.[3,4]
3. Measure the diameter of the zone obtained with a millimeter ruler or caliper.

User Quality Control: At the time of use, check performance with pure cultures of stable control organisms producing known desired reactions. The use of *S. pneumoniae* ATCC® 6305 is recommended to demonstrate zone formation (14 mm or larger in diameter) and *S. pyogenes* ATCC 12384 is recommended for use as a negative (no zone) control.

Quality control requirements must be performed is accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

RESULTS

Zones of inhibition of 14 mm or more are formed with pure cultures of *S. pneumoniae*. Other organisms may show zone sizes less than 14 mm in diameter. A diameter between 6 and 14 mm is questionable for pneumococci and the strain should be presumptively identified as a pneumococcus only if it is bile soluble.[4,5]

LIMITATIONS OF THE PROCEDURE

Taxo P Disc tests are presumptive. Positive results should be followed with more specific tests. Additional tests for pneumococci include bile solubility, the Neufeld (quellung) reaction and biochemical and serological procedures.[4,5]

Occasional strains of pneumococci not inhibited by optochin have been reported and strains of alpha streptococci have been reported to form zones of approximately 10 to 12 mm when light inocula were used.[6]

PERFORMANCE CHARACTERISTICS

Prior to release, all lots of Taxo™ P Discs are tested for performance characteristics. Representative samples of the lot are assayed for ethylhyrocuprein hydrochloride (optochin) content using a chemical assay procedure.

Additionally, plates of **Trytlcase** Soy Agar with 5% Sheep Blood are swab-inoculated with cultures diluted 10^{-1} of *Streptococcus pneumoniae* (ATCC 6305), *S. pneumoniae* (Wilson), *S. pneumoniae* (SPA-18), *S. pneumoniae* (III), *Streptococcus pyogenes* (ATCC 12384) and *Streptococcus faecalis* (ATCC 10541). Representative samples of the lot are placed on the inoculated plates and incubated at 35 ±2 °C for 24 h. The plates are then read for zone size around the **Taxo** P Disc with a millimeter ruler. The average zone size with *S. pneumoniae* cultures is at least 14 mm in diameter. No zones are observed around the Taxo P Disc with the *S. pyogenes* and *S. faecalis* cultures.

AVAILABILITY

Cat. No.	Description
231046	BD BBL™ Taxo™ P, 50
231047	BD BBL™ Taxo™ P, 6 x 50
231048	BD BBL™ Taxo™ P, 50
231554	BD BBL™ Taxo™ P, 10 x 50

#91.9.

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Technical Information: In the United States contact BD Technical Service and Support at 800-638-8663 or www.bd.com/ds.

BD BBL Taxo P Discs
pour la différenciation des pneumocoques

Français

APPLICATION

Les **Taxo** P Discs (disques Taxo P) sont recommandés pour l'identification présomptive des pneumocoques et sont prévus pour être utilisés avec des cultures pures.

RESUME ET EXPLICATION

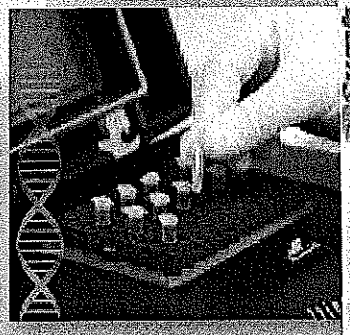
Les disques **Taxo** P sont imprégnés de chlorhydrate d'éthylhydrocupréine (optochine), un médicament utilisé dans la thérapie des pneumonies avant l'introduction des sulfamides. La croissance des pneumocoques, mais pas celle des autres streptocoques, est significativement inhibée par ce produit chimique.[1,2] Les pneumocoques peuvent donc être différenciés des autres streptocoques alpha-hémolytiques par la formation d'une zone d'inhibition de croissance autour du disque Taxo P placé sur la surface d'une gélose au sang préalablement ensemencée avec un inoculum important provenant d'une culture pure présumée contenir une souche de *Streptococcus pneumoniae*.[2]

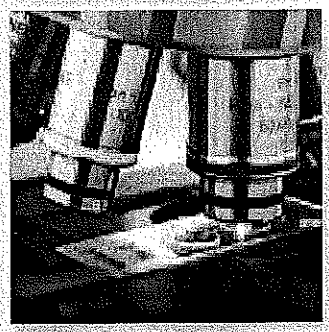
eSwab™

#96.1-96.3

LIQUID BASED MULTIPURPOSE COLLECTION AND TRANSPORT SYSTEM

COLLECTION | TRANSPORT | PRESERVATION





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eSwab™

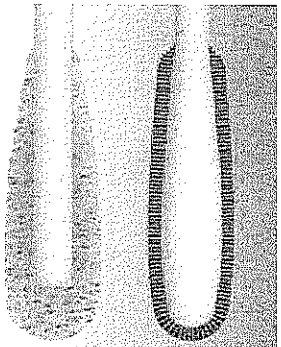
NEW LIQUID BASED TRANSPORT FOR MICROBIOLOGY

Each COPAN ESwab comprises of a 1 mL of Liquid Amies and a flocked swab.

COPAN ESwab is the only liquid-based, multipurpose, open platform, collection and preservation system that maintains viability of aerobic, anaerobic and fastidious bacteria for up to 48 hours at refrigerator and room temperature.

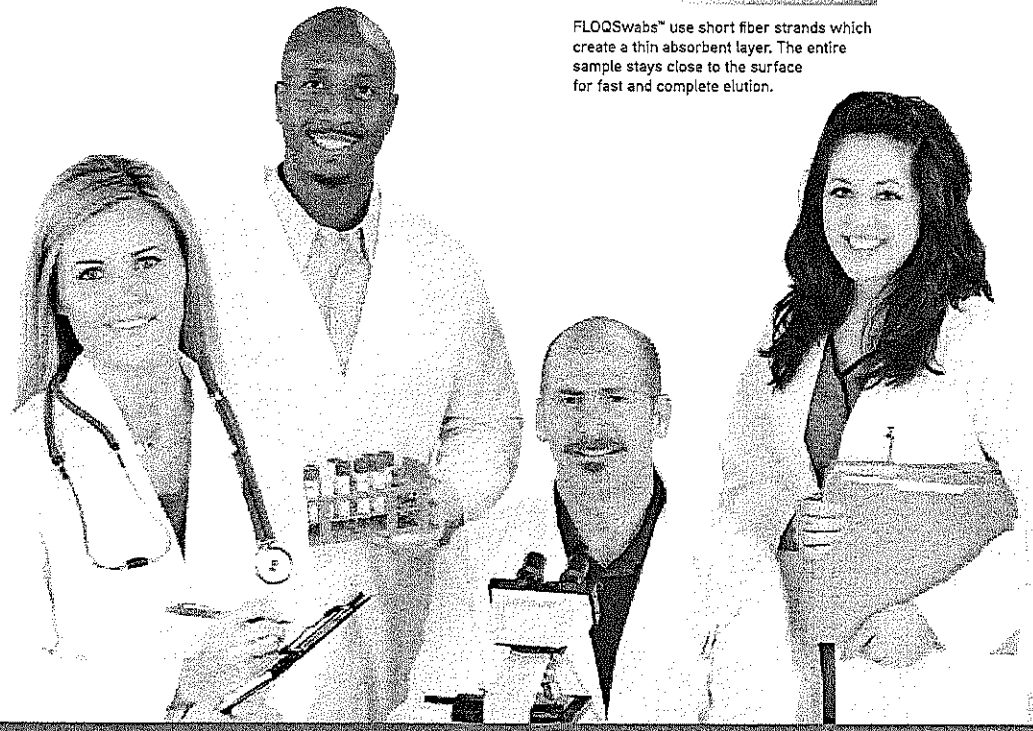
Elutes all the specimen into solution
Amplifies your culture and assay sensitivity!

ABOUT COPAN FLOQSwabs™



Traditional Fiber Swab Flocked Swab

FLOQSwabs™ use short fiber strands which create a thin absorbent layer. The entire sample stays close to the surface for fast and complete elution.



> ESWAB ADVANTAGE

1. USING COPAN'S PATENTED FLOQSWABS™ ESwab elutes the entire sample upon contact with 1 ml Liquid Aimes preservation medium.
2. ESWAB IS THE ONLY UNIVERSAL LIQUID BASED, MULTIPURPOSE, OPEN PLATFORM COLLECTION AND PRESERVATION SYSTEM that maintains viability of aerobic, anaerobic and fastidious bacteria for up to 48 hours at refrigerator and room temperature*.
3. ESWAB EXPANDS TESTING CAPABILITIES with identical aliquots of liquid sample suspension allowing for multiple tests from the same specimen.
4. EXPERIENCE SIGNIFICANT COST SAVINGS by replacing multiple SKU's with just one, eliminating the need to stock multiple types of swabs.
5. ESWAB IS THE ONLY LIQUID TRANSPORT SWAB SYSTEM WHICH ALLOWS FOR AUTOMATED SPECIMEN PROCESSING.
6. ESWAB CREATES MORE CONSISTENT GRAM STAINS since the entire specimen elutes from the FLOQSwab™ creating a homogenous suspension for a more precise and even smear.

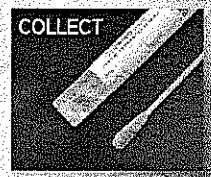
* Product tested and validated in full compliance with CLSI M40-A: Quality Control of Microbiological Transport System standard, including Neisseria gonorrhoeae survival at 24 hours.

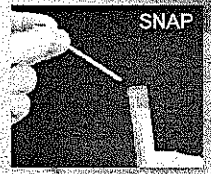
MULTIPURPOSE COPAN ESWAB WORKS FOR:

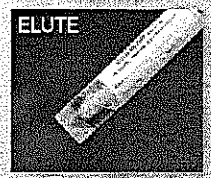
- Automation
- Gram Stains
- Traditional Bacteriology Culture
- Rapid Antigen Tests*
- Molecular Assays*

At COPAN, we make specimen collection and preservation as easy as we can for our partners; physicians, nurses and laboratorians alike. Because when they can do their job efficiently, we know that we did our job efficiently.

* Self validation required

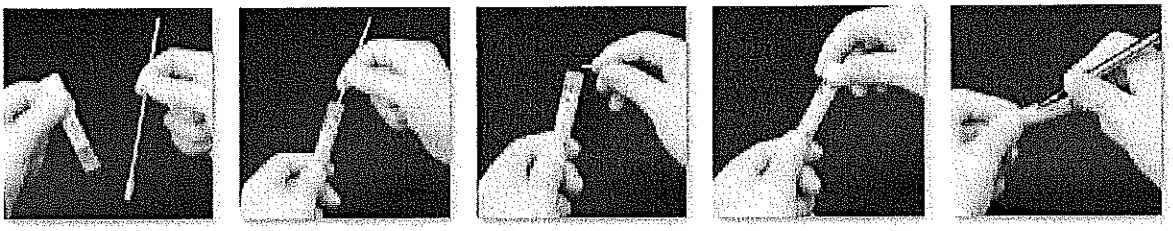






SIMPLIFY AND STREAMLINE SPECIMEN COLLECTION

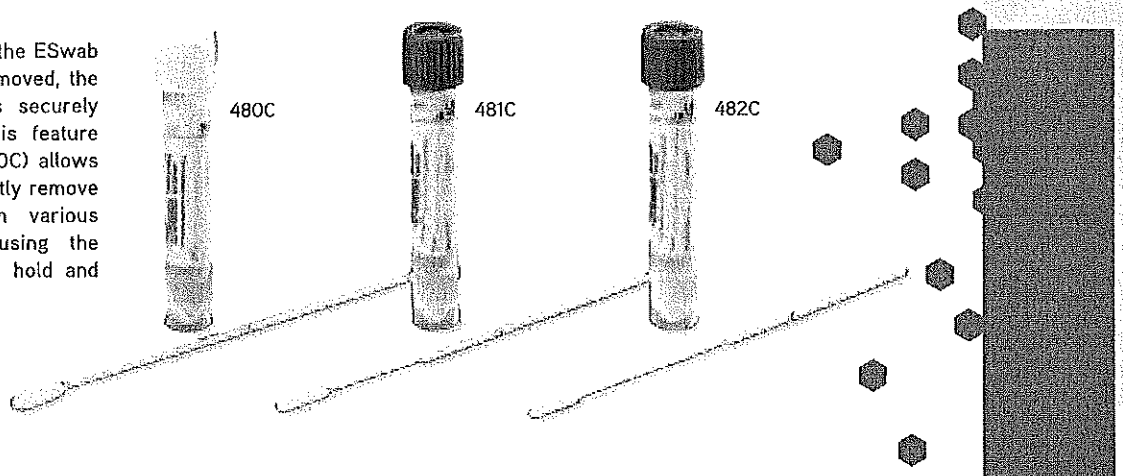
eSwab™ HOW TO USE THE ESWAB SYSTEM



Cat No.	Cap Color	Copan ESwab - Product Description	Pack Size	Sampling Sites	Capture Cap
✓480C	white cap	Sterile single use sample collection pack containing: Polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium and one regular size FLOQSwab™.	50 kits per shelf pack 10 x 50 kits per box	Nose, throat, vagina and wounds	YES
✓481C	green cap	Sterile single use sample collection pack containing: Polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium and one minitip size FLOQSwab™.	50 kits per shelf pack 10 x 50 kits per box	Eye, ear, nasal passages, urogenital tracts	NO
✓482C	blue cap	Sterile single use sample collection pack containing: Polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium and one flexible minitip size FLOQSwab™.	50 kits per shelf pack 10 x 50 kits per box	Nasopharynx and pediatric sample collection	NO

#961,
#963,
#962,

In the testing laboratory, the ESwab cap is unscrewed and removed, the swab applicator stick is securely attached to the cap. This feature (available only on the 480C) allows the operator to conveniently remove the swab and perform various microbiology analyses using the tube cap as a handle to hold and manipulate the swab.



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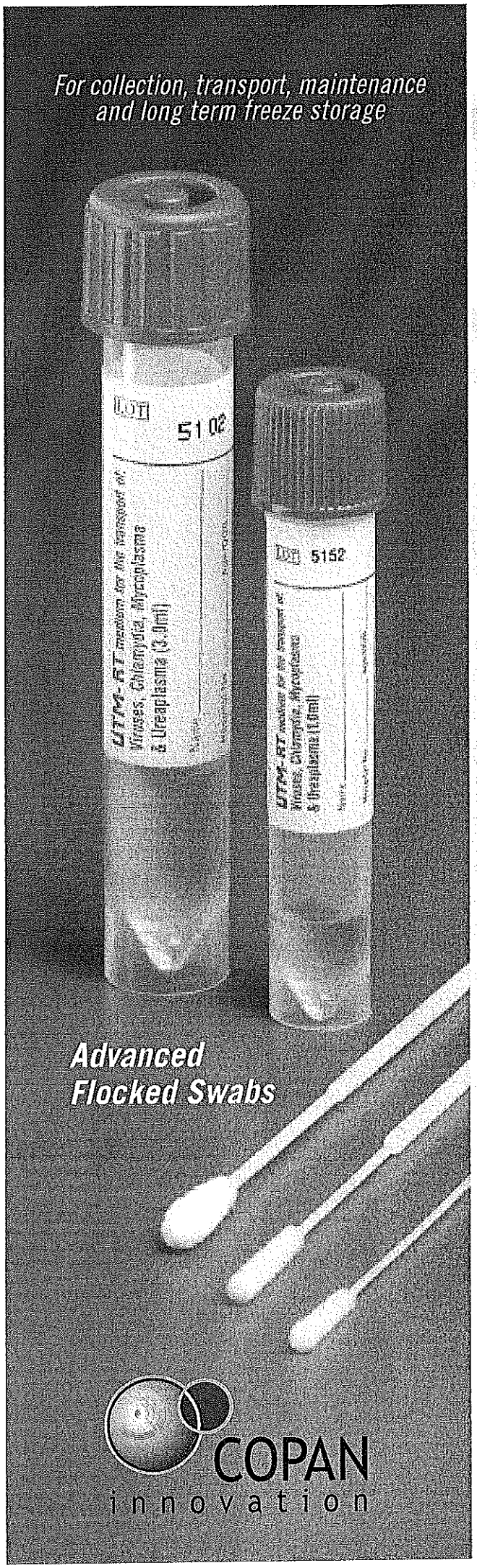


Virus, Chlamydia, Mycoplasma and Ureaplasma

UTM

UNIVERSAL TRANSPORT MEDIUM #96.4.

• *Room Temperature Stable* •

One transport - multiple tests - no sample rejection

- Culture - all viruses, Chlamydia, mycoplasma and ureaplasma
- Enzyme Immuno Assays (EIA)
- PCR
- Nucleic acid amplification assays including *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (Ct/Ng).

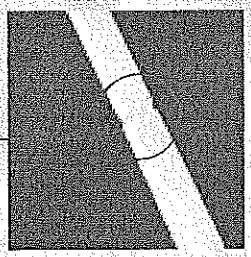
Product stable at room temperature for 12 months

Organism viability maintained at room temperature and on ice

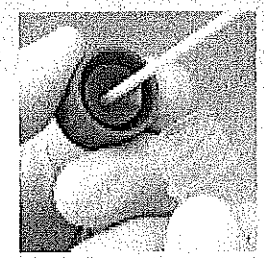
Choice of tube size, medium fill volume and product format
Variety of patient specimen collection kits available comprising tubes of media and swabs or bulk packs of media tubes only.

Advanced nylon flocked swabs increase sample release
UTM is supplied with unique flocked swabs which increase sample release and sensitivity in tissue culture or assays.

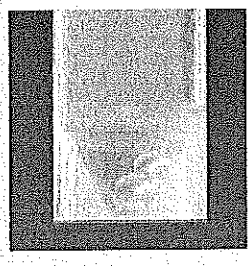
Precision snap molded breakpoint on swab shafts
Plastic swab applicators supplied with UTM kits feature exclusive molded breakpoints.



Capture cap docks and locks-in the swab stick
UTM tube caps incorporate a unique internal design which functions like a docking system automatically capturing the end of the swab stick and securing it firmly into the cap.



Internal conical shaped tube
Tubes stand upright on the bench without the need for tube racks.



Glass beads in each tube assist the release of sample from the swab and mixing prior to analysis when used with a vortex mixer.

