



Date: 29/Sep/2022

Subject: Updated Label Information for Thermo Scientific™ Dehydrated Culture Media and Supplements

Dear Customer,

Thermo Fisher Scientific Inc. is the world leader in serving science. Our mission is to enable our customers to make the world healthier, cleaner, and safer.

We help our customers accelerate life sciences research, solve complex analytical challenges, improve patient diagnostics, and increase laboratory productivity. We offer an unmatched combination of innovative technologies, purchasing convenience and comprehensive support.

The In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746 was implemented in the European Union (EU) on 26/May/2022. Thermo Fisher Scientific Microbiology Division (MBD) is committed to ensuring our core clinical IVD products meet the requirements of the In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746.

Compliance to this regulation enables manufacturers to continue to support compliance to the regulation and apply the CE mark to their products. As part of this transition the product labelling of the dehydrated culture media and supplements has been revised. This has resulted in the preparation instructions, typical formula and pH details being transferred from the product labelling to the instructions for use and/or product specifications due to space constraints on the products themselves (see the attached for a list of products affected). This change was implemented to comply with the revised labelling requirements of the In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746 and to provide additional language translations. Preparation instructions, typical formula and pH can be found on the instructions for use and/or the product specifications, these can be accessed on www.thermofisher.com (please see on the following pages how to access these documents).

For any further questions on IVDR, please visit our website www.thermofisher.com/IVDR-microbiology/. Here you will also find more answers to frequently asked questions and more details in relation to the implementation of the IVDR by Thermo Fisher Scientific Microbiology Division (MBD).

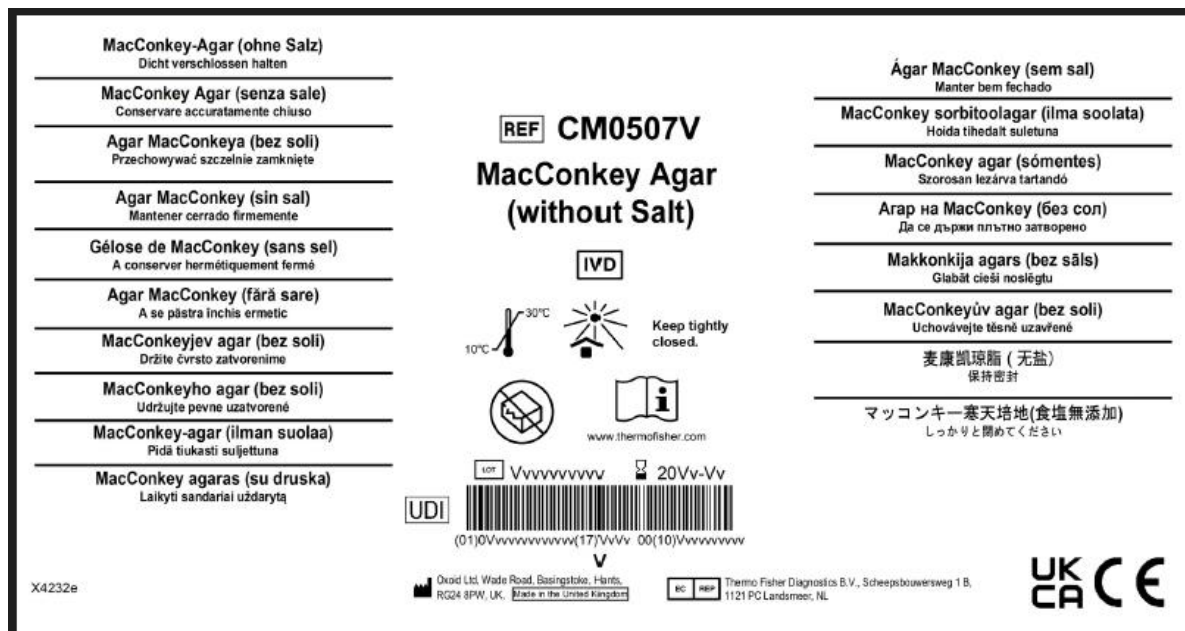
Should you have any specific questions please do not hesitate to contact the Microbiology Division (MBD) to discuss this matter further. Please contact your local customer service or technical support team, contact details of these teams is attached.

