

DECLARACIÓN CE DE CONFORMIDAD
EC DECLARATION OF CONFORMITY

Producto
Product

See Product List annex
Ver Lista de productos anexa

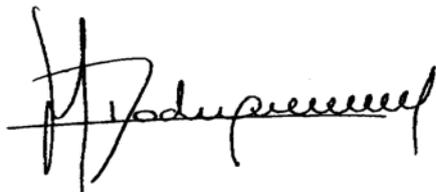
Por el presente documento LINEAR Chemicals, S.L., con domicilio social en Joaquim Costa, 18 2a planta, 08390 Montgat (Barcelona), España, declara,

Que los productos mencionados y comercializados bajo la marca Cromatest® / Linear o su equivalente en bulk, cumplen todos los requisitos esenciales (Anexos I y III) de la Directiva Europea 98/79/EC sobre productos sanitarios para diagnóstico in vitro y del RD 1662/2000, transposición española de dicha directiva.

We, LINEAR Chemicals, S.L., located in Joaquim Costa, 18 2a planta, 08390 Montgat (Barcelona), Spain, hereby certify,

That the above mentioned and commercialised products under Cromatest® / Linear brand name or its equivalent in bulk, comply with the essential requirements (Annex I and III) of the European Directive 98/79/EC related to in vitro diagnostics medical devices and the RD 1662/2000, its Spanish transposition.

Signed by,



Manuel Rodríguez
General & Technical Director

Montgat, January 09th 2009

CLINICAL CHEMISTRY / QUIMICA CLINICA

REAGENTS AND INSTRUMENTS / REACTIVOS E INSTRUMENTOS

Code	Description	
1100005	Acid Phosphatase 4x10 mL	kit
1101000	Albumin 2x50 mL	kit
1101010	Albumin 4x100 mL	kit
1102015	Alkaline Phosphatase 5x10 mL	kit
1102020	Alkaline Phosphatase 20x10 mL	kit
1103005	Alkaline Phosphatase BR 2x50 mL	kit
1103010	Alkaline Phosphatase BR 3x100 mL	kit
1105000	ALT/GPT BR opt. 2x50 mL	kit
1105010	ALT/GPT BR opt. 3x100 mL	kit
1107005	Amylase MR 5x20 mL	kit
1109000	AST/GOT BR opt. 2x50 mL	kit
1109010	AST/GOT BR opt. 3x100 mL	kit
1109030	AST/GOT BR. Opt. 12x20 mL	kit
1110005	Direct Bilirubin 2x50 mL	kit
1111010	Total Bilirubin 2x100 mL	kit
1112005	Total and Direct Bilirubin 2x100 mL	kit
1113000	Calcium Arsenazo III Color 2x50 mL	kit
1115000	Calcium OCC 2x50 mL	kit
1115010	Calcium OCC 4x100 mL	kit
1116005	Chloride 2x50 mL	kit
1118005	Cholesterol MR 2x50 mL	kit
1118010	Cholesterol MR 4x100 mL	kit
1118015	Cholesterol MR 4x250 mL	kit
1119005	Cholinesterase (Total and Inhibited) 30 Tests	kit
1120005	Creatine Kinase BR 2x50 mL	kit
1120010	Creatine Kinase BR 1x25 mL	kit
1121005	Creatine Kinase-MB 1x25 mL	kit
1123005	Creatinine 2x50 mL	kit
1123010	Creatinine 4x100 mL	kit
1123020	Creatinine 4x250 mL	kit
1126005	GGT BR opt. 2x50 mL	kit
1126010	GGT BR 3x100 mL	kit
1129005	Glucose MR 2x50 mL	kit
1129010	Glucose MR 4x100 mL	kit
1129015	Glucose MR 4x250 mL	kit
1129020	Glucose MR 5x50 mL	kit
1130010	GOT Color 2x100 mL	kit
1132010	GPT Color 2x100 mL	kit
1133010	HDL-Cholesterol 2x40 mL	kit
1133105	LDL-Cholesterol 1x5 mL	kit
1133505	HDL-Cholesterol Direct 40 mL	kit
1133510	HDL-Cholesterol Direct 320 mL	kit
1133515	HDL-Cholesterol Direct 1000 mL	kit
1134015	Hemoglobin 2x5 mL	kit
1135005	Iron Ferrozine 2x50 mL	kit
1135105	Iron Cromazurol	kit
1137010	TIBC 50 Tests	kit
1141010	LDH BR 2x50 mL	kit
1142005	LDL-Cholesterol Direct 40 mL	kit
1142010	LDL-Cholesterol Direct 320 mL	kit
1144005	Magnesium 2x50 mL	kit
1148010	Phosphorus 3x50 mL	kit
1149005	Phosphorus UV 2x50 mL	kit
1149010	Phosphorus UV 4x100 mL	kit
1150010	Potassium 3x50 mL	kit
1151010	Sodium 2x60 mL	kit