Copan Italia S.p.A.
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Copan UTM Ordering Information

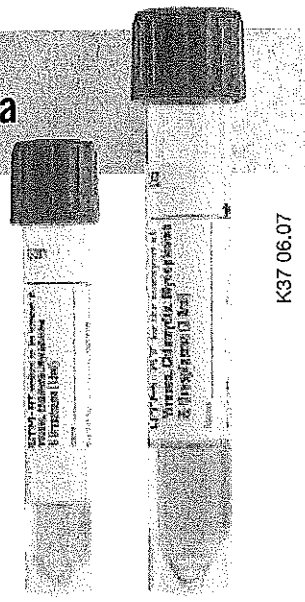
UTM
UNIVERSAL TRANSPORT MEDIUM

Catalog No.	COPAN UTM - BULK TUBES (NO SWABS)	Packaging
330C	16x100 mm tube, 3 ml UTM medium (bulk pack)	6 x 50 kits
350C	12x80 mm mini tube, 1 ml UTM medium (bulk pack)	6 x 50 kits

Catalog No.	COPAN UTM - TUBE & FLOCKED SWAB	Packaging
346C	16x100 mm tube, 3 ml UTM medium, 1 Regular FLOCKED Swab, Molded Breakpoint	6 x 50 kits
307C	16x100 mm tube, 3 ml UTM medium, 1 Minitip FLOCKED Swab, Molded Breakpoint	6 x 50 kits
305C	16x100 mm tube, 3 ml UTM medium, 1 Flexible Nasopharyngeal FLOCKED Swab, Molded Breakpoint	6 x 50 kits
359C	12x80 mm mini tube, 1 ml UTM medium, 1 Regular FLOCKED Swab, Molded Breakpoint	6 x 50 kits
361C	12x80 mm mini tube, 1 ml UTM medium, 1 Minitip FLOCKED Swab, Molded Breakpoint	6 x 50 kits
360C	12x80 mm mini tube, 1 ml UTM medium, 1 Flexible Nasopharyngeal FLOCKED Swab, Molded Breakpoint	6 x 50 kits

Catalog No.	COPAN UTM - TUBE & STANDARD SWABS	Packaging
302C	16x100 mm tube, 3 ml UTM medium, 2 regular size plastic/polyester applicators	6 x 50 kits
✓303C	16x100 mm tube, 3 ml UTM medium, 2 plastic/polyester applicators (1 regular, 1 minitip)	6 x 50 kits #196.4.
328C	16x100 mm tube, 3 ml UTM medium, 1 regular size plastic/polyester applicator	6 x 50 kits
335C	16x100 mm tube, 3 ml UTM medium, 3 plastic/polyester applicators (2 regular, 1 minitip)	6 x 50 kits
343C	16x100 mm tube, 1,5 ml UTM medium, no glass beads, 2 regular size plastic/polyester applicators	6 x 50 kits

Collection of Virus, Chlamydia, Mycoplasma and Ureaplasma



For collection, transport, maintenance and long term freeze storage

UTM
UNIVERSAL TRANSPORT MEDIUM

K37 06.07

COPAN
innovation

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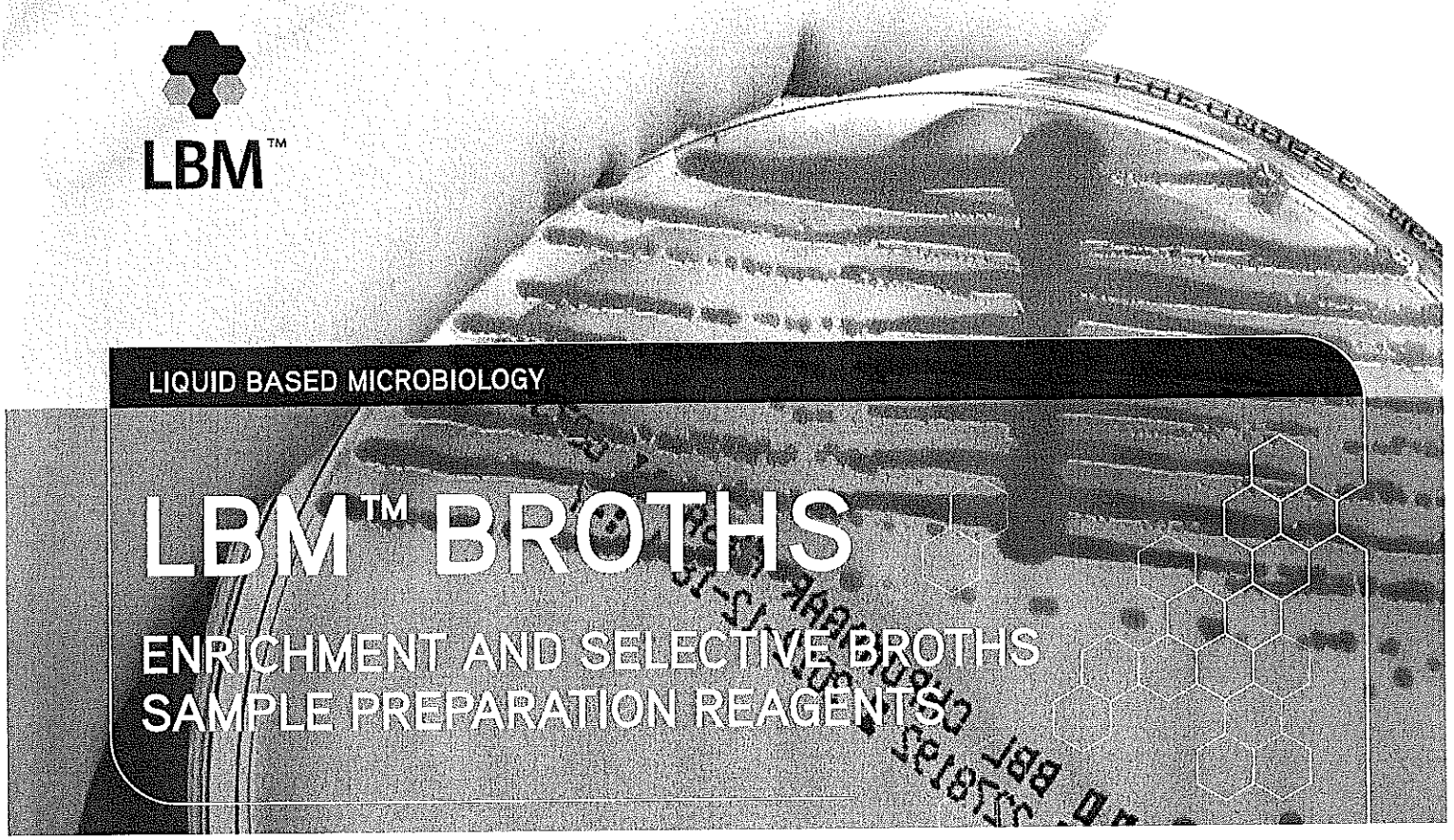
E-mail: info@copanitalia.com Check out our website: www.copaninnovation.com

Copan Flocked Swabs:
Worldwide Patent No. WO 2004/086979 CE 0344

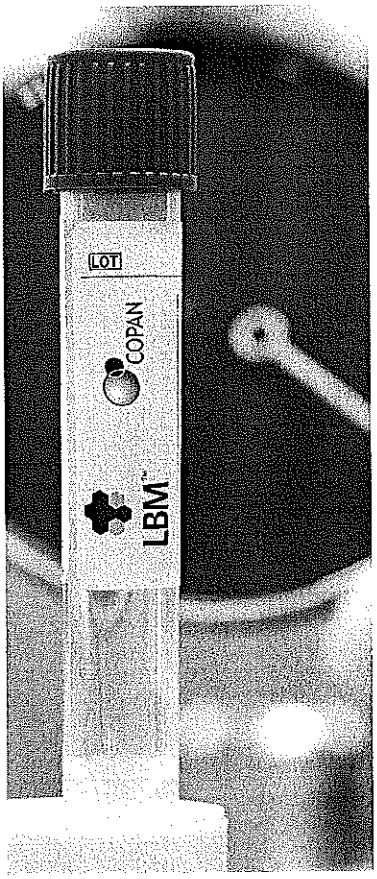
LBM™



LIQUID BASED MICROBIOLOGY

LBM™ BROTHS

ENRICHMENT AND SELECTIVE BROTHS
SAMPLE PREPARATION REAGENTS



LBM™

#96.5

WHAT IS LBM™ BROTHS RANGE

Thanks to the invention of FLOQSwabs™ patented technology, Copan has made the concept of Liquid Based Microbiology (or LBM) and microbiology automation a reality. Along with collection, preservation and transport systems ideal for bacteriology samples, virology culture, and molecular-based assays, Copan's portfolio also includes a full range of enrichment and selective broths, as well as sample preparation reagents.
Copan's strong and continuous commitment to be innovative delivers cost-effective and convenient pre-analytical solutions to improve the microbiology laboratory workflow efficiently.

› PLUS FEATURES

- › Long shelf-life and stability at room temperature
- › Standardized format: 12x80mm screw cap tube
- › Ready to use and convenient
- › No pretreatment and no preparation requirement
- › Available also as collection and transport kits with FLOQSwab™*

*applicable to specific product references.

COPAN
Innovating Together™

copanitalia.com

BHI Broth brain heart infusion

Enrichment broth for fastidious bacteria, including Streptococcus spp and Pneumoniae spp.

Cat. No	Description	Pack Size
474CE	BHI Broth 3ml in 12X80mm Screw Cap Tube in bulk	50 pcs per box 6X50 per case

TSB Kit tryptic soy broth kit

Generic multiuse enrichment broth without salt for aerobes, moulds and yeasts.

Cat. No	Description	Pack Size
468CE02	TSB kit 2ml in 12X80mm Screw Cap Tube + 2 regular FLOQSwabs™	50 pcs per box 6X50 per case

BPW 1% buffered peptone water

Generic enrichment broth for serial dilutions and pre-enrichment - for industrial use only.

Cat. No	Description	Pack Size
972C	BPW Solution 1%, 2ml in 12X80mm Screw Cap Tube in bulk - not for diagnostic use	50 pcs per box 6X50 per case

CAT Broth candida and trichomonas

Enrichment broth for isolation of Candida and Trichomonas.

Cat. No	Description	Pack Size
094CE.A	CAT Broth 2ml Medium in 12X80mm Screw Cap Tube in bulk	50 pcs per box 6X50 per case

Thiol Broth

Universal Enrichment Broth for anaerobs bacteria and obligatory microrganisms.

Cat. No	Description	Pack Size
087CU.A	THIOL Broth 4ml in 12X80mm Screw Cap Tube in bulk	15 pcs per box 10X15 per case

TSB Salt Broth tryptic soy broth salt

Enrichment broth for S. aureus spp. with 2,5% of NaCl.

Cat. No	Description	Pack Size
477CE	TSB Broth Plus 2,5% NaCl, 2ml in 12X80mm Screw Cap Tube in bulk	50 pcs per box 6X50 per case
477CE03	TSB Kit Plus 2,5% NaCl, 2ml in 12X80mm Screw Cap Tube + 3 regular FLOQSwabs™	50 pcs per box 6X50 per case

All above products are suitable for WASP™ automation system. Please contact info@copanitalia.com for additional information.

eMRSA Broth

Enrichment broth for S. aureus spp (including MRSA and MSSA).

Cat. No	Description	Pack Size
086CE01.A	eMRSA Broth 2ml in 12x80 Screw Cap Tube + 1 regular FLOQSwab™	50 pcs per box 6X50 per case

Fungi Swab

Selective and Enrichment broth for Fungi and Dermatophytes.

Cat. No	Description	Pack Size
090CN	FUNGI Swab in 16x100 tube blue cap + 1 Plastic Applicator, Rayon tip (not suitable for automation)	50 pcs per box 6X50 per case

SELENITE Broth

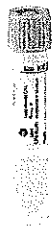
Selective and Enrichment broth for Salmonella enterica spp and Shigella sonnei.

Cat. No	Description	Pack Size
475CE	SELENITE Broth 2ml in 12X80mm Screw Cap Tube in bulk	50 pcs per box 6X50 per case

GN Broth gram negative

Selective and Enrichment broth for Gram Negative, in particular for Salmonella enterica spp and Shigella spp.

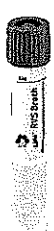
Cat. No	Description	Pack Size
085CU.A	GN Broth 4ml in 12x80 Screw Cap Tube in bulk	50 pcs per box 6X50 per case



LIM Broth

Selective and Enrichment broth for Group B Streptococcus.

Cat. No	Description	Pack Size
476CE	LIM Broth 2ml in 12 X 80mm Screw Cap Tube	50 pcs per box 6X50 per case
476CE01	LIM Kit 2ml in 12 X 80mm Screw Cap Tube + 1 regular FLOQSwabs™	50 pcs per box 6X50 per case #96,5.



RVS Broth rappaport vassiliadis soy broth

Enrichment broth for Salmonella spp. - for clinical and industrial use.

Cat. No	Description	Pack Size
479CE	RAPPAPORT Broth 2ml in 12x80 Screw Cap Tube in bulk	50pcs per box 6x50 per case

All above products are suitable for WASP™ automation system. Please contact info@copanitalia.com for additional information.

LBM™

HF Broth (Half Fraiser)

Differential broth for Lysteria spp - for industrial use only.

Cat. No	Description	Pack Size
970C	**Half-Fraiser Broth** 2ml in 12x80mm Screw Cap Tube- not for diagnostic use	50 pcs per box 6X50 per case

SL solution

Ready to use reagent for Liquefying Sputum Samples

Cat. No	Description	Pack Size
097CE	**SLSolution** 1ml of DTT solution in liquid phase in 12x80 Screw Cap Tube in bulk	50 pcs per box 6X50 per case
095CE	**SLSolution kit :** 1ml of DTT solution in liquid phase in 12X80mm Screw Cap Tubes + 1 sterile Pasteur Pipette for sputum sample transfer	20 pcs per box 10X20 per case
099CE	**SLSolution** 0,5ml of DTT solution in liquid phase in 12x80 Screw Cap Tube in bulk	50 pcs per box 6X50 per case

All above products are suitable for WASP™ automation system. Please contact info@copanitalia.com for additional information.

QUALITY & REGULATORY INFORMATION

By being ISO 9001:2008 and ISO 13485:2012 Certified, Copan Italia has demostrated its ability to not only provide products that meet customer and regulatory requirements, but also its commitment to improve CUSTOMER SATISFACTION through the effective application of its quality management system.

ISO9001:2008
ISO9001:2008 is a standard on quality management system (QMS) promoting a systematic approach towards the management of product quality.

ISO13485:2012
Quality management system specific for medical device manufacturer and related services.

CE MARKING
CE marking ensures the free movement within the European market of products that conform to the requirements of EU legislation and it is a key indicator of a product's compliance with the In Vitro Diagnostics Directive (98/79/EEC).
By Placing CE marking on product, manufacturer declare their responsibility that the product comply with all the legal requirements in force in Europe

COPAN
Innovating Together™

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JMKC002 Rev.00 Date 201311

ESwab

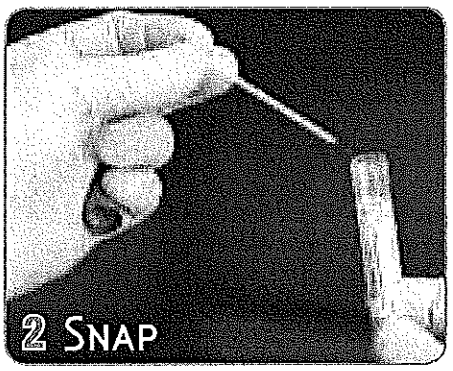
Multipurpose Collection and Transport System, Maintains Viability of Aerobes, Anaerobes and Fastidious Bacteria, Preserves Nucleic Acids and Antigens

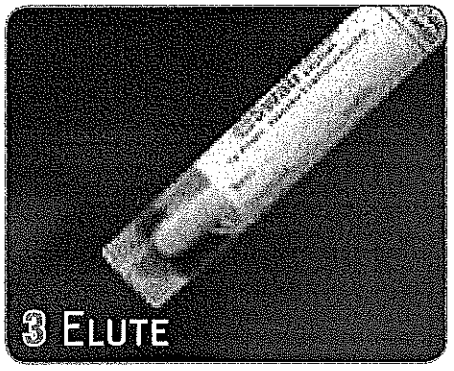
96,6,

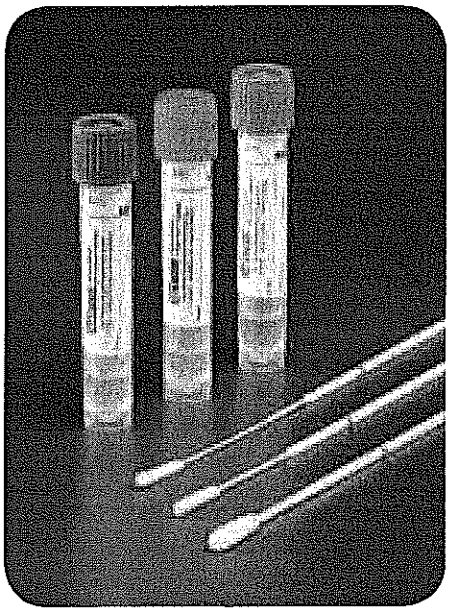
ESwab is the only liquid-based multipurpose collection and transport system that maintains viability of aerobic, anaerobic and fastidious bacteria for up to 48 hours at room and refrigerator temperature. ESwab is a truly open platform suitable for automation, gram stains, traditional culture, and molecular assays, just to name a few of the applications.

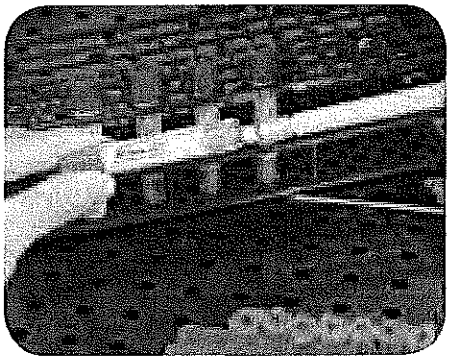
With a Flocked Swab and 1 ml of modified Liquid Amies, ESwab elutes the entire sample into the medium providing to the lab aliquots of liquid sample suspension which can be used to run multiple tests from a single specimen collected from a patient. ESwab is compatible with culture, as well as with molecular assays. It represents an ideal collection and transport system to be used for automated liquid handling, such as Copan's WASP®: Walk-Away Specimen Processor.

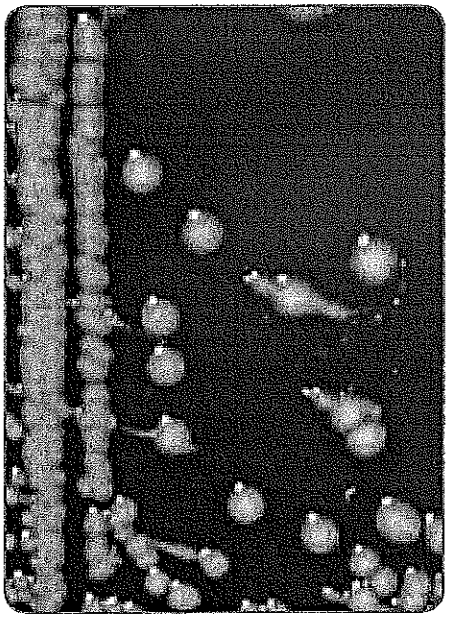
Thanks to the exclusive Flocked Swab technology, the specimen is instantaneously and completely eluted to liquid suspension, from the moment the swab is snapped inside the tube after sample collection. The liquid based specimen can then be divided in homogeneous aliquots, so that all investigations are performed from the same sample. After routine diagnostic investigations, residual specimen can be retained and archived for additional or repeat tests at a later date.







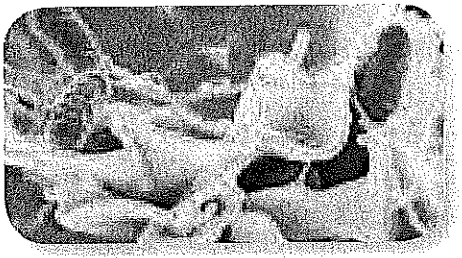




CLSI M40 COMPLIANT · for Rapid Antigen · for Culture · For Molecular Assays

eSwab

Product Features:



Top performance in preserving viability of Bacteria
ESwab complies with the M40-A Protocol as per CLSI Guidelines (DIN 58942). The compliance is endorsed by numerous independent scientific publications, all available on Copan website.

Facilitates Automation
Entire specimen moves from swab to liquid phase, allowing automated liquid handling, for both traditional testing techniques and molecular biology. ESwab smaller size container is compatible with tube sorting systems available at pre-analytics stations.

Expands Testing Capabilities
By using ESwab, laboratories can run multiple tests from the same specimen, using the 1ml of liquid sample suspension.

Replaces Multiple Collection Devices with Just One
ESwab preserves nucleic acids and antigens of Bacteria, Viruses, Chlamydia, Ureaplasma and Mycoplasma. Its versatility allows laboratories to simplify and streamline specimen management at all steps. Original specimen is available for back up purposes.

Easy to Use
Simply collect the sample and snap the applicator. The sample elutes immediately and is spontaneously and completely drained from the Flocked Swab as soon as it is placed in the transport medium.