Yours sincerely,

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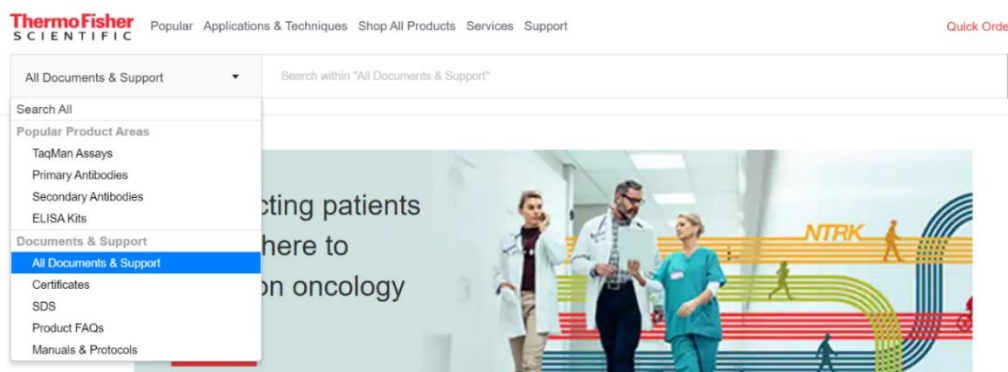
Example of the revised label format



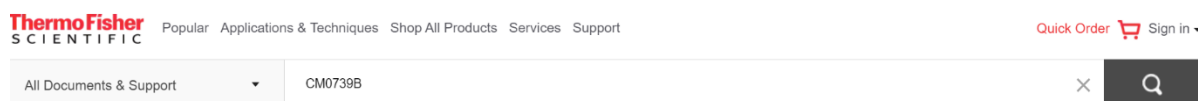
How to access product documents – IFUs and Product Specifications

You can find product documentation using search filters on thermofisher.com/microbiology. Utilise the left-side “Search All” menu.

1. Choose “All documents & Support” from the drop- down list under “Search All” menu.



2. Then, type the product code in the search bar, and select the search icon or your return key. This will display “Result Type” where the required document can be selected.



3. For Instructions for Use (IFU):

Choose “Manuals & Protocols” from the drop- down list under “Result Type”
Select the IFU link with the Product Code and Adobe™ PDF symbol. Do not select catalogue number as that will bring you to the product page.

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Manuals & Protocols CM07398

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MBD_BT_IFU-0427 CM07398_CM0739R_CM0739T BLOOD FREE CAMPY SELECT AGAR.pdf Manual / Product Insert

[Catalog #](#)

4. For Product Specifications:

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Select the “Product Specification” link with the Adobe PDF symbol.

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- ☐ Certificates (182)
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PRODUCT SPECIFICATION: CM0739 CAMPYLOBACTER BLOOD-FREE SELECTIVE AGAR BASE (v6) Product Literature

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Microbiology Product Catalog - Europe Product Literature

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Importer Details Product Literature

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5. Download the IFU or Product Specification document

ThermoFisher SCIENTIFIC	Document Owner Department: QC	BT-SPEC-0200
OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION		
CAMPYLOBACTER BLOOD-FREE SELECTIVE AGAR BASE CM0739		

CAMPYLOBACTER BLOOD-FREE SELECTIVE AGAR BASE		CM0739
Typical Formula*		
Nutrient Broth No. 2	grams per litre	25.0
Activated carbon		4.0
Casein hydrolysate		3.0
Sodium desoxycholate		1.0
Iron (II) sulphate		0.25
Sodium pyruvate		0.25
Agar		12.0
*adjusted to meet performance standards		
Directions		
Suspend 22.75g in 500ml of distilled water. Bring to the boil to dissolve completely. Sterilize by autoclaving at 121°C for 15 minutes. Cool to 50°C and aseptically add the contents of 1 vial of CCDA Selective Supplement (SR0155E) reconstituted as directed. Mix well and pour into sterile Petri dishes.		
Physical Characteristics		
Black, free-flowing powder		
Colour on reconstitution - black		
pH 7.4 ± 0.2 at 25°C		
Clarity - opaque		
Gel strength - firm, comparable to 12g/litre of agar		
Microbiological Tests Using Optimum Inoculum Dilution		
Control Medium : Columbia Blood Agar Base enriched with 7% v/v laked horse blood and Campylobacter Growth Supplement SR0232		
Reactions after incubation at 37 ± 2°C for 48 hours under microaerophilic conditions		
Tested with the addition of CCDA Selective Supplement SR0155		
Medium is challenged with 10-100 colony-forming units		
<i>Campylobacter jejuni</i>	ATCC®33560	0.5-2mm grey colonies

Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated)*

CM0739B, CM0739R and CM0739T

*These Instructions for Use (IFU) are intended to be read in conjunction with the IFU for Oxoid Limited's CCDA Selective Supplements (product codes: SR0155E, SR0155R).