1153005	Total Protein 2x50 mL	kit
1153010	Total Protein 4x100 mL	kit
1153020	Total Protein 4x250 mL	kit
1155005	Triglycerides MR 2x50 mL	kit
1155010	Triglycerides MR 4x100 mL	kit
1156010	Urea Berthelot 2x50 mL	kit
1156015	Urea Berthelot 4x100 mL	kit
1158005	Urea/BUN BR 2x50 mL	kit
1158010	Urea/BUN BR 3x100 mL	kit
1161005	Uric Acid MR 2x50 mL	kit
1161010	Uric Acid MR 4x100 mL	Kit
1161015	Uric Acid MR 4x250 mL	kit
1162005	Protein (Urine and CSF) 2x50 mL	kit
1180005	iso-Clean 4x100 mL	kit
1803050	HERA Semi-automatic Clinical Analyzer	uni.
1805000	LIDA-300 Automatic Clinical Analyzer	uni.
1805200	LIDA-200 Automatic Clinical Analyzer	uni.
1805120	LIDA-120 Automatic Clinical Analyzer	uni.
1901005	Albumin Standard 5g/dL 3 mL	kit
1912005	Bilirubin Standard 1 mL	Kit
1913005	Calcium Standard 10mg/dL 3 mL	Kit
1916005	Chloride Standard 125 mEq/L 3 mL	Kit
1918005	Cholesterol Standard 200 mg/dL 3 mL	Kit
1923005	Creatinine Standard 2 mg/dL 3 mL	Kit
1929005	Glucose Standard 100 mg/dL 3 mL	Kit
1933005	HDL-Cholesterol Standard 50mg/dL 3 mL	kit
1933105	LDL-Cholesterol Standard 50 mg/dL 3 mL	kit
1934005	Hemoglobin Standard 12g/dL 1 mL	kit
1938005	Iron Standard 100 mcg/dL 3 mL	Kit
1944005	Magnesium Standard 2 mg/dL 3 mL	Kit
1949005	Phosphorus Standard 5 mg/dL 3 mL	Kit
1953005	Total Protein Standard 7g/dL 3 mL	Kit
1955005	Triglycerides Standard 200 mg/dL 3 mL	kit
1958005	Urea Standard 50 mg/dL 3 mL	Kit
1961005	Uric acid Standard 6mg/dL 3 mL	kit
1962005	Urine CSF-Protein Standard 2g/L 3 mL	Kit
1972005	LDL/HDL-Cholesterol Calibrator 1 mL	Kit
1975005	Multicalibrator CC/H 5x5 mL	kit
1980005	Human Multisera normal 5x5 mL	kit
1985005	Human Multisera abnormal 5x5 mL	kit
1980105	Human Multisera normal Control de Calidad externo 5x5 mL	kit
1985105	Human Multisera abnormal Control de Calidad externo 5x5 mL	kit

RAPID TEST / PRUEBAS RAPIDAS

AGGLUTINATION TESTS / ENSAYOS DE AGLUTINACIÓN

2100005	Brucella abortus 5 mL	kit
2104005	Brucella melitensis 5 mL	kit
2106005	Brucella suis 5 mL	kit
2107005	Proteus OX19 5 mL	kit
2109005	Proteus OX2 5 mL	kit
2111005	Proteus OXK 5 mL	kit
2113005	S. paratyphi A-H 5 mL	kit
2117005	S. paratyphi A-O 5 mL	kit
2119005	S. paratyphi B-H 5 mL	kit
2123005	S. paratyphi B-O 5 mL	kit
2125005	S. paratyphi C-H 5 mL	kit
2127005	S. paratyphi C-O 5 mL	kit
2135005	S. typhi H 5 mL	Kit
2139005	S. typhi O 5 mL	kit
2199300	Febrile Antigens 8 Vials x 5 mL	kit
2199435	Febrile Antigens 6 Vials x 5 mL	kit
2199500	Febrile Antigens 8 Vials	kit
2199510	Febrile Antigens 8 Vials	kit
2210005	Rose Bengal 100 Tests	kit
2340005	ASLO-Latex 50 Tests	kit
2340010	ASLO-Latex 100 Tests	kit
2340025	ASLO-Latex (Antigen) 150 Tests	kit
2355005	RF-Latex 50 Tests	Kit
2355010	RF-Latex 100 Tests	Kit
2355025	RF-Latex (Antigen) 150 Tests	Kit
2375005	RF-Waaler 50 Tests	Kit
2375010	RF-Waaler 100 Tests	Kit
2410005	CRP-Latex 50 Tests	Kit
2410010	CRP-Latex 100 Tests	Kit
2410025	CRP-Latex (Antigen) 150 Tests	Kit
2510010	RPR-Carbon 100 Tests	kit
2510025	RPR-Carbon 500 Tests	kit
2520005	TPHA 200 Tests	kit
2540005	VDRL MR (Antigen) 250 tests	kit
2540010	VDRL MR (controls included) 250 Tests	kit
2610005	hCG-Latex 50 Tests	kit
2610015	hCG-Latex 100 Tests	kit
2720005	IM-Latex 50 Tests	Kit
2921105	Salmonella Positive control 1 mL	kit
2921205	Brucella Positive control 1 mL	kit
2921305	Proteus Positive control 1 mL	kit
2929910	Aglutinin Control Negativo 1 mL	kit