Cat No	Description	Pack Size	Color Code	Sampling Sites
480CE	**Sterile single use sample collection pack containing** polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium. •One regular size applicator swab with flocked nylon fiber tip.	50 kits per box 10 x 50 kits per case	Pink	Nose, Throat, Vagina, Rectum, Wound and Fecal Samples
481CE	**Sterile single use sample collection pack containing** polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium. •One minitip applicator swab with flocked nylon fiber tip.	50 kits per box 10 x 50 kits per case	Orange	Eye, Ear, Throat, Nasal Passages, Urogenital Tracts
482CE	**Sterile single use sample collection pack containing** polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium. •One pernasal applicator swab with flocked nylon fiber tip.	50 kits per box 10 x 50 kits per case	Blue	Nasopharynx and Pediatric Sample Collection
483CE	**Sterile single use sample collection pack containing** Polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium. •One urethral applicator swab with flocked nylon fiber tip.	50 kits per box 10 x 50 kits per case	Orange	Urogenital Tract
484CE	**Sterile single use sample collection pack containing** Polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium. •One pediatric applicator swab with flocked nylon fiber tip.	50 kits per box 10 x 50 kits per case	Blue	Pediatric Sample Collection
480CESR	**Sterile single use sample collection pack containing** polypropylene screw-cap tube with internal conical shape filled with 1ml Modified Liquid Amies Medium, and one regular size applicator swab with flocked nylon fiber tip •Double Wrapped Packaging for use in sterile zone	50 kits per box 6 x 50 kits per case	Pink	Nose, Throat, Vagina, Rectum, Wound and Fecal Samples
√ 493CE02 # 96.6.	**Sterile single use sample collection pack containing ESwab MRSA System** Polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium. •Two regular applicator swabs with flocked nylon fiber tip.	50 kits per box 10 x 50 kits per case	Pink	MRSA Sample Collection
493CE03	**Sterile single use sample collection pack containing ESwab MRSA System:** •Polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium. •Three regular applicator swabs with flocked nylon fiber tip.	50 kits per box 10 x 50 kits per case	Pink	MRSA Sample Collection

In the testing laboratory, when the ESwab cap is unscrewed and removed, the swab applicator stick is securely attached to the cap. This capture cap feature allows the operator to conveniently remove the swab and perform various microbiology analyses using the tube cap as a handle to manipulate the swab. The capture cap feature is available with 480CE and 480CESR. The ESwab product line includes a range of regular size and minitip applicator swabs for different applications, including a system for MRSA screening.

FUNGIFAST

Identification of yeasts and antifungal susceptibility testing

8 tests (REF 44408)
30 tests (REF 44430) ✓ # 101.1.

EN-2010-06

CE

1 - INTENDED USE

The FUNGIFAST kit allows the identification of the main human pathogenic yeasts as well as the testing of their susceptibility to various antifungal agents used in the treatment of superficial or systemic mycoses.

2 - INTRODUCTION

Fungal infections and especially those caused by yeasts have increased significantly in recent years. Of the *Candida species*, only about ten are responsible for human infections (candidiasis). These are the causative agents of superficial infections (cutaneous and mucocutaneus candidiasis) mainly due to *Candida albicans*, and deep-seated or systemic infections due to *C. albicans* as well as *C. glabrata*, *C. tropicalis* and *C. parapsilosis*. The *Candida* species are also responsible for nosocomial infections. Among the other yeasts, *Cryptococcus neoformans* has been incriminated in serious infections especially in immunocompromized patients.
With the commercialization of new drugs, and the appearance of treatment-resistant mycoses, there is a necessity to evaluate the activity of antifungal agents in yeasts.

3 - PRINCIPLE

3.1 - Identification

The identification of yeasts is based upon:
The detection of the presence or absence of various enzymes by means of colour producing reactions. The enzymatic activities are revealed via three types of reaction:

Hydrolysis of chromogenic substrates

The osidase and peptidase activities of the yeasts are responsible for the hydrolysis of the chromogenic substrates to release para-nitrophenol or para-nitroaniline, both yellow-coloured compounds (wells ß-NAG and PRO).

Assimilation of natural substrates

- Sugar uptake is revealed by the colour change of bromocresol purple (BCP) from violet to brown or yellow, or even to colourless (wells TRE, MAL, CEL, RAF, LAC)
- The hydrolysis of urea brings about the release of ammonia, which alkalinizes the medium and causes the phenol red (PR) to change to fuchsia-pink (well URE)

Oxidation of synthetic substrates

The activity of phenoloxidase in the presence of caffeic acid produces a brown colour (well POX).
Each FUNGIFAST tray also includes a positive control well (well C+) which reveals the assimilation of glucose.

3.2 - Susceptibility testing

The determination of antifungal susceptibility is based upon the growth or the absence of growth of yeasts in the presence of various antifungal agents. Yeast growth is demonstrated by the colour change of the medium. The fermentation of glucose by the yeasts leads to an acidification of the medium that turns the resazurine present in the medium from dark-violet to violet, pink or colourless.

4 - REAGENTS

Description	Quantity 44408	Quantity 44430
SUSPENSION FUNGI : 4 mL-vial of buffered semi-agar medium for colony suspension and identification, containing Bacto Agar, colimycin and vancomycin.	10	35
MES FUNGI : 5 mL-vial of liquid medium (modified RPMI medium) for susceptibility testing, containing resazurin (growth indicator) and glucose.	8	30
TC FUNGI : 4 mL vial of barium sulphate solution for the control of inoculum standardization.	1	1
FUNGIFAST : 20 well-tray individually packed in an aluminium sachet.	8	30

Identification row

- well 1 (C+): positive control well containing glucose and BCP
- well 2 (ß-NAG): contains a chromogenic substrate for N-acetyl-ß-D-glucosaminidase
- well 3 (PRO): contains a chromogenic substrate for L-proline-amidase
- well 4 (TRE): contains trehalose and BCP
- well 5 (MAL): contains maltose and BCP
- well 6 (CEL): contains cellobiose and BCP
- well 7 (RAF): contains raffinose and BCP
- well 8 (LAC): contains lactose and BCP
- well 9 (POX): contains a substrate for phenoloxidase
- well 10 (URE): contains urea and PR.

Susceptibility testing row

Well 11 is an empty growth control well (C+). Wells 12 to 20 contain different antifungal agents as follows :

well 11 (C+) : (0 µg/mL)	well 16 (ITZ) : (0.125 µg/mL)
well 12 (AB) : (0.5 µg/mL)	well 17 (ITZ) : (0.5 µg/mL)
well 13 (AB) : (2 µg/mL)	well 18 (FCZ) : (8 µg/mL)
well 14 (5FC) : (4 µg/mL)	well 19 (FCZ) : (32 µg/mL)
well 15 (5FC) : (16 µg/mL)	well 20 (VRZ) : (1 µg/mL)

Molecule	***Abbr.***	***Commercial name***
Amphotericin B	AB	FUNGIZONE (conventional) ABELCET, AMBISONE (liposomal)
Flucytosine	5FC	ANCOTIL
Fluconazole	FCZ	TRIFLUCAN
Itraconazole	ITZ	SPORANOX
Voriconazole	VOR	VFEND

5 - PRECAUTIONS

- The reagents are intended for *in vitro* diagnostic use only and must be handled by authorized personnel.
- The samples and inoculated reagents are potentially infectious; they must be handled with caution, in observance of hygiene rules and the current regulations for this type of product in the country of use.
- Certain wells on the tray contain raw materials of animal origin and must be handled with caution.
- Certain wells on the tray contain chemical substances and must be handled with caution.
- Do not use reagents after the expiry date.
- Do not use reagents that have been damaged or that have been poorly conserved before use.

6 - SPECIMEN COLLECTION

The colonies used for identifying and performing the susceptibility testing should be young (up to 24 hours old) and perfectly isolated at 37 °C on an agar medium, preferably in a Petri dish.
It is recommended that isolation be made on media that are specific for yeasts such as Sabouraud medium or chromogenic media (CANDICHROM II, REF 44211).

7 - REAGENT STOCKAGE

The reagents stored at 2-8 °C in their original state are stable until the expiry date indicated on the box.
SUSPENSION FUNGI, MES FUNGI as well as the FUNGIFAST trays are ready-to-use and should be used immediately after opening.

8 - REAGENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- Paraffin oil
- Sterile PASTEUR pipettes
- Incubator at 37 °C
- Container for contaminated waste

9 - PROCEDURE

Allow the reagents to reach room temperature (18-25 °C) before use

9.1. Preparation of the inoculum

Pick up two or three isolated colonies with a wire loop or an occluded Pasteur pipette. Inoculate a vial of SUSPENSION FUNGI with the colonies. Mix well. The standardization of the inoculum can be performed in three different ways:

- **With Respect to the TC FUNGI Vial**

Adjust the opacity of the inoculated SUSPENSION FUNGI to that of the TC FUNGI with the aid of the black lines printed on the vial labels. If the suspension medium is lighter (insufficient inoculum), reseed the vial until the opacity obtained equals that of the control vial.
If the suspension medium is more turbid (inoculum too rich), dilute it with a freshly opened SUSPENSION FUNGI vial until the correct turbidity is obtained.

- **With a Densitometer**

Verify with a densitometer that the turbidity of the inoculated suspension medium is equal to **2 Mac Farland**. If necessary, proceed as above to adjust the turbidity.

9.2. Inoculation of the tray

Identification row

Mark the FUNGIFAST tray to identify the specimen being tested. Lift the adhesive tape and dispense into each of the 10 wells as follows :
- 100 µL of seeded and standardized SUSPENSION FUNGI.
Reseal the tray with the adhesive tape.

Susceptibility testing row

First, inoculate a MES FUNGI medium with 10 µL of seeded SUSPENSION FUNGI that has previously been standardized. Mix well.
Then, lift the adhesive tape and dispense into each of the wells of the susceptibility testing row:
- 100 µL of seeded MES FUNGI,
- 2 drops of paraffin oil.
Reseal the tray with the adhesive tape.

9.3. Incubation of the tray

Incubate the tray at 37 °C for 24 hours. If necessary and depending upon the strain continue incubation for up to 48 or even 72 hours (§10.1).
Note: Do not read after an incubation of only 18-20 hours.

10 - READING AND INTERPRETATION

10.1 IDENTIFICATION

10.1.1. Validation (well 1)

After 24 hours incubation, read the tray once the positive control well has turned from violet to yellow/colourless; if it is still violet, prolong the incubation time. Do not prolong the incubation for more than 48 hours except for when *Cryptococcus neoformans* is suspected. In this case incubation may be prolonged up to a maximum of 72 hours.

10.1.2. Reading (wells 2 to 10)

Read the test-tray by referring to the "colour chart" included in the kit. Colours are stable for 4 hours on the bench.

The interpretation of the tray is performed either by a coding system or by the identification table included in the kit. If, after incubation for 24 hours the code obtained is not referenced, continue to incubate for a further 24 hours. If, after incubation for 48 hours the code is still not referenced, refer to the identification table. For a given yeast, all the predominant characteristics mentioned in this table must be positive.
In order to determine the code, the characteristics are listed in triplets:
- ß-NAG, PRO, TRE
- MAL, CEL, RAF
- LAC, POX, URE
Each characteristic is ascribed a zero value if the element is negative. If the element is positive, its value depends on its position in the triplet:
- 1 for position 1
- 2 for position 2
- 4 for position 3.
In the same triplet the values are added to obtained a 3-digit number. This number is then identified in the enclosed list.

ß-NAG	PRO	TRE
+	+	+
1	2	4
7		

MAL	CEL	RAF
+	-	-
1	0	0
1		

LAC	POX	URE
-	-	-
0	0	0
0		

For example : code 710; this code corresponds to *C. albicans or C. dubliniensis* in the list. These two species can be differentiated by using the **ELITex Bicolor dubliniensis test (REF 44502)**
If a results obtained does not correspond to a listed yeast species, a more comprehensive identification test should be used in order to identify the yeast (**ELIchrom FUNGI, REF 44328**).
Note: The diagram printed on the "colour chart" or on the "result sheet" can also be used to help in the identification process. Read the last positive well to the right of the ß-NAG well, but before the LAC well, should be located. The name of the germ is printed at the intersection of the positive characteristic (lower rows) or negative characteristic (upper rows) of the PRO wells and the identified sugar.

10.1.3. Differential diagnosis

In order to confirm the identification of *Candida krusei* (code 000) supplementary tests should be carried out:
- On CANDICHROM II medium *Candida krusei* gives very large, non downy colonies that have a matt creamy white aspect and a distinct irregular scalloped outline.
- **The ELITex krusei test (Ref. 44504)** allows the rapid identification of *Candida krusei* directly from colonies.

10.2 SUSCEPTIBILITY TESTING

In order to facilitate reading and interpretation, use the "colour chart" and the "result sheet" included in the kit.

10.2.1. Validation (well 11)

Verify that the growth control (C+) medium has turned pink or colourless, otherwise prolong the incubation time for up to 48 or 72 hours. With regards to the identification (wells 1 to 10) of *Cryptococcus neoformans*, prolong the incubation at 30 °C for up to a maximum of 72-96 hours.

10.2.2. Reading (wells 12 to 20)

A colour change of the medium, initially dark violet to violet, pink or to colourless, indicates that the tested strain is able to grow in the presence of the antifungal concentration tested in that well.
However, when no colour change is observed, the strain has been inhibited at the concentration of the antifungal tested.

10.2.3. Interpretation of the results

The strain is Susceptible (S), Intermediate (I) / Susceptible - Dose Dependant (S-DD) or Resistant (R) depending upon the growth or the non-growth in the presence of critical concentrations of the antifungal agents.
In order to facilitate interpretation, use the result sheet included in the kit.

10.2.4. Critical concentrations

The critical concentrations (µg/mL) that are commonly used for the interpretation of results are given in the table below:

	S	I	SDD	R
Amphotericin*	ND	ND	-	ND
Flucytosine**	≤ 4	8-16	-	≥ 32
Itraconazole**	≤ 0.125	-	0.25-0.5	≥ 1
Fluconazole**	≤ 8	-	16-32	≥ 64
Voriconazole **	≤ 1	-	2	≥ 4

ND : Non determined.
* : For amphotericin, a MIC > 2 µg/mL indicates possible resistance. The criteria for interpretation are:
S: ≤1 µg/mL, I: = 2 µg/mL, R: > 2 µg/mL.
** : Concentrations determined by the CLSI.

Notes

C. krusei is intrinsically resistant to fluconazole and should systematically be reported as (R) for this antifungal agent.

11 - QUALITY CONTROL

It is recommended that the standardization of the method be verified from time to time using the reference strains, *Candida albicans* ATCC 90029 and *Candida krusei* ATCC 6258.
The expected MIC values are given in the following table:

Strain	*Expected results*									
C.albicans ATCC 90028 (24 hours)	C+	ßNAG	PRO	TRE	MAL	CEL	RAF	LAC	POX	URE
	+	+	+	+	+	-	-	-	-	-
	C+	AB	AB	5FC	5FC	ITZ	ITZ	FCZ	FCZ	VRZ
	+	S		S		S or SDD		S		S
C. krusei ATCC 6258 (24 hours)	C+	ßNAG	PRO	TRE	MAL	CEL	RAF	LAC	POX	URE
	+	-	+	-	+	-	-	-	-	-
	C+	AB	AB	5FC	5FC	ITZ	ITZ	FCZ	FCZ	VRZ
	+	S		S or I		S or SDD		SDD or R		S

12 - CAUSES OF ERROR

- Preparation of the inoculum from a mixed culture.
- Non incubation of the tray and/or the isolation medium at 37 °C.

12.1 Identification

- Adhesive film not attached to the tray during incubation.
- Tray incubated for more than 48 hours except for *C. neoformans*.

12.2 Susceptibility testing

- Preparation of an inoculum that is either too concentrated or not concentrated enough.
- Preparation of the inoculum with isolated colonies grown for more than 48 hours.
- No adding paraffin oil to wells 11 to 20.
- Tray read before a 24 hour incubation period.
- Tray read before the apparition of a colour change of the growth indicator.
- Tray read 24 or 48 hours after the medium has changed colour in the growth control well, and in general, the non-respect of the recommendations contained within these instructions.

13 - LIMITATIONS

13.1 Identification

The FUNGIFAST test allows only the identification of the species described in the data base.

13.2 Susceptibility testing

This *in vitro* method for the determination of the susceptibility to antifungal agents has an indicative value for the antifungal-yeast interaction during *in vivo* treatment.

14 - PERFORMANCE CHARACTERISTICS

Identification: A parallel comparative study was carried out with the Biorad AUXACOLOR 2 method by using 94 yeasts (50 *Candida albicans / dubliniensis*, 15 *C. tropicalis*, 5 *C. glabrata*, 4 *C. guillermondii*, 3 *C. kefyr*, 3 *C. krusei*, 3 *C. lusitaniae*, 4 *C. parapsilosis*, 4 *Saccharomyces cerevisiae*, 3 *Cryptococcus neoformans*), for the most isolated from clinical samples. 93/94 (98.9%) strains were correctly identified:
- 89 strains were correctly identified by both methods.
- 3 *Saccharomyces cerevisiae* strains were identified by FUNGIFAST only.
- 1 *C. guillermondii* strain was correctly identified by FUNGIFAST and misidentified by AUXACOLOR 2.
- 1 *C. lusitaniae* strain was misidentified by FUNGIFAST and non identified by AUXACOLOR 2.

Susceptibility testing: A parallel comparative study was carried out with the Biomérieux ATB FUNGUS 3 by using 109 different yeasts ((55 *Candida albicans*, 21 *C. glabrata*, 6 *C. parapsilosis*, 5 *C. tropicalis*, 5 *C. lusitaniae*, 6 *C. krusei*, 3 *C. kefyr*, 2 *C. guilliermondii*, 5 *Saccharomyces cerevisiae*, 1 *Cryptococcus neoformans*), for the most freshly isolated from clinical samples.
The percentages of category agreement are given in the table below:

n = 109	AB	5-FC	ITZ	FCZ	VRZ
me	0	12	18	11	1
ME	0	0	7	7	8
VME	0	0	4*	0	0
% Agree.	100%	89%	73,4%	83,5%	91,7%

me: minor error ME: Major Error
VME: Very Major Error % Agree. : Percentage of agreement
* The 4 VME was obtained with *S. cerevisiae* strains.
The overall agreement was 87.5%.

15 - WASTE ELIMINATION

Waste should be disposed of in accordance with the hygiene rules and current regulations for this kind of product in the country of use.

16 - BIBLIOGRAPHY

Michel-Nguyen A., M.L. Darde, A. Penaud et B. Bouteille. 1997. Evaluation de la galerie colorimétrique FUNGIFAST® (TWIN identifiant dix espèces de levures d'intérêt médical. J. Mycol. Méd. 7: 81-86.

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FUNGIFAST® AFG

Antifungal susceptibility testing in yeasts

12 tests (Cat. N° 44412) V#101.2.

EN-2009-03

CE

1 - INTENDED USE

The FUNGIFAST AFG kit allows the determination of the susceptibility of the main human pathogenic yeasts to various antifungal agents used in the treatment of superficial or systemic mycoses.

2 - INTRODUCTION

The frequency of nosocomial or community acquired fungal infections is increasing, as is the appearance of treatment-resistant mycoses. With the commercialization of new drugs, there is a necessity to evaluate the activity of antifungal agents in yeasts.
The CLSI (Clinical Laboratory Standards Institute), and the EUCAST (European Committee on Antibiotic Susceptibility Testing) reference methods for antifungal susceptibility testing, are laborious techniques that are unsuitable for routine use.
The FUNGIFAST AFG test uses a colorimetric broth microdilution method. The test is rapid, easy-to-use, easy-to-read and suitable for all clinical laboratories. Moreover there is good agreement between FUNGIFAST AFG and the standard methods.

3 - PRINCIPLE

The determination of antifungal susceptibility is based upon the growth or the absence of growth of yeasts in the presence of various antifungal agents tested at three or four concentrations.
Growth in a liquid medium is demonstrated by the colour change of the medium. The fermentation of glucose by the yeasts leads to reduction of the redox indicator, resulting in a colour change of the medium from dark-violet to pink or colourless.
The results are interpreted after incubation for 24 hours, immediately following a colour change in the growth positive control well (C+). The corresponding well, free of antifungal agent, is inoculated with seeded MES FUNGI medium.
The absence of a colour change in the negative control well (C-) facilitates the interpretation of the results in the other wells. The corresponding well, free of antifungal agent, is inoculated with non-seeded MES FUNGI medium.