Intended Use

Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated) (CM0739B, CM0739R or CM0739T) when supplemented with CCDA Selective Supplements (SR0155E or SR0155R), is a blood-free selective medium intended for the isolation of Campylobacter species from faecal samples.

Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated), with CCDA Selective Supplement added, is intended to be used as a diagnostic workhorse to aid clinicians in determining potential treatment options for patients suspected of having campylobacteriosis.

The device is for professional use only, is not automated, nor is it a companion diagnostic.

Summary and Explanation

Campylobacter species are Gram-negative rods in appearance. Two of the most medically relevant Campylobacter species isolated from human samples are Campylobacter coli and Campylobacter jejuni. The symptoms of Campylobacter spp. infections are characterised by vomiting, nausea, body aches, abdominal pain and in some cases bloody diarrhoea. In acute stages, the symptoms of Campylobacter infections mimic ulcerative colitis and appendicitis. Long term complications of Campylobacter infections include arthritis, Guillain-Barre Syndrome (GBS) and Irritable Bowel Syndrome (IBS).

The implications of Campylobacter infections can vary from person to person. In most cases, pregnant ladies, patients with AIDS, other blood disorders, the immunosuppressed, patients undergoing chemotherapy and those with a weakened immune system are at high risk. Moreover, the resistance shown by the Campylobacter species to fluoroquinolones (the significant compounds treatment) CCDA Selective Medium (P0019A) and Campylobacter Blood-Free Selective Agar Base (Dehydrated) (CM0739B/RT) with CCDA Selective Supplements (SR0155E/RT) are therefore a key tool for the clinician to support the isolation of Campylobacter species from faecal samples.

Principle of Method

The formulation of Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated) (CM0739B, CM0739R and CM0739T) contains a nutrient broth comprised of peptone and Lio-Lemco powder which with casein hydrolysate are sources of nitrogen and other nutrients. Ferrous sulphate, sodium pyruvate and charcoal replace the blood used in other formulations of campylobacter culture media. Charcoal acts as an adsorbent for toxic components. Sodium desoxycholate is added to suppress the growth of Gram-positive organisms. CCDA Selective Supplements (SR0155E and SR0155R) added to DCM contains

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cefoperazone, a cephalosporin that acts as a broad-spectrum antimicrobial with activity against a wide range of microorganisms including *Enterobacteriaceae* and *Pseudomonas* species. Amphotericin B is added to inhibit fungi, this is required when medium is incubated at 37°C to prevent overgrowth of yeasts.

Typical Formula	
Nutrient Broth No. 2	25.0
Activated carbon	4.0
Casein hydrolysate	3.0
Sodium desoxycholate	1.0
Iron (II) sulphate	0.25
Sodium pyruvate	0.25
Agar	12.0

Materials Provided

- CM0739B, 500g pot
- CM0739R, 250g pot
- CM0739T, 75g pot

Materials Required but Not Supplied

- Insulating loops, swabs, collection containers
- Incubator
- Quality control organisms
- Selective supplements (SR0155E or SR0155R)
- Petri Dishes

Storage

Store dehydrated media in its original packaging between 10°C and 30°C. Keep out of direct sunlight. Keep away from moisture.

Once reconstituted, store media between 2°C and 12°C.

Warnings and Precautions

- DO NOT USE SUPPLEMENTS IF YOU ARE PREGNANT OR CONTEMPLATING PREGNANCY
- For professional use only.
- Inspect the product packaging before first use.
- Do not use the product if there is any visible damage to the packaging.
- Do not use the product beyond the stated expiry date.
- Do not use the device if signs of contamination are present.
- Do not use the device if the colour has changed or there are other signs of deterioration.
- It is the responsibility of each laboratory to manage waste produced according to their nature and degree of hazard and to have them treated or disposed of in accordance with any federal, state and local applicable regulations. Directions should be read and followed carefully. This includes the disposal of used or unused reagents as well as any other contaminated disposable material following procedures for infectious or potentially infectious products.
- Do not inhale.
- Causes serious eye irritation.
- May cause allergic or asthma symptoms or difficulty breathing if inhaled.
- May cause an allergic skin reaction.
- If on skin wash with plenty of soap and water.
- If in eyes, rinse cautiously with water for several minutes.
- Remove contact lenses, if present and easy to do. Continue rinsing.
- If eye irritation persists, seek medical advice/attention.