4 - REAGENTS

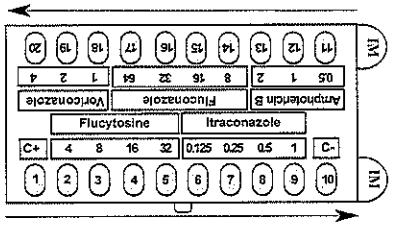
Description	Quantity
SUSPENSION FUNGI : 4 mL-vial of buffered semi-agar medium containing Bacto Agar, colimycin and vancomycin, for colony suspension and standardization.	14
MES FUNGI : 5 mL-vial of liquid medium (modified RPMI medium) for susceptibility testing, containing resazurin (growth indicator) and glucose.	12
TC FUNGI : 4 mL vial of barium sulphate solution for the control of inoculum standardization.	1
FUNGIFAST AFG : 20 well-tray, allowing the testing of one sample, individually packed in an aluminium sachet.	12

Composition of the tray

The FUNGIFAST AFG tray contains various antifungal agents at the following concentrations :

well 1 (C+): (0 µg/mL)
well 2 (5FC): (4 µg/mL)
well 3 (5FC): (8 µg/mL)
well 4 (5FC): (16 µg/mL)
well 5 (5FC): (32 µg/mL)
well 6 (ITZ): (0.125 µg/mL)
well 7 (ITZ): (0.25 µg/mL)
well 8 (ITZ): (0.5 µg/mL)
well 9 (ITZ): (1 µg/mL)
well 10 (C-): (0 µg/mL)
well 11 (AB): (0.5 µg/mL)
well 12 (AB): (1 µg/mL)
well 13 (AB): (2 µg/mL)
well 14 (FCZ): (8 µg/mL)
well 15 (FCZ): (16 µg/mL)
well 16 (FCZ): (32 µg/mL)
well 17 (FCZ): (64 µg/mL)
well 18 (VRZ): (1 µg/mL)
well 19 (VRZ): (2 µg/mL)
well 20 (VRZ): (4 µg/mL)

Molecule	*Abbr.*	*Drug*
Amphotericin B	AB	FUNGIZONE (conventional) ABELCET, AMBISONE (liposomal)
Flucytosine	5FC	ANCOTIL
Fluconazole	FCZ	TRIFLUCAN
Itraconazole	ITZ	SPORANOX
Voriconazole	VOR	VFEND



5 - PRECAUTIONS

- The reagents are intended for *in vitro* diagnostic use only and must be handled by authorized personnel.
- The samples and inoculated reagents are potentially infectious; they must be handled with caution, in observance of hygiene rules and the current regulations for this type of product in the country of use.
- Trays containing dangerous substances must be handled with caution (for more information, refer to the material safety data sheet).
- Do not use reagents after the expiry date.
- Do not use reagents that have been damaged or that have been poorly conserved before use.

6 - SPECIMEN COLLECTION

The colonies used for performing the susceptibility testing should be young (up to 24 hours old) and perfectly isolated at 37 °C (or at 30 °C for *Cryptococcus neoformans*) on an agar medium, preferably in a Petri dish.
It is recommended that isolation be made on media that are specific for yeasts. The chromogenic CANDICHROM II medium from ELITech MICROBIO (Cat. N° 44211 or Cat. N° 44212) can be used.

7 - REAGENT STOCKAGE

The kit and its contents when stored at 2-8 °C in their original state are stable until the expiry date indicated on the box.
The reagents are ready-to-use and should be used immediately after opening.

8 - REAGENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- Paraffin oil
- Sterile PASTEUR pipettes / 10 µL and 100 µL micropipettes
- Incubator at 37 °C and 30 °C (only for *Cryptococcus*)
- Container for contaminated waste

9 - PROCEDURE

Allow the reagents to reach room temperature (18-25 °C) before use

9.1. Preparation of the inoculum

Pick up two or three isolated colonies with an occluded Pasteur pipette. Inoculate a vial of SUSPENSION FUNGI with the colonies. Mix well. The standardization of the inoculum can be performed in three different ways:

- With a Densitometer

Verify with a densitometer that the turbidity of the inoculated suspension medium is equal to **2 Mac Farland**. If necessary, proceed as above to adjust the turbidity.

- With Respect to the TC FUNGI Vial

Adjust the opacity of the inoculated SUSPENSION FUNGI to that of the TC FUNGI with the aid of the black lines printed on the vial labels.
If the suspension medium is lighter (insufficient inoculum), reseed the vial until the opacity obtained equals that of the Turbidity Control vial.
If the suspension medium is more turbid (inoculum too rich), dilute it with SUSPENSION FUNGI from another freshly opened vial until the correct turbidity is obtained.

- Enumeration in Malassez Cell

It is possible to standardize the inoculum by counting the yeasts in a Malassez cell. A solution of 10^6 to 10^7 yeasts per mL must be obtained.

9.2. Inoculation of the tray

Negative control

Mark the FUNGIFAST AFG tray to identify the specimen being tested.

Lift the adhesive tape and dispense into well 10 (C-) as follows :

- 100 µL of non-seeded MES FUNGI,
- 2 drops of paraffin oil.

Inoculation of the MES FUNGI medium

Inoculate a MES FUNGI medium with 10 µL of seeded SUSPENSION FUNGI that has previously been standardized (§9.1). Mix well.

Inoculation of the tray

Distribute into each of the wells, except into well 10 (C-) already been filled, as follows:

- 100 µL of seeded MES FUNGI,
- 2 drops of paraffin oil.

Reseal the tray with the adhesive tape.

9.3. Incubation of the tray

Incubate the tray at 37 °C for 24 hours; if necessary and depending on the strain, this incubation may be prolonged up to 48 hours.

Note: Do not read after an incubation of only 18-20 hours, even if the positive control well has changed colour. A period of 24 hours should be respected before reading the results.

- For *Cryptococcus neoformans*, incubate the tray at 30 °C and, if necessary, prolong the incubation time for up to 72 or 96 hours.

10 - READING AND INTERPRETATION

A colour change of the medium, initially dark violet to pink or to colourless, indicates that the tested strain is able to grow in the presence of the antifungal concentration tested in that well.

However, when no colour change is seen, the strain has been inhibited at the concentration of the antifungal tested.

10.1 Validation (positive control well C+)

Verify that the growth control (C+) medium has turned pink or colourless, otherwise prolong the incubation time (9.3).

For *C. neoformans*, the results can be read as soon as the medium of the C+ well has turned light violet.

10.2 Reading of the negative control (negative control well C-)

Compare the colour change with the negative control well (C-) that contains the original colour of the medium.

10.3 Interpretation of the results

In order to facilitate interpretation, use the result sheet included in the kit. The results can be expressed as minimal inhibitory concentrations or as clinical categorizations.

Minimal Inhibitory Concentration (MIC)

The MIC is given as the lowest concentration at which no growth can be observed (first well remaining dark-violet).

Clinical categorization (S / I or S-DD / R)

The strain is Susceptible (S), Intermediate (I) / Susceptible - Dose Dependant (S-DD) or Resistant (R) according to the antifungal agent critical values described in the following table.

Critical values in µg/mL for *Candida spp.* :

	S	I	SDD	R
Amphotericin B*	ND	ND	-	ND
Flucytosine**	≤ 4	8-16	-	≥ 32
Itraconazole**	≤ 0.125	-	0.25-0.5	≥ 1
Fluconazole**	≤ 8	-	16-32	≥ 64
Voriconazole **	≤1	-	2	≥4

ND : Non determined.

* : For amphotericin, a MIC > 2 µg/mL indicates possible resistance.

** : Concentrations determined by the CLSI.

~~*** : For voriconazole, the preliminary concentrations are S : ≤1 µg/ml, SDD : 2 µg/ml, R : ≥ 4 µg/ml.~~

10.4 Notes

C. krusei is intrinsically resistant to fluconazole and should systematically be reported as (R) for this antifungal agent.

11 - QUALITY CONTROL

It is recommended that the standardization of the method be verified from time to time using the reference strains, *Candida albicans* ATCC 90029 and *Candida krusei* ATCC 6258.

The expected MIC values are given in the following table:

Antifungal tested	*Candida albicans* ATCC 90028	*Candida krusei* ATCC 6258
	24 hours	24 hours
Amphotericin B	≤ 0.5 µg/mL	≤ 0.5 µg/mL
Flucytosine	≤ 4 µg/mL	≤ 4-16 µg/mL
Itraconazole	≤ 0.125 - 0.5 µg/mL	0,125-1 µg/mL
Fluconazole	≤ 8 µg/mL	32 - ≥ 64 µg/mL
Voriconazole	≤ 1 µg/mL	≤ 1 µg/mL

12 - CAUSES OF ERROR

- Preparation of the inoculum from a mixed culture or with isolated colonies grown for more than 24 hours.
- Incubation of the tray at a temperature superior to 38 °C.
- Tray read before a 24 hour incubation period (ex: 18-20 hours)
- Tray read before the apparition of a colour change of the growth indicator.
- Tray read 24 or 48 hours after the medium has changed colour in the growth control well.

In general, the non-respect of the recommendations contained within these instructions.

13 - LIMITATIONS

- This *in vitro* method for the determination of the susceptibility to antifungal agents has an indicative value for the antifungal-yeast interaction during *in vivo* treatment.
- With regards to itraconazole, fluconazole and voriconazole, a trailing-growth phenomenon can occur, in particular with *Candida albicans*. This is characterised by an incomplete colour change (light violet) that is identical in all of the wells containing the same antifungal.

14 - PERFORMANCE CHARACTERISTICS

Evaluation of the performance characteristics was carried out upon different strains (*Candida albicans*, *C. glabrata*, *C. parapsilosis*, *C. tropicalis*, *C. lusitaniae*, *C. krusei*, *C. kefyr*, *C. guilliermondii*, *Saccharomyces cerevisiae*, *Cryptococcus neoformans*) isolated from mycological samples obtained from different departments of hospitals and from patients in community health practices.

A parallel comparative study was carried out with the reference methods: the EUCAST microdilution method (except for Amphotericin B) and the E-Test method from AB Biodisk. The percentages of category agreement are given in the table below:

	AB	5-FC	ITZ	FCZ	VRZ	%CA
	ND	n = 56	n = 56	n = 56	n = 56	-
EUCAST	**ND**	**92.9%**	**69.6%**	**73.2%**	**92.9%**	**82.2%**
	n = 100	n = 99	n = 99	n = 99	n = 100	-
E-Test	**99%**	**90.9%**	**79.8%**	**84.8%**	**97%**	**90.3%**

ND: Non determined

% CA: % of Category Agreement.

With regards to incubation times, 93.3% (97/104) of the strains gave a result after 24 hours.

15 - WASTE ELIMINATION

Waste should be disposed of in accordance with the hygiene rules and current regulations for this kind of product in the country of use.

16 - BIBLIOGRAPHY

Subcommittee of Antifungal Testing of the European Committee on Antibiotic Susceptibility Testing of the European Society of Clinical Microbiology and Infectious Diseases. 2002. Method for the determination of Minimum Inhibitory Concentration (MIC) by Broth Dilution of Fermentative Yeasts. EUCAST Discussion document E. Dis. 7.1 ESCMID.

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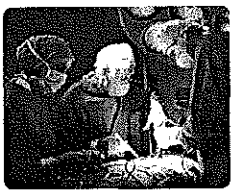
new standard for **microbiology swabs**

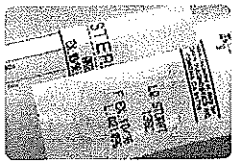
#102.

Manufacturer and product conform to highest medical device classification:
Class IIa - Surgically Invasive Transient Use.

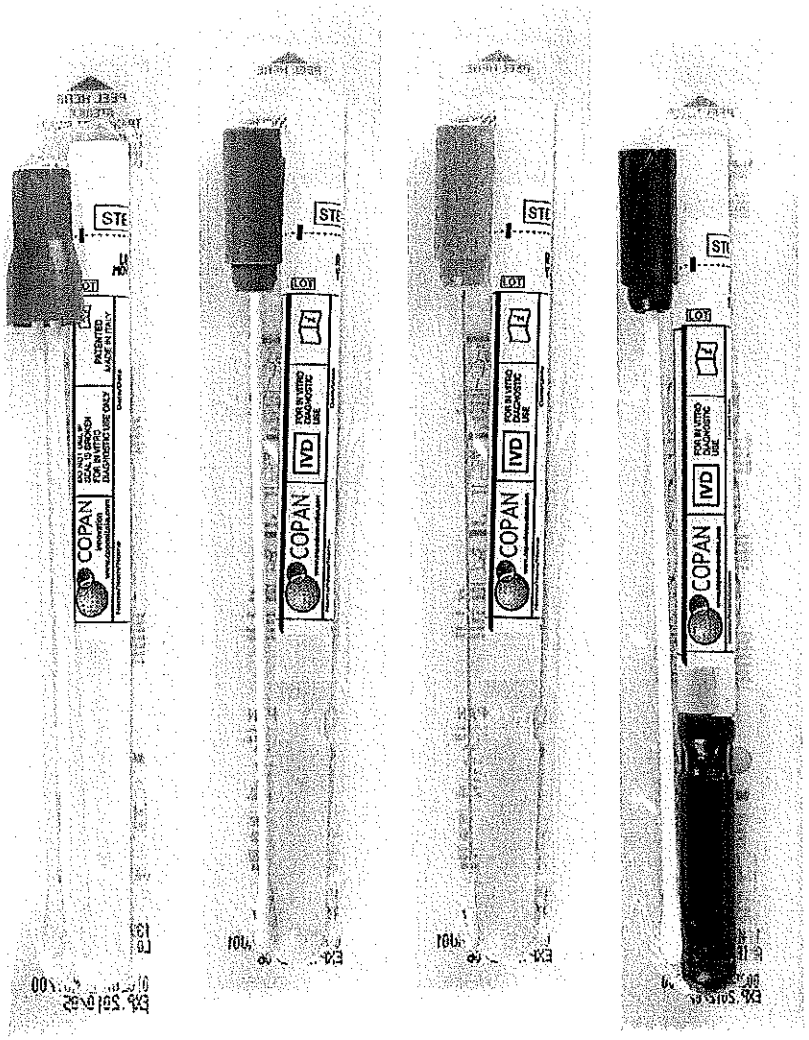


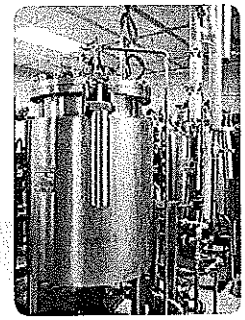
Quality, safety and performance is guaranteed, even in the most critical of situations. Class IIa means swabs can be used for sampling body surfaces, body orifices e.g. nose, throat and vagina and deep invasive surgical wounds.

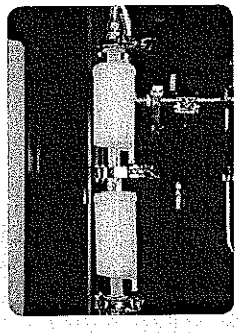
100% traceability

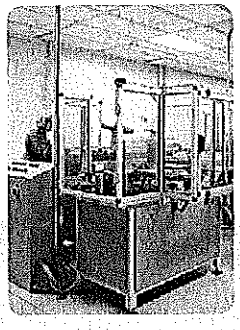


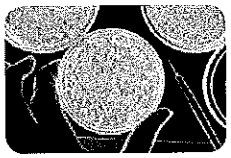
Lot number, expiry date and product description clearly printed on the outside of every swab pack and on every tube. Every unit of production can be identified. Important for quality control, facilitates efficient product recall and correct stock rotation within prescribed dating.

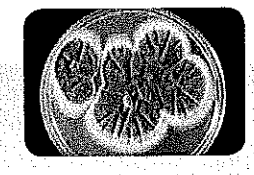




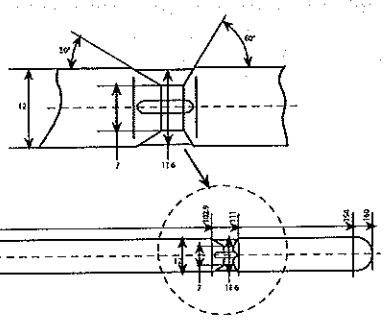




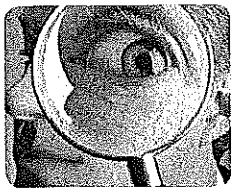




Manufacturers must have Certified Quality Management System and comply with new manufacturing standards for medical devices.

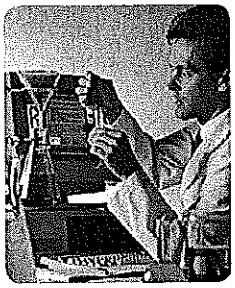


Class IIa manufacturers undergo regular inspections and audits by independent government appointed agencies



Necessary requirement for manufacturers to maintain CE mark accreditation.

Control of manufacturing environment and level of expertise



Manufacturer required to design and maintain good medical device standard production facility. Must also demonstrate correct technical knowledge, skill and expertise. Qualified design team, engineers and microbiologists on site.

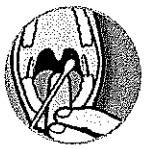
Tough bio-burden controls directly influences manufacturing process

Demands for low bio-burden influences how the productis made. In order to comply manufacturers need high technology and automation to ensure product is made in best possible way to meet bio-burden targets.

ISO 9001 & EC93/42 Annex II Controls all product design

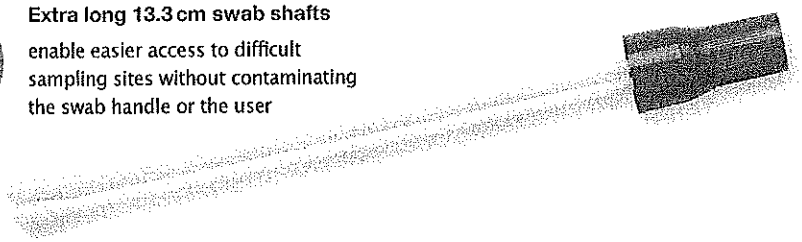
From initial concept through to finished product, the system of design and manufacture must conform to new medical device standards.

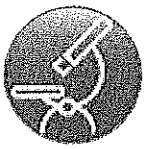
COPAN



Extra long 13.3 cm swab shafts

enable easier access to difficult sampling sites without contaminating the swab handle or the user





Low bioburden

All media contain less than 2 non-viable bacterial cells per 10 high power microscopic fields

Soft rayon swab tips

are inert and non-toxic to micro-organisms and patients

Tamper evident tube seal

maintains product integrity and ensures first time use

Smooth round bottomed tubes

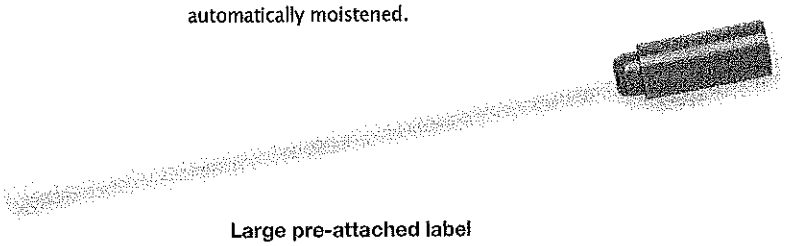
avoid jagged or sharp edges associated with crimped end tubes. No risk of puncturing specimen transport bags. Tubes conveniently fit regular test tube racks facilitating safer transport and easy storage

Extra large size polyurethane foam sponge

soaked with liquid transport medium, stays anchored in place, providing a reservoir of moisture for the wab sample

No activation step necessary

no glass ampoules to break or seals to puncture in order to release transport media. Swabs are automatically moistened.



Double action security cap

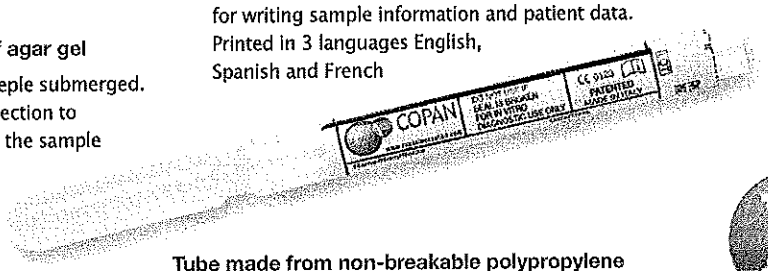
maintains product integrity slides over the neck of the swab tube and tightly grips the inside and outside of the tube

Large pre-attached label

for writing sample information and patient data. Printed in 3 languages English, Spanish and French

Large 5ml depth of agar gel

so swab is always deeple submerged. Gives maximum protection to fastidious bacteria in the sample



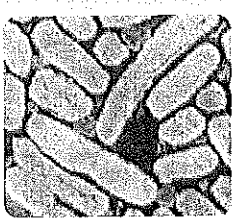
Tube made from non-breakable polypropylene

to protect the specimen, medical and technical staff handling samples

Venturi Hour Glass tube design enhances performance

eliminates undesirable bubbles and breaks in the deep agar gel column. As the swab is inserted into the tube, air bubbles and breaks in the agar gel are squeezed out.

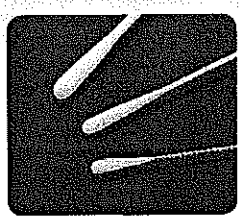
Complete Range of Liquid & Agar Gel Swabs



Quality Control

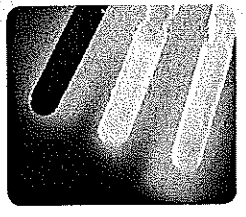
Each lot is stringently tested against a diverse selection of ATCC and NCTC control organisms.

Certificates of Analysis and data available on request.



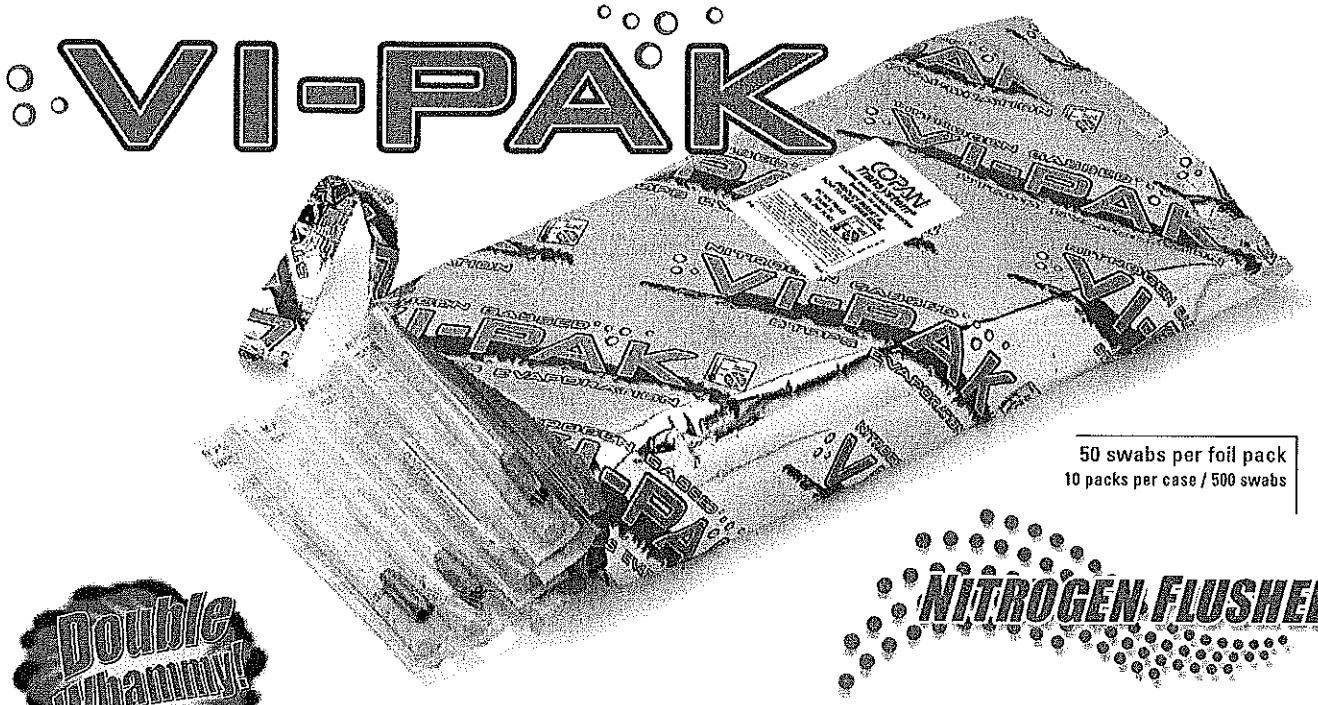
Minitip Swabs

ENT, Nasopharyngeal and urethral swabs with your choice of medium



Amies Stuart & Cary-Blair Medium

VIPAK barrier outer foil pack

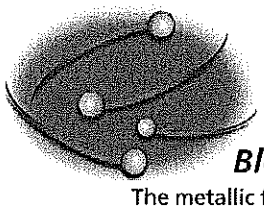


Barrier Plastic and Barrier Foil!

Ultimate product protection and shelf life stability afforded by Copan's unique combination of barrier plastic film swab pouches and barrier outer foil packs. Creates a closed system maintaining stable optimum performance of medium over it's long shelf life.

Nitrogen Flushed - Active Packaging

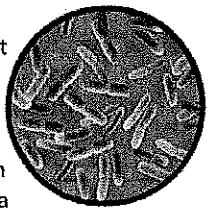
The Vi-Pak concept works continually to maintain the vitality of the medium delivering it to the point of care perfect for maintaining all those difficult and demanding microbes. Nitrogen gas inside the foil pack and the individual plastic film swab pouches work synergistically with sodium thioglycollate in the transport medium to create an ideal Eh potential for Neisseria, Haemophilus, Streptococci, and Anaerobes.



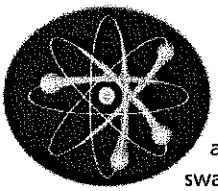
Fantastic Stability - Blocks Oxygen Entry

The metallic foil and plastic film block oxygen entry preventing unwanted oxidation of the transport medium. The integrity of the medium and product performance are extremely stable.

Prevents Media Dehydration - Bugs Always Moist



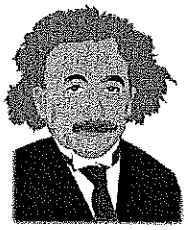
Moisture, provided by the transport medium, is critical for the survival of bacteria in clinical samples. Vi-Pak's unique combination of metallic foil and barrier plastic film stops liquid evaporation and media dehydration. It prevents hard to detect shrinkage and cracking of agar gel medium and ensures that swabs transported in liquid medium are always moist.



No Superoxide or Free Radicals

Combination of nitrogen rich atmosphere, impermeable barrier swab pouches and foil outer packs prevents the formation of free radicals and superoxide in the transport medium. These components, which can be triggered by the sterilization process or exposure of the medium to UV light, are harmful to the survival of bacteria.

Independent Studies



For free copies of independent published studies documenting the survival of aerobic and anaerobic bacteria in Copan swabs, call or email us today.

COPAN

No Glass Ampoules To Break, No Seals or Barriers to Puncture. No Dry Swabs!

5ml Deep Gel Column,
Affords Maximum Protection,
Improves Sample Viability

Prevents Disintegration or Breakdown of Gel Column During Specimen Transport

Undesirable Bubbles and Breaks in Gel Automatically Squeezed Out As Swab is Inserted

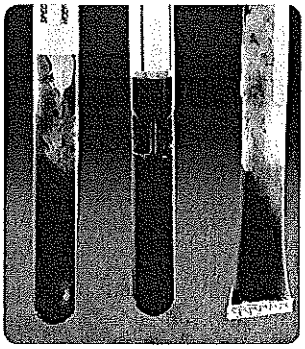
Eliminates Air Pockets Harmful to Fastidious Bacteria

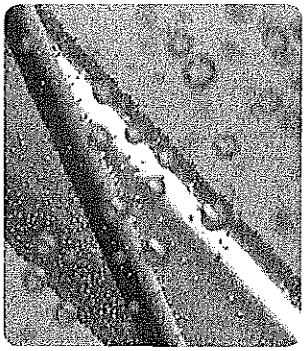
Capsulated Environment
Seals and Protects Bacteria

Unique Venturi Hour Glass Tube Design Enhances Performance

Optimizes Moisture Control

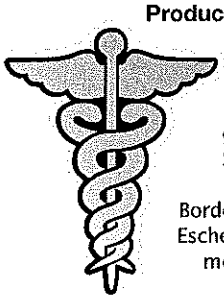
Amies medium available with or without charcoal plus Stuart and Cary-Blair medium



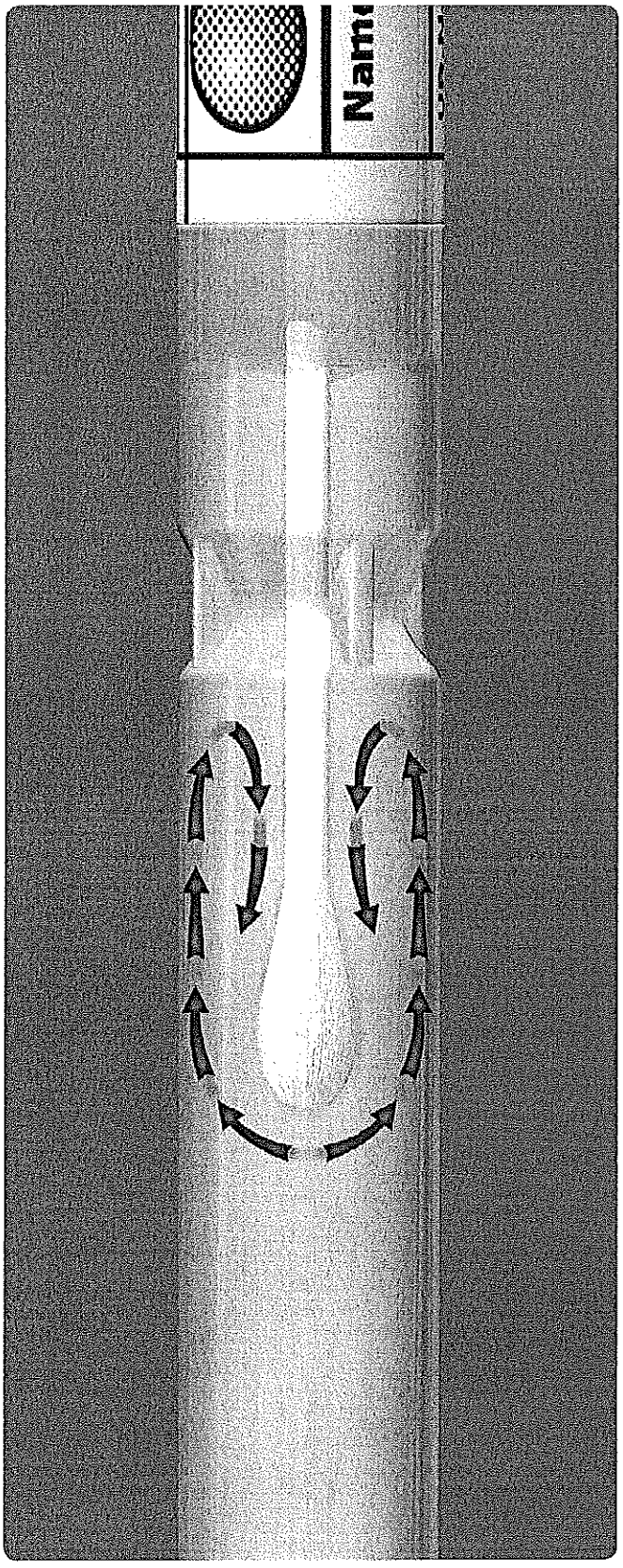


No Bubbles-No troubles!

Stringent QC of Raw Materials and Finished Product Guarantees Performance and Very Low Level Non-Viable Bacteria.



Routine performance tests incorporate a diverse selection of bacteria; Neisseria gonorrhoeae, Streptococcus pyogenes, Staphylococcus aureus, Pseudomonas aeruginosa, Haemophilus influenzae, Bordetella pertussis, Neisseria meningitidis, Escherichia coli, Bacteroides fragilis, Prevotella melaninogenica, Clostridium perfringens, Campylobacter jejuni, Shigella flexneri and Yersinia enterocolitica



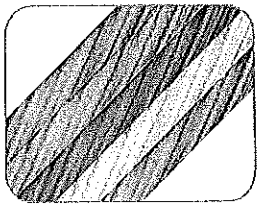
fastidious **anaerobe transport**

Fastidious anaerobe transport swabs

Range of agar gel culture swabs specifically designedto maintain the viability of anaerobic bacteria in clinical swab specimens during transport to the laboratory.

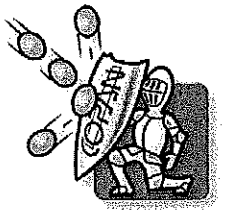
Packed in unique laminated film

Swabs are sealed inside a new and unique plastic film pouch. The film is composed of 5 different types of plastic material sandwiched together.



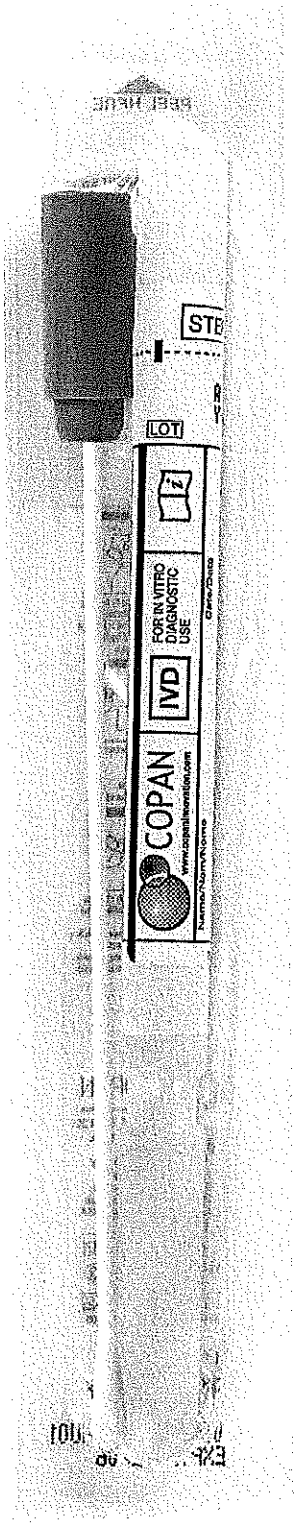
Oxygen entry blocked

The plastic film acts like a barrier preventing penetration of atmospheric oxygen. Atmosphere inside the package is stabilized during the products shelf life.



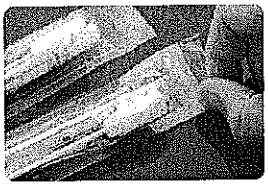
Nitrogen gassed

During product assembly the tube and swab package are flushed with nitrogen gas to drive out any atmospheric air.



Tamper evident seal - changes color when opened

Package seal immediately changes color from clear to white as soon as pack is peeled open. Provides visual guarantee of first time use, product sterility and integrity.



Designed for anaerobes

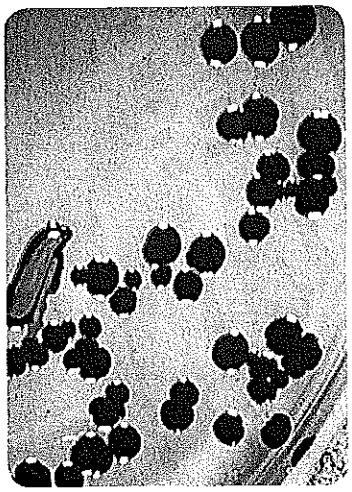
Large 6cm depth of agar gel ensures that the swab is always deeply submerged in medium. A deep gel column combined with a narrow hour glass tube constriction, to reduce surface area available for oxygen penetration, provides the maximum protection for anaerobic bacteria in the sample.

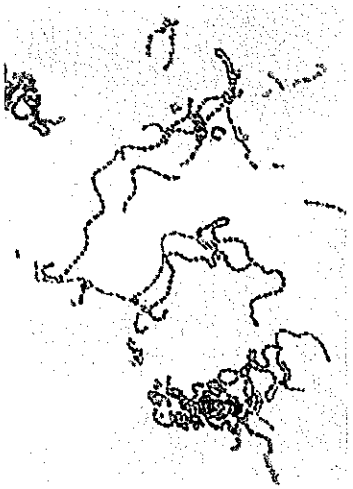
Performance tested using fastidious anaerobes

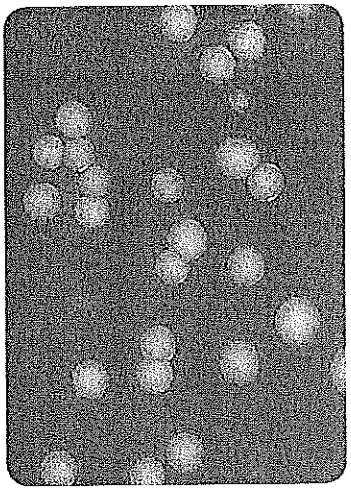
Product is routinely tested using a variety of fastidious anaerobes to guarantee performance when used correctly.

Test organisms include:

Organism	ATCC#
Fusobacterium nucleatum	25586
Bacteroides levii	29147
Peptostreptococcus anaerobius	27337
Clostridium perfringens	13124
Bacteroides fragilis	25285
Fusobacterium necrophorum	25286
Clostridium difficile	9689
Bacteroides thetaiotaomicron	29741
Bacteroides vulgatus	8482
Proprionibacterium acnes	6919
Prevotella melaninogenica	25485
Porphyromonas gingivalis	33277



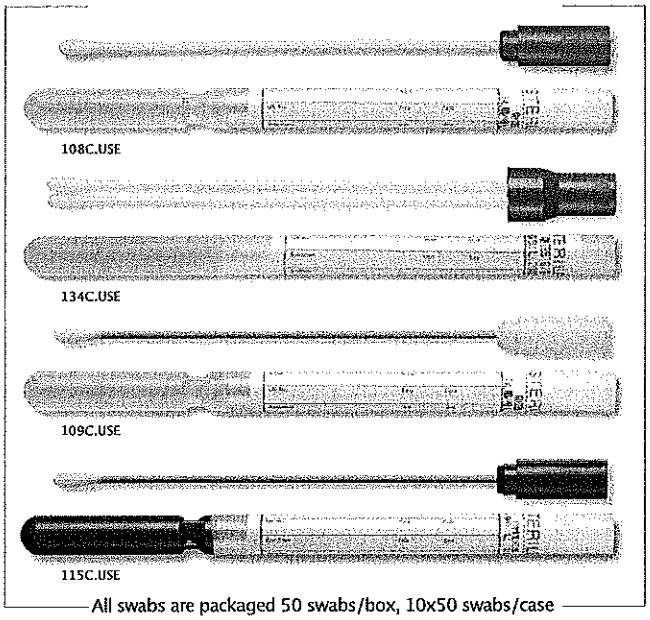




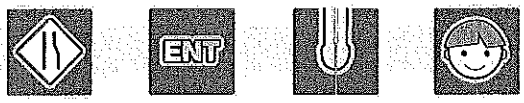
Amies Agar Gel-No Charcoal

Suitable for throat, vaginal, wound and skin swabs.