Code	Product Name
CM0007B	MACCONKEY AGAR
CM0007K	MACCONKEY AGAR
CM0007R	MACCONKEY AGAR
CM0033B	KLIGLER IRON AGAR
CM0041B	SABOURAUD DEXTROSE AGAR
CM0041K	SABOURAUD DEXTROSE AGAR
CM0041R	SABOURAUD DEXTROSE AGAR
CM0041T	SABOURAUD DEXTROSE AGAR
CM0053B	UREA AGAR BASE
CM0055B	BLOOD AGAR BASE
CM0055T	BLOOD AGAR BASE
CM0069B	EOSIN METHYLENE BLUE AGAR
CM0069K	EOSIN METHYLENE BLUE AGAR
CM0069T	EOSIN METHYLENE BLUE AGAR
CM0071B	Urea Broth Base
CM0083B	HOYLE MEDIUM BASE
CM0085B	MANNITOL SALT AGAR
CM0085K	MANNITOL SALT AGAR
CM0085R	MANNITOL SALT AGAR
CM0085T	MANNITOL SALT AGAR
CM0085W	MANNITOL SALT AGAR
CM0099B	S S AGAR
CM0099K	S S AGAR
CM0115B	MAC-CONKEY AGAR No 3
CM0115K	MAC-CONKEY AGAR No 3
CM0115Q	MAC-CONKEY AGAR No 3
CM0115R	MAC-CONKEY AGAR No 3
CM0115T	MAC-CONKEY AGAR NO 3
CM0115V	MAC-CONKEY AGAR No 3
CM0115W	MAC-CONKEY AGAR No 3
CM0119B	CHARCOAL AGAR
CM0129B	TRYPTONE SOYA BROTH
CM0129K	TRYPTONE SOYA BROTH
CM0129R	TRYPTONE SOYA BROTH
CM0129T	TRYPTONE SOYA BROTH
CM0129V	TRYPTONE SOYA BROTH
CM0131B	TRYPTONE SOYA AGAR
CM0131K	TRYPTONE SOYA AGAR
CM0131Q	TRYPTONE SOYA AGAR
CM0131R	TRYPTONE SOYA AGAR
CM0131T	TRYPTONE SOYA AGAR
CM0131V	TRYPTONE SOYA AGAR
CM0131W	TRYPTONE SOYA AGAR
CM0149B	REINFORCED CLOSTRIDIAL MEDIUM
CM0149T	REINFORCED CLOSTRIDIAL MEDIUM
CM0151B	REINFORCED CLOSTRIDIAL AGAR
CM0189B	TODD-HEWITT BROTH
CM0201B	CM0201B
CM0227B	DESOXYCHOLATE CITRATE AGAR
CM0227R	DESOXYCHOLATE CITRATE AGAR
CM0227T	DESOXYCHOLATE CITRATE AGAR
CM0233B	TRYPTOSE BLOOD AGAR BASE
CM0233T	TRYPTOSE BLOOD AGAR BASE
CM0271B	BLOOD AGAR BASE No 2
CM0271K	BLOOD AGAR BASE No 2
CM0271R	BLOOD AGAR BASE No 2
CM0271T	BLOOD AGAR BASE No 2
CM0277B	TRIPLE SUGAR IRON AGAR
CM0301B	C L E D MEDIUM
CM0301K	C L E D MEDIUM
CM0301R	C L E D MEDIUM
CM0301T	C L E D MEDIUM
CM0301V	C L E D MEDIUM