Catalog No.	Description	Cap color
108C.USE	Single plastic swab	blue
134C.USE	Double plastic swabs	blue
109C.USE	Single wooden swab	white
115C.USE	Single wooden swab	black



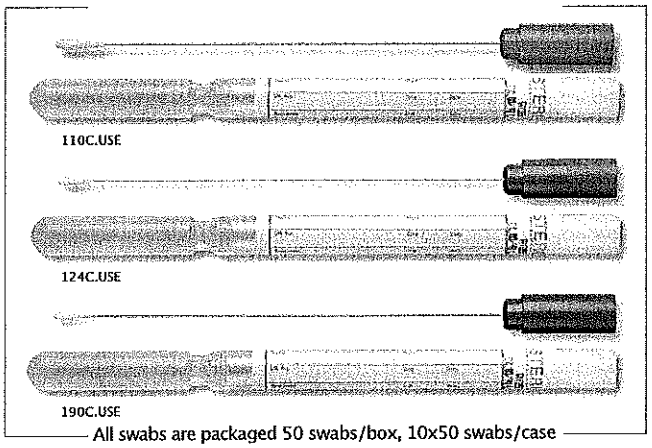
All swabs are packaged 50 swabs/box, 10x50 swabs/case



Mini Tip Amies-No Charcoal

Suitable for ear, nose, throat, eye and male urethral swab sampling. The narrow dimension of the swab shafts and small tip provides a more practical device for some pediatric swab sampling.

Catalog No.	Description	Cap color
110C.USE	Regular aluminum wire	orange
124C.USE	Soft aluminum wire	green
190C.USE	Flexible twisted wire	blue

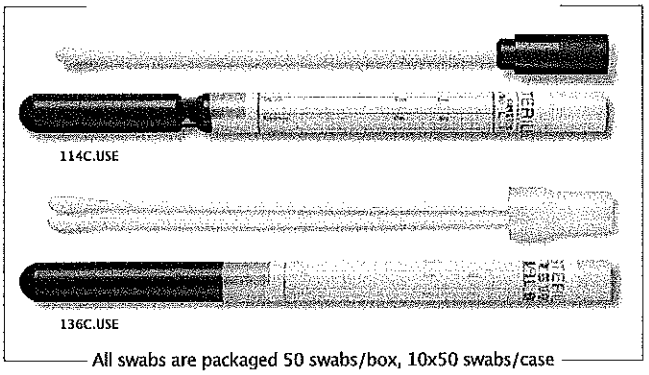


All swabs are packaged 50 swabs/box, 10x50 swabs/case

Amies Agar Gel-With Charcoal

Suitable for throat, vaginal, wound and skin swabs.

Catalog No.	Description	Cap color
114C.USE	Single plastic swab	black
136C.USE	Double plastic swabs	white

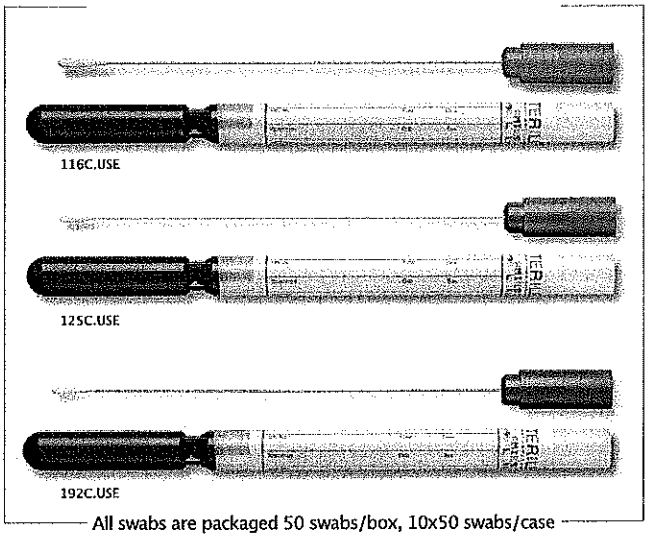


All swabs are packaged 50 swabs/box, 10x50 swabs/case

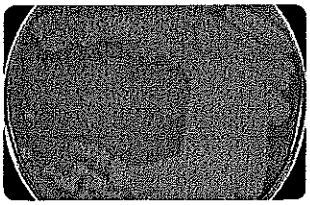
Mini Tip Amies-With Charcoal

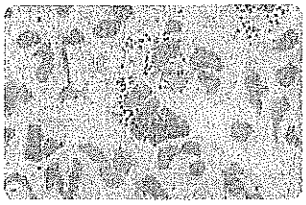
Suitable for ear, nose, throat, eye and male urethral swab sampling. The narrow dimension of the swab shafts and small tip provides a more practical device for some pediatric swab sampling.

Catalog No.	Description	Cap Color
116C.USE	Regular aluminum wire	orange
125C.USE	Soft aluminum wire	green
192C.USE	Flexible twisted wire	blue



All swabs are packaged 50 swabs/box, 10x50 swabs/case

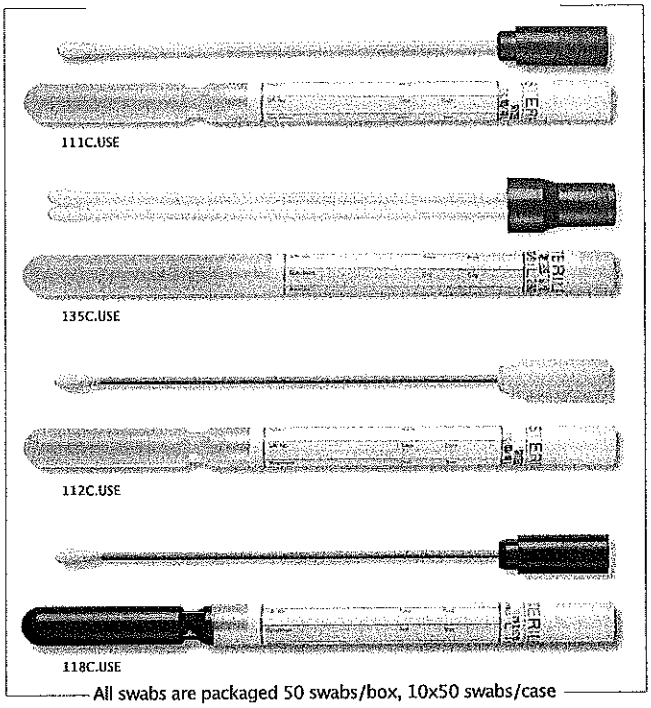




Stuart Agar Gel Medium

Suitable for throat, vaginal, wound and skin swabs.

Catalog No.	Description	Cap Color
111C.USE	Single plastic swab	blue
135C.USE	Double plastic swabs	blue
112C.USE	Single wooden swab	white
118C.USE	Single wooden swab	black

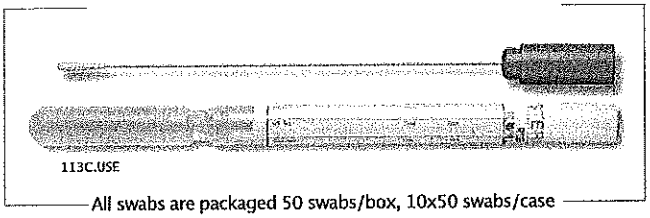


All swabs are packaged 50 swabs/box, 10x50 swabs/case

Mini Tip Stuart Agar Gel

Suitable for ear, nose, throat, eye and male urethral swab sampling. The narrow dimension of the swab shafts and small tip provides a more practical device for some pediatric swab sampling.

Catalog No.	Description	Cap Color
113C.USE	Regular aluminum wire	orange



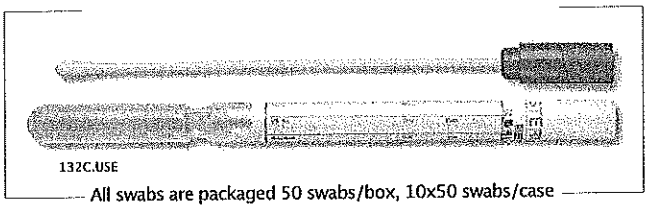
All swabs are packaged 50 swabs/box, 10x50 swabs/case

Cary-Blair Agar Gel Medium

Suitable for rectal or fecal samples for enteric pathogens.

Catalog No.	Description	Cap Color
132C.USE	Single Plastic Swab	red

#102.3.

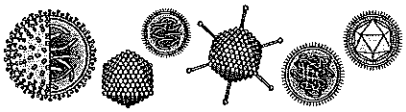


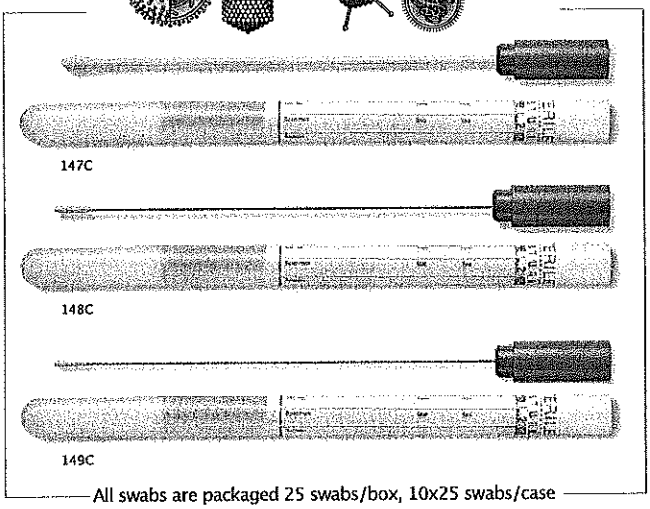
All swabs are packaged 50 swabs/box, 10x50 swabs/case

Virus Transport Swabs

Liquid virus transport medium is contained into the sponge deposited in the tube bottom. Very easy to use, this swab format does not require medium activation.

Catalog No.	Description	Cap Color
147C	Single plastic swab	pink
148C	Regular aluminum wire	pink
149C	Flexible twisted wire	pink



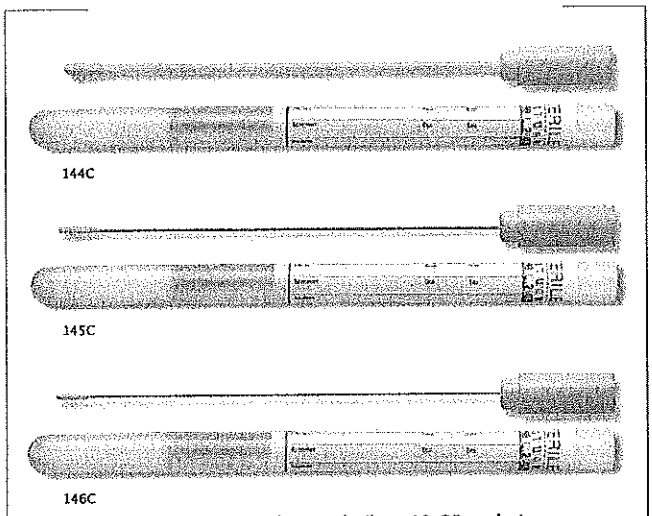


All swabs are packaged 25 swabs/box, 10x25 swabs/case

Chlamydia Transport Swabs

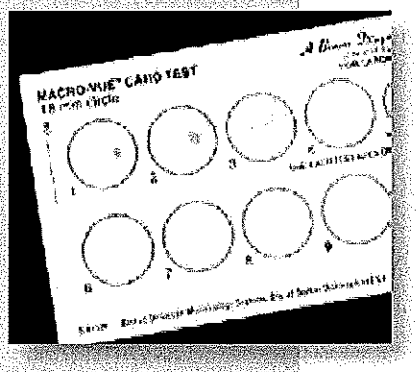
Liquid Chlamydia transport medium is contained into the sponge deposited in the tube bottom. Very easy to use, this swab format does not require medium activation.

Catalog No.	Description	Cap Color
144C	Single plastic swab	yellow
145C	Regular aluminum wire	yellow
146C	Flexible twisted wire	yellow



All swabs are packaged 25 swabs/box, 10x25 swabs/case

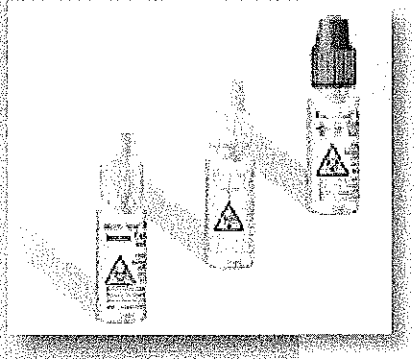
Syphilis Testing



BD Macro-Vue™ RPR Kit

CAT. NO.	SIZE	DESCRIPTION
275005	500 tests	BD Macro-Vue™ RPR - Card Test Kit No. 110

Nontreponemal testing procedure for the serological detection of syphilis. (500 qualitative tests) containing:
- 3 x 3 ml ampules antigen
- 20 G dispensing needle
- antigen dispensing bottle
- 50 cards with 10 x 18 mm circle spots each
- BD Dispenstirs™ devices, 0.05 ml delivery



BD Macro-Vue™ RPR Control

CAT. NO.	SIZE	DESCRIPTION
276909	1	BD Macro-Vue™ RPR - Liquid Controls

BD Macro-Vue™ RPR (Rapid Plasma Reagin) Card Test Liquid Controls are designed as an unassayed control material to monitor, at three reaction levels, the precision of BD Macro-Vue™ RPR 18 mm Circle Card Test. RPR Test Reagents should be routinely tested for patterns of graded reactivity against controls with established patterns of reactivity. Contains pooled human serum with 0.1% sodium azide as a preservative.
Control ++, 1.5 ml BD Macro-Vue™ RPR Card Test Reactive Control Serum Positive. Control +, 1.5 ml BD Macro-Vue™ RPR Card Test Moderately Reactive Control Serum Weakly Positive.
Control -, 1.5 ml BD Macro-Vue™ RPR Card Test Negative Control Serum Negative Control.

Coagulase Testing

BD Coagulase Plasma

CAT. NO.	SIZE	DESCRIPTION
240658	10 x 3 ml	Coagulase Plasma
240661	10 x 15 ml	Used to qualitatively determine the pathogenicity of staphylococci using the direct tube method. Coagulase Plasma, Rabbit is lyophilised rabbit plasma with 0.85% sodium citrate and 0.85% sodium chloride, approximately. Reconstitutes to 3 ml, 15 ml or 25 ml for the Direct Tube Method.
240827	10 x 3 ml	Coagulase Plasma with EDTA
240826	10 x 15 ml	Used to qualitatively determine the pathogenicity of staphylococci using the direct tube method. Coagulase Plasma, Rabbit with EDTA is lyophilised rabbit plasma with 0.15% EDTA (ethylenediaminetetraacetic acid) and 0.85% sodium chloride, approximately. Reconstitutes to 3 ml, 15 ml or 25 ml for the Direct Tube Method.

✓

110

✓ 261187 50 ampules DMACA Indole

#112.

DMACA Indole Reagent Droppers are for the detection of indole production as an aid in the identification of aerobic, anaerobic, or facultatively anaerobic organisms. They are used in a rapid spot test for determining the ability of bacteria to produce indole by the deamination of tryptophan.The colour change with DMACA is both rapid and long lasting, making results easier to interpret than with more traditional reagents. Contains 0.5 ml of aqueous 1% p-Dimethylaminocinnamaldehyde in 10% hydrochloric acid.

✓ 261190 50 ampules Ferric Chloride

#114.

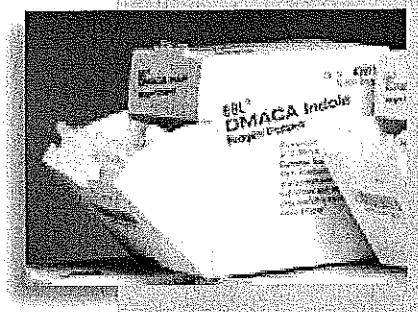
Ferric Chloride Reagent Droppers are intended for use in the differentiation of microorganisms capable of phenylalanine deamination. Contain 0.5 ml of 10% ferric chloride in aqueous solution.

261194 50 ampules India Ink

India Ink Reagent Droppers are used to enhance the microscopic detection of *Cryptococcus* spp. in wet preparations. India Ink Reagent Droppers may be used to stain pus, exudate, tissue, sputum and sediment of centrifuged urine and cerebral spinal fluid (CSF) specimens. Contains 0.5 ml of an aqueous suspension of India ink with suspending agent and preservative.

261185 50 ampules Indole

Indole Reagent Droppers (modified Kovacs' reagent) are used in determining the ability of bacteria to produce indole by the deamination of tryptophan. Contains 0.5 ml of 5% p-dimethylaminobenzaldehyde dissolved in a solution of 25% hydrochloric acid and 75% isobutyl alcohol.



261188 50 ampules Lactophenol Cotton Blue

The solution can be used in wet mounts in the examination of yeasts and molds and serves as both a mounting fluid and a stain.

✓ 261181 50 ampules Oxidase

#111.

Oxidase Reagent Droppers are used in the Kovacs oxidase test as a qualitative reaction in the identification of nonfermenters and miscellaneous Gram-negative bacteria. The oxidase test is based on the production of an enzyme called indophenol oxidase. This enzyme oxidises a redox dye (present in the reagent) which results in a colour change of yellow to dark purple. Contains 0.5 ml of a 1% aqueous solution of N,N,N',N'-tetramethylp-phenylenediamine dihydrochloride which has been formulated with agents to ensure maximum stability.

261191 50 ampules 10% Potassium Hydroxide

10% Potassium Hydroxide Reagent Droppers are intended for use in the examination of direct smears for fungal elements, most commonly with skin, hair, nail and sputum specimens. Contains 0.5 ml of 10% KOH with 1% dimethyl sulfoxide.

261196 50 ampules PYR

PYR Reagent Droppers are used in the rapid presumptive identification of group A β-haemolytic streptococci and group D enterococci.

261192 50 ampules Voges-Proskauer A

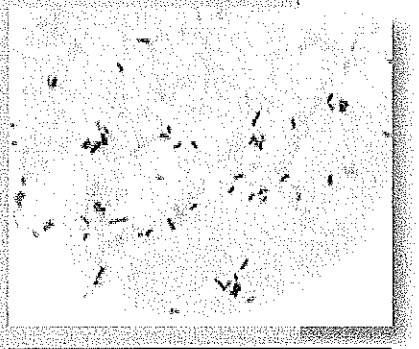
For use in the Voges-Proskauer test to distinguish between members of the Enterobacteriaceae. Contains 0.5 ml of 5% wt/vol alphanaphthol in absolute alcohol.

261193 50 ampules Voges-Proskauer B

Voges-Proskauer Reagent B Droppers contain 0.5 ml of 40% wt/vol potassium hydroxide in distilled water.