Code	Product Name
CM0301W	C L E D MEDIUM
CM0321B	DNASE AGAR
CM0329B	BRILLIANT GREEN AGAR MODIFIED
CM0329K	BRILLIANT GREEN AGAR MODIFIED
CM0329R	BRILLIANT GREEN AGAR MODIFIED
CM0329T	BRILLIANT GREEN AGAR MODIFIED
CM0331B	COLUMBIA BLOOD AGAR BASE
CM0331K	COLUMBIA BLOOD AGAR BASE
CM0331R	COLUMBIA BLOOD AGAR BASE
CM0331S	COLUMBIA BLOOD AGAR BASE
CM0331T	COLUMBIA BLOOD AGAR BASE
CM0331U	COLUMBIA BLOOD AGAR BASE
CM0331V	COLUMBIA BLOOD AGAR BASE
CM0331W	COLUMBIA BLOOD AGAR BASE
CM0331Y	COLUMBIA BLOOD AGAR BASE
CM0333B	T.C.B.S CHOLERA MEDIUM
CM0333T	T.C.B.S CHOLERA MEDIUM
CM0337B	MUELLER HINTON AGAR
CM0337D	MUELLER HINTON AGAR
CM0337K	MUELLER HINTON AGAR
CM0337Q	MUELLER HINTON AGAR
CM0337R	MUELLER HINTON AGAR
CM0337T	MUELLER HINTON AGAR
CM0337V	MUELLER HINTON AGAR
CM0337W	MUELLER HINTON AGAR
CM0361B	MRS AGAR
CM0361R	MRS AGAR
CM0361T	MRS AGAR
CM0395B	SELENITE BROTH BASE
CM0401B	MYCOPLASMA AGAR BASE
CM0403B	MYCOPLASMA BROTH BASE
CM0403T	MYCOPLASMA BROTH BASE
CM0405B	MUELLER HINTON BROTH
CM0405T	MUELLER HINTON BROTH
CM0419B	HEKTOEN ENTERIC AGAR
CM0419K	HEKTOEN ENTERIC AGAR
CM0419R	HEKTOEN ENTERIC AGAR
CM0419W	HEKTOEN ENTERIC AGAR
CM0423B	CLED MEDIUM WITH ANDRADE
CM0423K	CLED MEDIUM WITH ANDRADE
CM0423R	CLED MEDIUM WITH ANDRADE
CM0437B	SCHAEDLER AGAR
CM0437V	SCHAEDLER AGAR
CM0469B	XLD MEDIUM
CM0469R	XLD MEDIUM
CM0469T	XLD MEDIUM
CM0469W	XLD MEDIUM
CM0473B	ISOSENSITEST BROTH
CM0507B	MAC-CONKEY AGAR (WITHOUT SALT)
CM0507K	MAC-CONKEY AGAR (WITHOUT SALT)
CM0507R	MAC-CONKEY AGAR (WITHOUT SALT)
CM0507W	MAC-CONKEY AGAR (WITHOUT SALT)
CM0519B	CARY-BLAIR MEDIUM
CM0531B	DRIGALSKI LACTOSE AGAR
CM0533B	S S AGAR (MODIFIED)
CM0539B	DERMASEL AGAR BASE
CM0559B	PSEUDOMONAS AGAR BASE
CM0559R	PSEUDOMONAS AGAR BASE
CM0559T	PSEUDOMONAS AGAR BASE
CM0617B	PEMBA AGAR
CM0617R	PEMBA AGAR
CM0617T	PEMBA AGAR
CM0619B	WILKINS CHALGREN ANAEROBE AGAR

Code	Product Name
CM0619W	WILKINS CHALGREN ANAEROBE AGAR
CM0643B	WILKINS CHALGREN ANAEROBE BROTH
CM0653B	YERSINIA SELECTIVE AGAR BASE
CM0653T	YERSINIA SELECTIVE AGAR BASE
CM0689B	CAMPYLOBACTER AGAR BASE
CM0699B	SELENITE CYST.BROTH BASE
CM0699T	SELENITE CYST.BROTH BASE
CM0739B	BLOOD FREE CAMPY SELECT AGAR
CM0739R	BLOOD FREE CAMPY SELECT AGAR
CM0739T	BLOOD FREE CAMPY SELECT AGAR
CM0739V	BLOOD FREE CAMPY SELECT AGAR
CM0783B	MLCB AGAR
CM0813B	SORBITOL MACCONKEY AGAR
CM0813R	SORBITOL MACCONKEY AGAR
CM0854B	SHEEP BLOOD AGAR No 2
CM0888B	BILE AESCULIN AGAR
CM0888K	BILE AESCULIN AGAR
CM0898B	HAEMOPHILUS TESTING MEDIUM
CM0911B	FUNGAL (KIMMIG) AGAR
CM0935B	KARMALI AGAR BASE
CM0949C	BRILLIANCE UTI AGAR 400G
CM0949T	BRILLIANCE UTI AGAR
CM0972B	ANAEROBE BASAL AGAR
CM0981B	SORBITOL MACCONKEY AGAR WITH BCIG
CM0989B	MODIFIED TRYPTONE SOYA BROTH
CM0989G	MODIFIED TRYPTONE SOYA BROTH
CM0995B	BURKHOLDERIA CEPACIA AGAR BASE
CM1007B	SALMONELLA CHROMOGENIC AGAR BASE
CM1028B	ALKALINE PEPTONE WATER 500g
CM1032B	HEART INFUSION BROTH
CM1051T	CLED WITH ANDRADES
CM1061B	XLT-4 AGAR
CM1061T	XLT-4 AGAR
CM1062P	SABOURAUD DEXTROSE AGAR
CM1062T	SABOURAUD DEXTROSE AGAR
CM1062V	SABOURAUD DEXTROSE AGAR
CM1062W	SABOURAUD DEXTROSE AGAR
CM1092B	BRILLIANCE SALMONELLA AGAR BASE
CM1092T	BRILLIANCE SALMONELLA AGAR BASE
CM1106B	BRILLIANCE UTI CLARITY AGAR
CM1106T	BRILLIANCE UTI CLARITY AGAR
CM1106W	BRILLIANCE UTI CLARITY AGAR
CM1132T	ANAEROBE RECOVERY AND ISOLATION AGAR (ARIA)
CM1135B	BRAIN HEART INFUSION BROTH
CM1135K	BRAIN HEART INFUSION BROTH
CM1135R	BRAIN HEART INFUSION BROTH
CM1135T	BRAIN HEART INFUSION BROTH
CM1136B	BRAIN HEART INFUSION AGAR
CM1169B	MACCONKEY AGAR

Code	Product Name
SR0020K	UREA 40%
SR0030J	POTASSIUM TELLURITE 3.5%
SR0059C	MYCOPLASMA SUPPLEMENT G 1 X 10 VIALS
SR0069E	CAMPYLOBACTER SEL.SUPP.(SKIRROW)1X10VIAL
SR0069H	CAMPYLOBACTER SEL.SUPP.(SKIRROW)1X10VIAL
SR0070E	STAPH.-STREP.SELECT.SUPP.
SR0075E	DERMASEL SELECTIVE SUPPLEMENT
SR0078E	CHLORAMPHENICOL SEL.SUPP.1 X 10 VIALS
SR0078H	CHLORAMPHENICOL SEL.SUPP.1 X 10 VIALS
SR0082E	BORDETTELLA SELECTIVE SUPP.
SR0085E	CAMPYLOBACTER SEL.SUPP.(BUTZLER)1X10VIAL
SR0090A	VITOX SUPP+RECONSTITUTION FLUID 2X5VIALS
SR0090H	VITOX SUPP+RECONSTITUTION FLUID 10X2LTRS
SR0098E	CAMPYLO.SEL.SUPP.(BLASER-WANG)1X10 VIALS
SR0099E	BACILLUS CEREUS SEL.SUPP.
SR0102E	PSEUDOMONAS C-N SEL.SUPPL. 1 X 10
SR0103E	PSEUDOMONAS C-F-C SEL SUPP 1 X 10 VIALS
SR0109E	YERSINIA SELECTIVE SUPP.1 X 10 VIALS
SR0112C	NITROCEFIM+RECONSTITUTION FLUID 2X5VIALS
SR0113E	BROAD SPECTRUM BETA-LACTAMASE MIX 1X10VL
SR0119E	GARDNERELLA VAGINALIS SEL.SUPP.1X10VIALS
SR0126E	STREPTOCOCCUS SELECTIVE SUPPL.1X10 VIALS
SR0129B	PENASE 1 VIAL
SR0155E	CCDA SELECTIVE SUPPLEMENT 1 X 10 VIALS
SR0155H	CCDA SELECTIVE SUPPLEMENT 10X2 LITRES
SR0158E	HAEMOPHILUS TEST(HTM)SUPP.1X10V
SR0163H	NEOMYCIN SELECTIVE SUPP. 1 X 10 VIALS
SR0167E	CAMPYLOBACTER SEL.SUPP.(KARMALI)1X10VIAL
SR0172E	CEFEXIME TELLURITE SEL. SUP.
SR0172H	CEFEXIME TELLURITE SELECTIVE SUPP 2L
SR0176G	MODIFIED CNA SELECTIVE SUPP. 1 X 10
SR0181E	NOVOBIOCIN SUPPLEMENT
SR0189E	BURKHOLDERIA CEPACIA SELECTIVE SUPPLEM
SR0194E	SALMONELLA SELECTIVE SUPPLEMENT
SR0204E	MODIFIED PRESTON CAMPYLOBACTER SUPP
SR0205E	MODIFIED KARMALI SEL. SUPP.
SR0232E	CAMPYLOBACTER GROWTH SUPPLEMENT (LIQUID)
SR0233A	SPUTASOL (LIQUID)
SR0237C	XLT-4 SELECTIVE SUPPLEMENT
SR0047C	EGG YOLK EMULSION

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