Culture media	Ref. No.	Packaging	Type / Volume
Buffered Peptone Water For the enrichment of *Salmonella spp.* from food.	**162** **3043** **6019**	powder bottle tube	500 g 500, 200, 100 ml 5, 9 ml
Burkholderia Cepacia Agar base For the selective isolation of *Burkholderia cepacia.* *Supplements: Ticarcilin, Polymyxin (Ref. No. X140)*	**221** **3222**	powder bottle	500 g 200 ml
Burkholderia Cepacia Agar For the selective isolation of *Burkholderia cepacia.*	**1016**	plate	90 mm
CAMP Medium For the presumptive identification of *Streptococcus agalactiae* (Lancefield group B).	**1500**	plate	90 mm
Campylobacter Agar with 10% sheep blood For the selective isolation of *Campylobacter spp.* *Supplements: Sheep blood (Ref. No. 1000),* *Campylobacter supplement (Ref. No. 3055)*	**1291**	plate	90 mm
Casman Medium base For the cultivation of a wide variety of fastidious microorganisms, especially *Haemophilus influenzae* and *Neisseria gonorrhoeae.* *Supplements: Sheep blood (Ref. No. 1000)*	**145**	powder	500 g
Casman Medium with 5% sheep blood For the cultivation of a wide variety of fastidious microorganisms, especially *Haemophilus influenzae* and *Neisseria gonorrhoeae.*	**1036**	plate	90 mm
Cetrymide Agar For the isolation of *Pseudomonas aeruginosa.*	**126** **3045** **6110** **1310**	powder bottle tube plate	500 g 500, 200, 100 ml 7 ml 90 mm
Cetrymide Agar count-tact For the isolation of *Pseudomonas spp.* from sanitized surfaces with quaternary ammonium compounds.	**7017**	plate	65 mm
Charcoal Agar For the cultivation of a wide variety of fastidious microorganisms, especially *Bordetella pertussis.*	**222** **1004**	powder plate	500 g 90 mm
GC Agar (Chocolate Agar base) For the cultivation of a wide variety of fastidious microorganisms, including *Neisseria gonorrhoeae, Haemophilus spp.* *Supplements: Biovitex (Ref. No. 420009), Hemoglobin (Ref. No. 163)*	**109** **3019**	powder bottle	500 g 500, 200, 100 ml
Chocolate Agar with Poly Vitex For the cultivation of a wide variety of fastidious microorganisms, including *Neisseria gonorrhoeae, Haemophilus spp.*	**1080**	plate	90 mm
Christensen Agar (Urea Agar base) For the biochemical differentiation of *Enterobacteriaceae* on the basis of urease production. *Supplements: Agar, bacteriological (Ref. No.119)*	**157**	powder	500 g
Christensen Agar (slant) For the biochemical differentiation of *Enterobacteriaceae* on the basis of urease production.	**6111** **1235**	tube plate	7 ml 90 mm
Christensen Agar for dermatophytes (slant) For the selective isolation of dermatophytes.	**6112**	tube	7 ml

Culture media	Ref. No.	Packaging	Type / Volume
Christensen Agar with sodium citrate For the biochemical differentiation of *Enterobacteriaceae.*	**3209** **6018**	bottle tube	500, 200, 100 ml 7 ml
Christensen Broth For the biochemical differentiation of *Enterobacteriaceae* on the basis of urease production.	**3116** **6133**	bottle tube	500, 200, 100 ml 3 ml
CHROMagar Acinetobacter For the selective isolation of *Acinetobacter spp.*	**1481**	plate	90 mm
CHROMagar Candida For the isolation and differentiation of *Candida spp.*	**201** **3208** **1400**	powder bottle plate	1000, 5000 ml 500, 200, 100 ml 90 mm
CHROMagar CTX - M For the isolation of CTX-M-ESBL type producing gram negative bacteria.	**1472**	plate	90 mm
CHROMagar ECC For the isolation and enumeration of *Escherichia coli* and other coliform from food, clinical and water samples.	**227** **3211** **1401**	powder bottle plate	1000, 5000 ml 500, 200, 100 ml 90 mm
CHROMagar ESBL For the selective isolation of ESBL-producing bacteria.	**1470**	plate	90 mm
CHROMagar KPC For the selective isolation and differentiation of gram negative bacteria with a reduced susceptibility to most of the carbapenem agents.	**1471**	plate	90 mm
CHROMagar Listeria For the selective isolation of *Listeria monocytogenes* from clinical samples.	**1440**	plate	90 mm
CHROMagar MRSA For the selective isolation of methicillin-resistant *Staphylococcus aureus* (MRSA).	**266** **1402**	powder plate	1000, 5000 ml 90 mm
CHROMagar O157 For the selective isolation of *Escherichia coli* O157.	**204** **1430**	powder plate	1000, 5000 ml 90 mm
CHROMagar Orientation For the isolation and differentiation of urinary tract pathogens, including gram negative and gram positive bacteria.	**202** **3558** **1410**	powder bottle plate	1000, 5000 ml 500, 200, 100 ml 90 mm
CHROMagar Pseudomonas For the isolation and enumeration of *Pseudomonas spp.* from food, clinical and water samples.	**277** **3566** **1480**	powder bottle plate	5000 ml 500, 200, 100 ml 90 mm
CHROMagar Salmonella For the isolation and enumeration of *Salmonella spp.*, including *Escherichia coli* and *Proteus spp.* from food, clinical and water samples.	**203** **3555** **1420**	powder bottle plate	5000, 1000 ml 500, 200, 100 ml 90 mm
CHROMagar Salmonella PLUS For the selective isolation of *Salmonella spp,* including *Salmonella typhi, Salmonella paratyphi* and lactose positive *Salmonella.*	**267** **3556** **1421**	powder bottle plate	5000 ml 500, 200, 100 ml 90 mm
CHROMagar Staphylococous aureus For the selective isolation of *Staphylococcus aureus.*	**250** **1404**	powder plate	1000, 5000 ml 90 mm
CHROMagar Strep B For the selective isolation of *Streptococcus agalactiae.*	**280** **1007**	powder plate	5000 ml 90 mm



BD Difco™ - BD BBL™ - Stains, Droppers & Indicators

BD Stains, Kits & Reagents

CAT. NO.	SIZE	DESCRIPTION
212539	1 kit	Gram Stain Kit (with stabilised iodine)

Because inorganic iodine is rapidly oxidised and loses its effectiveness as a mordant, this Gram Stain Kit (Cat. No. 212539) differs from Gram's original formulation by offering a more stable organic iodine complex, L-polyvinylpyrrolidone-iodine. Each kit contains 1 bottle (250 ml) each of:

- Gram Crystal Violet
- Gram Iodine (Stabilised)
- Gram Decolouriser
- Gram Safranin

231401	50 x 50 tests	Gram Quality Control Slide

BD BBL™ Gram Stain QC Slides. Conventional 1" x 3" microscope slides imprinted with 10 squares. One square contains control organisms *Staphylococcus aureus* and *Escherichia coli*. Nine squares are available for staining test isolates. Gram Slides, individually wrapped, sufficient for 50 tests.

BD Diagnostic Reagent & Stain Droppers

CAT. NO.	SIZE	DESCRIPTION
261195	50 ampules	Calcofluor White

Calcofluor White Reagent Droppers are used in the rapid fluorescent microscopic detection of fungi in direct smears. It may be used on fresh, frozen, fixed, paraffin-embedded, and clinical specimens. It can be used in the detection of *Pneumocystis carinii* and other opportunistic fungal parasites in bronchoalveolar lavage (BAL) specimens and aspirates from immunosuppressed individuals such as AIDS patients. Contains 0.5 ml of a 0.05% solution of calcofluor white in distilled water.

261203	50 ampules	Catalase

Catalase Reagent Droppers are used in a qualitative procedure for determining catalase activity by bacteria. Catalase Reagent Droppers contain a hydrogen peroxide solution of approximately 3% (2.5% to 3.5%). This reagent has been frequently cited as a standard method for performing the catalase test. Contains (approximately) 3% Hydrogen Peroxide and 0.05% or less of stabiliser.

✓ 261183	50 ampules	Desoxycholate

#116.

Desoxycholate Reagent Droppers are used for the presumptive differentiation of pneumococci from other Gram-positive cocci by the bile solubility test. Each dropper is good for one day's use after ampule has been broken. Contains 0.5 ml of 10% aqueous solution of sodium desoxycholate.

Culture media	Ref. No.	Packaging	Type / Volume
TBX Agar (Tryptone Bile X-glucuronide Agar) For the isolation and enumeration of *Escherichia coli* from food and water.	**251** **3522** **1405**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
TCBS Agar (Thiosulphate-Citrate-Bile-Sucrose Agar) For the selective isolation of *Vibrio cholerae* and other enteropathogenic vibrios.	**259** **1351**	powder plate	500 g 90 mm
Thayer Martin Agar Modified For the selective isolation of *Neisseria gonorrhoeae* and *Neisseria meningitidis*.	**1083**	plate	90 mm
Thioglycollate Broth For the enrichment of a wide variety of fastidious microorganisms.	**128** **3038** **6040**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
Todd-Hewitt Broth For the cultivation of *Streptococcus spp.* and other fastidious microorganisms.	**140** **3041** **6090**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
Todd-Hewitt Gentamycin Nalidixic Acid Broth **Todd-Hewitt Colistin Nalidixic Acid Broth** For the selective enrichment of *Streptococcus* group B, especially *Streptococcus agalactiae* (GBS).	**6089** **6088**	tube tube	5 ml 5 ml
Transgrow Agar For the selective isolation of *Neisseria gonorrhoeae* and *Neisseria meningitidis*.	**1085**	plate	90 mm
Trichomedium For the selective enrichment of *Trichomonas vaginalis*.	**3042** **6120**	bottle tube	500, 200, 100 ml 2,5 ml
TSA (Tryptic Soy Agar) For the cultivation of a wide variety of microorganisms.	**121** **3031** **6093** **1180** **4008**	powder bottle tube plate plate	500 g 500, 200, 100 ml 7 ml 90 mm 140 mm
Tryptic Soy Agar with 5% sheep blood For the cultivation of a wide variety of fastidious microorganisms.	**1181**	plate	90 mm
Tryptic Soy Agar with 10% sheep blood For the cultivation of a wide variety of fastidious microorganisms.	**1183**	plate	90 mm
Tryptic Soy Agar with 5% horse blood For the cultivation of a wide variety of fastidious microorganisms.	**1184**	plate	90 mm
Tryptic Soy Agar with lecithin & Tween For the isolation of microorganisms from sanitized surfaces with quaternary ammonium compounds.	**167** **1013** **4009** **4008**	powder plate plate plate	500 g 90 mm 120 mm 140 mm
Tryptic Soy Agar with lecithin & Tween count-tact For the isolation of microorganisms from sanitized surfaces with quaternary ammonium compounds.	**7010**	plate	65 mm
TSB (Tryptic Soy Broth) For the enrichment of a wide variety of microorganisms.	**122** **3032** **6080**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
Tryptone Broth according to EN ISO 9308 For the biochemical differentiation of *Escherichia coli* in water samples on the basis of indole production.	**8039**	tube	5 ml

Culture media	Ref. No.	Packaging	Type / Volume
TSI Agar (Triple Sugar Iron Agar) For the biochemical differentiation of microorganisms on the basis of glucose, lactose, sucrose fermentation and H_2S production.	**272**	powder	500 g
TSI Agar (Triple Sugar Iron Agar) according to EN ISO 6579:2003 For the biochemical differentiation of microorganisms on the basis of glucose, lactose, sucrose fermentation and H_2S production.	**3084** **8015**	bottle tube	500, 200, 100 ml 7 ml
TSC Agar base (Tryptose Sulphite Cycloserine Agar) For the isolation and enumeration of *Clostridium perfringens* in food, water and clinical samples. *Supplements: Cycloserine (Ref. No. X194)*	**283**	powder	500 g
TSC Agar (Tryptose Sulphite Cycloserine Agar) For the isolation and enumeration of *Clostridium perfringens* from food, water samples and clinical samples.	**3081** **8022**	bottle plate	500, 200, 100 ml 90 mm
TSYEA (Tryptone Soya Yeast Extract Agar) according to EN ISO 11290 For the isolation of a wide variety of microorganisms, especially *Listeria spp.*	**1019** **6093a**	plate tube	90 mm 7 ml
TTC Agar base (Triphenyl Tetrazolium Chloride) For the selective isolation of coliform bacteria.	**277**	powder	500 g
TTC Agar (Triphenyl Tetrazolium Chloride) according to EN ISO 9308 For the selective isolation of coliform bacteria, early detection of *Escherichia coli*.	**3089** **8029**	bottle plate	500, 200, 100 ml 90 mm
Urea Agar according to EN ISO 6579 For the biochemical differentiation of microorganisms on the basis of urease production.	**6205**	tube	7 ml
VRBG Agar (Violet Red Bile Glucose Agar) For the isolation and enumeration of *Enterobacteriaceae* from food.	**245** **3006** **1341**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
VRBG Agar (Violet Red Bile Glucose Agar) count-tact For the isolation of *Enterobacteriaceae* from sanitized surfaces with quaternary ammonium compounds.	**7013**	plate	65 mm
VRBL Agar (Violet Red Bile Lactose Agar) For the enumeration of coliforms from food and dairy products.	**141** **3046** **1340**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
Wilkins Chalgren Agar For the enrichment of anaerobic microorganisms.	**142** **1517**	powder plate	500 g 90 mm
Wilkins Chalgren Agar with 5% sheep blood For the cultivation of anaerobic microorganisms.	**1204** **4020**	plate plate	90 mm 140 mm
Willis Hobbs Agar For the cultivation of anaerobic microorganisms.	**1010**	plate	90 mm
Wort Agar For the isolation and enumeration of yeasts.	**3025** **1501**	bottle plate	500, 200, 100 ml 90 mm
Wort Broth For the enrichment of yeasts.	**3024**	bottle	500, 200, 100 ml
XLD Agar (Xylose Lysine Deoxycholate Agar) For the selective isolation of *Salmonella spp.*	**130** **3514** **1330**	powder bottle plate	500 g 500, 200, 100 ml 90 mm

Culture media	Ref. No.	Packaging	Type / Volume
MacConkey Agar with sorbitol For the isolation of pathogenic *Escherichia coli.*	**136** **3008** **1021**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
MacConkey Agar with cefixime, tellurite, sorbitol (CT-SMAC) according to EN ISO 16654 For the isolation of *Escherichia coli* O157: H7.	**1027**	plate	90 mm
MacConkey Broth For the detection of coliform bacteria in milk and water.	**219** **3128** **6210**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
Maloniate Medium For the biochemical differentiation of microorganisms on the basis of maloniate decomposition.	**350** **3114** **6127**	powder bottle tube	500 g 500, 200, 100 ml 3 ml
Malt Extract Agar For the isolation of yeasts and molds.	**239** **3545**	powder bottle	500 g 500, 200, 100 ml
Malt Extract Chloramphenicol Streptomycin Agar For the isolation of yeasts and molds.	**1523**	plate	90 mm
Malt Extract Chloramphenicol Streptomycin Agar count-tact For the isolation of yeasts and molds from sanitized surfaces.	**7012**	plate	65 mm
MSA Agar (Mannitol Salt Agar) For the isolation of *Staphylococcus spp.*	**115** **3016** **1050**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
Maximum Recovery Dilluent For the optimal recovery of microorganisms. (for more see buffers)	**175**	powder	500 g
Milk Plate Count Agar For the isolation and enumeration of microorganisms in milk and dairy products.	**262** **8038** **1513**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
Mossel Broth (EE Broth) For the cultivation and enrichment of *Enterobacteriaceae* in food.	**217** **3140** **6082**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
MSRV Agar base (Modified Semisolid Rappaport-Vassiliadis) according to EN ISO 6579/A1 For the selective enrichment of *Salmonella spp.* *Supplements: Novobiocin (Ref. No. X150)*	**195**	powder	500 g
MSRV Agar (Modified Semisolid Rappaport-Vassiliadis) according to EN ISO 6579/A1 For the selective enrichment of *Salmonella spp.*	**3085**	bottle	500, 200, 100 ml
MRSA Agar (Methicillin-Resistant Staphylococcus aureus) For the selective isolation of methicillin-resistant *Staphylococcus aureus.*	**1173**	plate	90 mm
Mueller Hinton II Agar For use in antimicrobial susceptibility testing by the disk diffusion method.	**116** **3035** **1170** **4001** **4003**	powder bottle plate plate plate	500 g 500, 200, 100 ml 90 mm 140 mm 120 mm

Culture media	Ref. No.	Packaging	Type / Volume
Mueller Hinton II Agar according to EUCAST For use in antimicrobial susceptibility testing by the disk diffusion method.	**197** **3096** **1051** **4006**	powder bottle plate plate	500 g 500, 200, 100 ml 90 mm 140 mm
Mueller Hinton II Agar with 2% NaCl For the assay of MIC value.	**1177**	plate	90 mm
Mueller Hinton II Agar with 4% NaCl For the assay of MIC value.	**1175a**	plate	90 mm
Mueller Hinton II Agar with 5% NaCl For the susceptibility testing of methicillin-resistant *Staphylococcus aureus* isolated from clinical specimens.	**3034** **1175**	bottle plate	500, 200, 100 ml 90 mm
Mueller Hinton II Agar with 5% sheep blood For use in antimicrobial susceptibility testing by the disk diffusion method.	**1172** **4002**	plate plate	90 mm 140 mm
Mueller Hinton II Agar with 5% sheep blood + 2 mg/l NAD (MH-F) For use in antimicrobial susceptibility testing of a wide variety of fastidious microorganisms especially *Haemophilus influenzae* by the disk diffusion method.	**1370** **4011**	plate plate	90 mm 140 mm
Mueller Hinton Cloxacillin Agar For the isolation of plasmid-mediated AmpC beta-lactamases producing bacteria.	**1216**	plate	90 mm
Mueller Hinton Vancomycin Agar For the selective isolation of gram positive bacteria with high-level vancomycin resistance.	**1178** **4007**	plate plate	90 mm 140 mm
Mueller Hinton Broth For the cultivation of a wide variety of fastidious and nonfastidious microorganisms.	**232** **3512** **6302**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
Mueller Hinton Broth (Cation-Adjusted) For the susceptibility testing of rapidly-growing aerobic and facultatively anaerobic bacteria isolated from clinical specimens.	**6320**	tube	11 ml
Mueller Hinton Broth with beef extract For the susceptibility testing of rapidly-growing aerobic and facultatively anaerobic bacteria isolated from clinical specimens.	**3513**	bottle	500, 200, 100 ml
MKTTn base (Mueller Kauffman Tertathionate–Novobiocin Broth) For the selective enrichment of *Salmonella spp.* *Supplements: Novobiocin (Ref. No. X150)*	**282**	powder	500 g
MKTTn (Mueller Kauffman Tertathionate–Novobiocin Broth) For the selective enrichment of *Salmonella spp.*	**6092** **6092a**	tube tube	10 ml 10 ml
Mycological Agar For use in antimycotic susceptibility testing by the disk diffusion method.	**3216** **1176**	bottle plate	500, 200, 100 ml 90 mm
Nickerson Agar BIGGY (Bismuth Sulphite Glucose Glycine Yeast) For the isolation and enumeration of *Candida spp.*	**225** **1018**	powder plate	500 g 90 mm
Nutrient Agar 1,5% For the cultivation of a wide variety of fastidious microorganisms.	**151** **3205** **1503** **6014**	powder bottle plate tube	500 g 500, 200, 100 ml 90 mm 7 ml

#121.

Culture media	Ref. No.	Packaging	Type / Volume
Sabouraud Dextrose Chloramphenicol Actidione Agar For the selective isolation of fungi.	**3040** **6304** **1233**	bottle tube plate	500, 200, 100 ml 7 ml 90 mm
Sabouraud Dextrose Chloramphenicol Gentamycin Agar For the selective isolation of fungi.	**3030** **6301** **1232**	bottle tube plate	500, 200, 100 ml 7 ml 90 mm
Sabouraud Dextrose Agar with lecithin & Tween For the isolation of fungi.	**100**	powder	500 g
Sabouraud Dextrose Agar with lecithin & Tween count-tact For the isolation of yeasts and molds from sanitized surfaces.	**7020**	plate	65 mm
Sabouraud Dextrose Broth For the enrichment of fungi.	**150** **3050** **6010**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
Salmonella Shigella Agar For the isolation of *Salmonella spp.* and some strains of *Shigella spp.*	**120** **3018** **1250**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
Schaedler Agar base For the cultivation of anaerobic microorganisms. *Supplements: Sheep blood (Ref. No.1000)*	**138**	powder	500 g
Schaedler Agar base with vit. K-3 For the cultivation of anaerobic microorganisms.	**3036**	bottle	500, 200, 100 ml
Schaedler Agar with 5% sheep blood For the cultivation of anaerobic microorganisms.	**1200**	plate	90 mm
Schaedler Agar with 5% sheep blood and vit. K-3 For the cultivation of anaerobic microorganisms.	**1201**	plate	90 mm
Schaedler CNA Agar with 5% sheep blood For the selective isolation of anaerobic gram positive cocci *Peptococcus* and *Peptostreptococcus spp.* *Supplements: Colistin, Nalidixic acid (Ref. No. X011)*	**1202**	plate	90 mm
Schaedler Kanamycin Vancomycin Agar with 5% sheep blood For the selective isolation of the anaerobic gram negative microorganisms, especially *Bacteroides spp.*	**1207**	plate	90 mm
Schaedler Neomycin Vancomycin Agar with 5% sheep blood For the selective isolation of anaerobic microorganisms.	**1205**	plate	90 mm
Schaedler Vancomycin Agar with 5% sheep blood For the selective isolation of anaerobic microorganisms, especially *Bacteroides spp.*	**1206**	plate	90 mm
Schaedler Broth For the enrichment of anaerobic microorganisms.	**139** **3207** **6100**	powder bottle tube	500 g 500, 200, 100 ml 10 ml
Schaedler Broth with vit. K-3 (agar 0,02%) For the enrichment of anaerobic microorganisms.	**6102**	tube	10 ml
Schaedler Broth with vit. K-3 (agar 0,2%) For the enrichment of anaerobic microorganisms.	**6101**	tube	10 ml

Culture media	Ref. No.	Packaging	Type / Volume
Selenite Cystine Broth For the selective enrichment of *Salmonella spp.* from clinical samples.	**156** **3044** **6313**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
Selenite F Broth For the selective enrichment of *Salmonella spp.*	**124** **3037** **6030**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
Semi Fraser Broth base For the selective isolation of *Listeria spp.* *Supplements: Semi Fraser supplement (Ref. No. 3062)*	**226**	powder	500 g
Semi Fraser Broth according to EN ISO 1129-1:1999 For the selective isolation of *Listeria spp.*	**3005** **6007**	bottle tube	225 ml 10 ml
Simmons Citrate Agar For the biochemical differentiation of microorganisms on the basis of citrate utilization.	**127** **3112** **6125**	powder bottle tube	500 g 500, 200, 100 ml 3 ml
Singer Medium For the biochemical differentiation of microorganisms on the basis of urea decomposition and indole production.	**6140**	tube	1,5 ml
Slanetz-Bartley Agar base For the isolation and enumeration of *Enterococcus spp.* in water by the membrane filtration technique.	**3301**	bottle	500, 200, 100 ml
Slanetz-Bartley Agar according to EN ISO 7899-2 For the isolation and enumeration of *Enterococcus spp.* in water by the membrane filtration technique.	**234** **3401** **8019**	powder bottle plate	500 g 100 ml 90 mm
Sodium Chloride (NaCl) 6,5% Broth For the selective enrichment of *Enterococcus spp.*	**3121** **6122**	bottle tube	500, 200, 100 ml 5 ml
Standard Agar For the cultivation of the wide spectrum of microorganisms.	**3048** **6123** **1504**	bottle tube plate	500, 200, 100 ml 7 ml 90 mm
Standard Broth For the cultivation of a wide spectrum of microorganisms.	**3120** **6121**	bottle tube	500, 200, 100 ml 5 ml
Standard Methods Agar (PCA) For the cultivation of a wide variety of microorganisms.	**252** **3533** **1342**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
Standard Methods Agar (PCA) count-tact For the isolation of microorganisms from sanitized surfaces.	**7015**	plate	65 mm
Sulphite Iron Agar according to EN 26461-2 For the isolation and enumeration of *Clostridium spp.* in water.	**8040** **6023** **1270**	bottle tube plate	500, 200, 100 ml 7 ml 90 mm
Streptococcus Selective Agar For the selective isolation of *Streptococcus spp.*	**1006**	plate	90 mm
Stonebrink Medium For the cultivation of *Mycobacterium spp.*	**6150**	tube	7 ml
Sugar Agar with 3% sheep blood according to Zeissler For the isolation of spore forming bacteria reducing sulphates.	**1380**	plate	90 mm

Culture media	Ref. No.	Packaging	Type / Volume
HTM Agar base (Haemophilus Test Medium) For the susceptibility testing of *Haemophilus influenzae.* *Supplements: HTM supplement (Ref. No. 3127)*	**3506**	bottle	500, 200, 100 ml
HTM Agar (Haemophilus Test Medium) For the susceptibility testing of *Haemophilus influenzae.*	**1260**	plate	90 mm
Hugh-Leiffson Agar For the detection and differentiation of *Pseudomonas aeruginosa* on the basis of oxidation and fermentation.	**6139**	tube	5 ml
Indole Medium (tryptone–tryptophane) For the biochemical differentiation of *Enterobacteriaceae* on the basis of indole production. *Reagents: Ehrlich's reagent (Ref. No. 3130), Kovac's reagent (Ref. No. 3135)*	**3550** **6144**	bottle tube	500, 200, 100 ml 3 ml
Indole - Urease Medium For the biochemical differentiation of microorganisms on the basis of urease, indole production.	**3119** **6137**	bottle tube	500, 200, 100 ml 3 ml
Karmali Agar for Campylobacter For the isolation of *Campylobacter spp.*	**1009**	plate	90 mm
Kessler-Swenarton Agar For the selective isolation of *Escherichia coli.*	**3516**	bottle	500, 200, 100 ml
King A Agar (Pseudomonas P) For the selective isolation of *Pseudomonas aeruginosa* on the basis of pyocyanin production.	**1025**	plate	90 mm
King B Agar (Pseudomonas F) For the selective isolation of *Pseudomonas aeruginosa* on the basis of fluorescin production.	**3534** **6022** **1015**	bottle tube plate	500, 200, 100 ml 7 ml 90 mm
Kligler Iron Agar For the biochemical differentiation of microorganisms on the basis of dextrose and lactose fermentation and hydrogen sulphite production.	**112** **3111** **6070** **6124**	powder bottle tube tube	500 g 500, 200, 100 ml 7 ml 3 ml
Lactobacilli MRS Agar For the cultivation of *Lactobacillus spp.*	**212** **3029** **1512**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
Lactobacilli MRS Broth For the enrichment of *Lactobacillus spp.*	**185** **3608** **6078**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
LPB Broth (Lactose Bromocresol Purple Broth) For the isolation of *Escherichia coli* in water.	**3086** **8023**	bottle tube	500, 200, 100 ml 10 ml
Lactose Broth according to EN ISO 9308 For the biochemical differentiation of microorganisms on the basis of lactose fermentation.	**8024** **6034**	bottle tube	500, 200, 100 ml 5 ml
Lactose Broth For the biochemical differentiation of *Enterobacteriaceae* on the basis of lactose fermentation.	**129** **3143**	powder bottle	500 g 500, 200, 100 ml
Lauryl Sulphate Broth For the detection of coliform bacteria in water and wastewater.	**213** **3003** **6025**	powder bottle tube	500 g 500, 200, 100 ml 5 ml

Culture media	Ref. No.	Packaging	Type / Volume
Lauryl Sulphate Broth with MUG (4-methylumbelliferyl-β-D-glucuronide) For the detection of coliforms and the fluorogenic detection of *Escherichia coli.*	**148** **3004** **6026**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
Lauryl Tryptose Mannitol Broth (with Durham's tube) For the biochemical differentiation of *Escherichia coli* in water samples on the basis of gas and indole production.	**8035** **6002**	bottle tube	500, 200, 100 ml 5 ml
Letheen Agar with lecithin & Tween 80 For the cultivation of microorganisms in cosmetics.	**260** **3150** **1215**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
Letheen Broth with lecithin & Tween 80 For the enrichment of microorganisms in cosmetics.	**261** **3541**	powder bottle	500 g 500, 200, 100 ml
Levine Eosin Methylene Blue Agar (LEMB) For the isolation and differentiation of gram negative enteric bacilli.	**104** **3033** **1011**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
Loeffler Medium For the cultivation of *Corynebacterium spp.*	**6003**	tube	4 ml
Lowenstein-Jensen Agar without malachite green For the cultivation of *Mycobacterium spp.*	**6160**	tube	7 ml
Lowenstein-Jensen Agar with malachite green For the cultivation of *Mycobacterium spp.*	**6161**	tube	7 ml
Lysine Decarboxylase Broth For the biochemical differentiation of microorganisms, especially enteric bacilli on the basis of lysine decarboxylation.	**6146**	tube	5 ml
mCCD Agar (Campylobacter Blood-Free Selective Agar base) according to EN ISO 10272-1:2006 For the isolation of *Campylobacter spp.* *Supplements: Cefoperazone, Amphotericin (Ref. No. X112)*	**281**	powder	500 g
mCCD Agar (Campylobacter Blood-Free Selective Agar) according to EN ISO 10272-1:2006 For the isolation of *Campylobacter spp.*	**1008**	plate	90 mm
mFC Agar according to EN ISO 9308 For the isolation and enumeration of coliform bacteria in water by the membrane filtration technique.	**8021**	plate	55 mm
m-CP Agar For the isolation of *Clostridium perfringens* in water by the membrane filtration technique.	**1032**	plate	90 mm
M (Mannose) Broth For the cultivation of *Salmonella spp.*	**179** **6312**	powder tube	500 g 10 ml
MacConkey Agar with crystal violet For the isolation and differentiation of gram negative enteric bacilli.	**113** **3017** **1020**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
MacConkey Agar, CS (Controlled Swarming) For the isolation and differentiation of gram negative enteric bacilli from specimens containing swarming strains of *Proteus spp.*	**299** **1026**	powder plate	500 g 90 mm

Culture media	Ref. No.	Packaging	Type / Volume
Nutrient Agar For the cultivation of a wide variety of fastidious microorganisms.	**6310**	tube	7 ml
Nutrient Agar according to ISO 21528-1 For the cultivation of a wide variety of microorganisms, especially *Enterobacteriaceae.*	**1522**	plate	90 mm
Nutrient Agar according to EN ISO 9308-1 For the cultivation of a wide variety of microorganisms, including *Escherichia coli.*	**3092** **8027**	bottle tube	500, 200, 100 ml 7 ml
Nutrient Agar according to EN 12780 For the cultivation of a wide variety of microorganisms, including *Pseudomonas aeruginosa.*	**1520**	plate	90 mm
Nutrient Broth For the enrichment of a wide variety of fastidious microorganisms.	**176** **3227**	powder bottle	500 g 500, 200, 100 ml
Nystatin Actidione Medium For the isolation of bacteria.	**1023**	plate	90 mm
Nitrate Medium For the biochemical differentiation of microorganisms on the basis of nitrate reduction.	**3517** **6212**	bottle tube	100 ml 3 ml
OGYE Agar base (Oxytetracycline-Glucose-Yeast Extract Agar) For the selective isolation of yeasts and molds from food. *Supplements: Oxytetracycline (Ref. No. X089)*	**199**	powder	500 g
OGYE Agar (Oxytetracycline-Glucose-Yeast Extract Agar) For the selective isolation of yeasts and molds from food.	**1113**	plate	90 mm
OGYE Agar (Oxytetracycline-Glucose-Yeast Extract Agar) with lecithin and Tween 80 For the selective isolation of yeasts and molds from food.	**1114**	plate	90 mm
O.R.S.I.M base (Oxacyllin Resistance Staphylococci Isolation Medium) For the selective isolation of methicillin-resistant *Staphylococcus aureus.* *Supplements: Oxacylin, Polymyxin B (Ref. No. X192)*	**269**	powder	500 g
O.R.S.I.M (Oxacyllin Resistance Staphylococci Isolation Medium) For the selective isolation of methicillin-resistant *Staphylococcus aureus.*	**1174**	plate	90 mm
Oxford Agar base For the selective isolation of *Listeria spp.* *Supplements: Oxford Listeria supplement (Ref. No. X122)*	**236**	powder	500 g
Oxford Agar For the selective isolation of *Listeria spp.*	**1292**	plate	90 mm
PP Agar (Motility Test Agar) For the differentiation of microorganisms on the basis of motility.	**254** **3502**	powder bottle	500 g 500, 200, 100 ml
PP Agar (Motility Test Agar) For the differentiation of *Enterococcus spp.* on the basis of motility.	**6241**	tube	3 ml
PP Agar (Red Motility Agar) For the differentiation of *Enterobacterioceae* on the basis of motility and colour reaction.	**6141**	tube	3 ml

Culture media	Ref. No.	Packaging	Type / Volume
Palcam Agar base For the selective isolation of *Listeria spp.* *Supplements: Palcam supplement (Ref. No. X144)*	**230**	powder	500 g
Palcam Agar For the selective isolation of *Listeria spp.*	**1502**	plate	90 mm
Peptone Water For the cultivation of non-fastidious microorganisms.	**206** **3039** **6060**	powder bottle tube	500 g 500, 200, 100 ml 5 ml
Phenyloalanine Agar For the biochemical differentiation of microorganisms on the basis of phenyloalanine deamination.	**3115** **6126**	bottle tube	500, 200, 100 ml 3 ml
Potato Dextrose Agar For the cultivation of fungi.	**271**	powder	500 g
Potato Dextrose Chloramphenicol Agar For the isolation of fungi.	**1236**	plate	90 mm
Potato Dextrose Chloramphenicol Gentamycin Agar For the isolation of fungi.	**1237**	plate	90 mm
Pseudomonas Isolation Agar For the isolation of *Pseudomonas aeruginosa* and other *Pseudomonas spp.*	**152** **1507**	powder plate	500 g 90 mm
Pseudomonas CFC (Cetrymide, Fucidin, Cephalosporin) Agar according to ISO 13720 For the selective isolation of *Pseudomonas aeruginosa.*	**1311**	plate	90 mm
Pseudomonas CN (Cetrymide, Nalidixic Acid) Agar base For the selective isolation of *Pseudomonas aeruginosa.* *Supplements: C.N. (Cetrymide, Nalidixic Acid) supplement (Ref. No. X107)*	**238**	powder	500 g
Pseudomonas CN (Cetrymide, Nalidixic Acid) Agar according to EN 12780 and EN ISO 16266 For the selective isolation of *Pseudomonas aeruginosa.*	**8046** **1022**	bottle plate	500, 200, 100 ml 90 mm
R2 Agar For the enumeration and cultivation of bacteria in potable water.	**249** **8044** **1544**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
Rappaport-Vassiliadis Broth For the selective isolation of *Salmonella spp.*	**155** **3204**	powder bottle	500 g 500, 200, 100 ml
Rappaport-Vassiliadis Broth according to EN ISO 6579 For the selective isolation of *Salmonella spp.*	**6011** **6011a**	tube glass tube	10 ml 10 ml
Sabouraud Dextrose Agar For the isolation of fungi.	**117** **3010** **1230**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
Sabouraud Dextrose Actidione Agar For the selective isolation of fungi.	**1234**	plate	90 mm
Sabouraud Dextrose Chloramphenicol Agar For the selective isolation of fungi.	**114** **3020** **6303** **1231**	powder bottle tube plate	500 g 500, 200, 100 ml 7 ml 90 mm

Culture media	Ref. No.	Packaging	Type / Volume
XLD Agar (Xylose Lysine Deoxycholate Agar) according to EN ISO 6579 For the selective isolation of *Salmonella spp.*	**303** **8013** **3091**	powder bottle plate	500 g 500, 200, 100 ml 90 mm
XLT 4 Agar base For the isolation of non-typhi *Salmonella spp.*	**263** **3554**	powder bottle	500 g 500, 200, 100 ml
XLT 4 Agar with Tergitol T4 For the isolation of non-typhi *Salmonella spp.*	**1518**	plate	90 mm
Yeast Extract Agar For the enumeration of microorganisms in potable and fresh water samples.	**287**	powder	500 g
Yeast Extract Glucose Agar according to EN ISO 7218 For the isolation of molds and yeasts from enviroment.	**287** **8030**	powder plate	500 g 90 mm
YGC Agar (Yeast Extract Glucose Chloramphenicol Agar) according to EN ISO 7218 For the selective isolation of molds and yeasts from enviroment.	**291** **6047** **8047**	powder tube plate	500 g 15 ml 90 mm
YGC Agar (Yeast Extract Glucose Chloramphenicol Agar) according to ISO 7954 For the cultivation and selective isolation of molds and yeasts.	**291** **3088** **6036** **8036**	powder bottle tube plate	500 g 500, 200, 100 ml 15 ml 90 mm
Yeast Extract Agar without glucose according to EN ISO 6222 For the cultivation of total count of microorganisms in water.	**284** **8026** **6048**	powder bottle tube	500 g 500, 200, 100 ml 15 ml
Yersinia CIN (Cefsulodin-Irgasan-Novobiocin) Agar base For the selective isolation of *Yersinia spp.* *Supplements: CIN (Cefsulodin-Irgasan-Novobiocin) supplement (Ref. No. X120)*	**123** **3515**	powder bottle	500 g 500, 200, 100 ml
Yersinia CIN (Cefsulodin-Irgasan-Novobiocin) Agar For the selective isolation of *Yersinia spp.*	**1090**	plate	90 mm
Yersinia PSB Broth according to EN ISO 10273 For the selective enrichment of *Yersinia enterocolitica.*	**3523** **6175**	bottle tube	500, 200, 100 ml 5 ml

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1.2 CULTURE MEDIA ON MULTIPLATES

Bi-plates	Ref. No.	Packaging	Type
Brain Heart Infusion Streptomycin Agar / Brain Heart Infusion Gentamycin Agar For the selective isolation of *Enterococcus spp.* with high-level aminoglycoside resistance.	**2046**	plate	90 mm/2
Brain Heart Infusion Vancomycin Agar / Brain Heart Infusion Agar For the selective isolation of *Enterococcus spp.* with high-level vancomycin resistance.	**2045**	plate	90 mm/2
Buffered Charcoal Yeast Extract Agar (BCYE) / Buffered Charcoal Yeast Extract Agar (BCYE) with cysteine For the isolation of *Legionella spp.*	**2067**	plate	90 mm/2

Bi-plates	Ref. No.	Packaging	Type
Buffered Charcoal Yeast Extract Agar (BCYE) with vancomycin and colistin / Buffered Charcoal Yeast Extract (BCYE) Agar without cysteine with pimaricin For the isolation of *Legionella spp.*	**2071**	plate	90 mm/2
Bordetella Agar with 15% sheep blood / Bordetella Agar with charcoal and 7% horse blood For the cultivation of *Bordetella pertussis* and *Bordetella parapertussis* from clinical samples.	**2008**	plate	90 mm/2
Brucella Agar with 5% sheep blood, hemine and vit. K / CDC Kanamycin Vancomycin Agar with lysed sheep blood For the isolation of a wide variety of anaerobic microorganisms.	**2008** **2006**	plate plate	90 mm/2 90 mm/2
CHROMagar VRE / CHROMagar KPC For the detection of antibiotic resistance mechanisms in bacteria.	**2019**	plate	90 mm/2
Campylobacter Agar (acc. Butzler) with 7% horse blood / Clostridium Difficile Agar with 7% sheep blood For the isolation of anareobic bacteria from clinical samples.	**2007**	plate	90 mm/2
CHROMagar Salmonella / CHROMagar O157 For the isolation of *Salmonella spp.* and *Escherichia coli* O157 from faecal specimens.	**2056**	plate	90 mm/2
CHROMagar ESBL / CHROMagar VRE For the detection of antibiotic resistance mechanisms in bacteria.	**2057**	plate	90 mm/2
CHROMagar Listeria / CHROMagar StrepB For the isolation of *Streptococcus agalactiae* (GBS) and *Listeria spp.* from vaginal swabs.	**2062**	plate	90 mm/2
CHROMagar MRSA / Mannitol Salt Agar For the selective isolation of methicillin-resistant *Staphylococcus aureus* (MRSA).	**2026**	plate	90 mm/2
Columbia Agar with 5% sheep blood / Columbia Agar with 5% sheep blood For the cultivation of a wide variety of fastidious microorganisms.	**2001**	plate	90 mm/2
Columbia Agar with 5% sheep blood / Chocolate Agar For the cultivation of a wide variety of fastidious microorganisms.	**2061**	plate	90 mm/2
Columbia Agar with 5% sheep blood / Sabouraud Dextrose Chloramphenicol Agar For the isolation of fungi from faecal specimens.	**2065**	plate	90 mm/2
Columbia CNA (Colistin, Nalidixic Acid) Agar with 5% sheep blood / Chocolate Agar For the cultivation of a wide variety of fastidious microorganisms.	**2052**	plate	90 mm/2
Columbia CNA (Colistin, Nalidixic Acid) Agar with 5% sheep blood / Enterococcosel Agar For the isolation of gram positive microorganisms.	**2022**	plate	90 mm/2
Columbia CNA (Colistin, Nalidixic Acid) Agar with 5% sheep blood / Mannitol Salt Agar (MSA) For the isolation of gram positive microorganisms, especially *Staphylococcus aureus.*	**2032**	plate	90 mm/2