IMMUNOLOGY / INMUNOLOGIA

TURBIDIMETRY / TURBIDIMETRIA

3110025	ASLO-Turbidimetric 1x50 mL	kit
3110030	ASLO-Turbidimetric 2x50 mL	kit
3110035	ASLO-Turbidimetric 2x200 mL	kit
3120025	CRP-Turbidimetric 1x50 mL	kit
3120030	CRP-Turbidimetric 2x50 mL	kit
3120035	CRP-Turbidimetric 2x200 mL	kit
3125005	us-CRP-Turbidimetric 1x50 mL	kit
3130025	RF-Turbidimetric 1x50 mL	kit
3130030	RF-Turbidimetric 2x50 mL	kit
3130035	RF-Turbidimetric 2x200 mL	kit
3140005	Ferritin-Turbidimetric 1x50mL	kit
3140010	Ferritin-Turbidimetric 2x50mL	kit
3150005	Microalbumin-Turbidimetric 1x50mL	kit
3100025	i-FOB-Turbidimetric 1x50 mL	kit
3100030	i-FOB-Turbidimetric 2x50 mL	kit
3169010	a1 Ac. Glycoprotein at 1x50 mL	kit
3162510	IgA at 1x50 mL	kit
3165010	IgG at 1x50 mL	kit
3167510	IgM at 1x50 mL	kit
3168010	Transferrin at 1x50 mL	kit
3170005	C3 at 1x50 mL	kit
3171005	C4 at 1x50 mL	kit
3910005	Plasma Protein Multicalibrator 1x2 mL	kit
3915010	Plasmatic Protein Control (N-I) 1x2 mL	kit
3915015	Plasmatic Protein Control (N-II) 1x2mL	kit
3925005	us-CRP-Turbidimetric Calibrator 1x2mL	kit
3925010	us-CRP-Turbidimetric Control 1x2 mL	kit
3931105	ASLO Turbidimetric Calibrator 1 mL	Kit
3931205	CRP Turbidimetric Calibrator 1 mL	Kit
3931305	RF Turbidimetric Calibrator 1x2 mL	Kit
3940005	Ferritin-Turbidimetric Calibrator 1x3mL	kit
3950005	Microalbumin-Turbidimetric Calibrator 1x1 mL	kit
3950010	Microalbumin-Turbidimetric Control 1x2 mL	kit
3900005	i-FOB Calibrator 1x2 mL	kit
3900040	i-FOB Control 2x2 mL	kit

RADIAL IMMUNODIFUSION / INMUNODIFUSIÓN RADIAL

3300305	IgA id 1x15 Tests	kit
3300405	IgM id 1x15 Tests	Kit
3300505	IgG id 1x15 Tests	kit
3300605	IgA-IgG-IgM-id 3x5 Tests	Kit
3300805	Transferrin id 1x15 Tests	Kit
3300905	Fibrinogen id 1x15 Tests	Kit
3307005	Antithrombin III id 1x15 Tests	Kit
3339005	C3 id 1x15 Tests	Kit
3340105	C4 id 1x15 Tests	Kit

COAGULATION / COAGULACIÓN

3510101	PT-HS 10x5 mL	kit
3510201	APTT (Ellagic Acid) 10x4 mL	kit
3510301	Fibrinogen 5x2 mL	kit
3510401	Calcium Chloride 0.020M 3x16 mL	kit
3520101	Plasma Control Level 1 10x1 mL	kit
3520201	Plasma Control Level 2 10x1 mL	kit
3801000	ARES Coagulation Analyzer	1 unit
3801005	ARES NE Coagulation Analyzer	1 unit

RAPID TEST / PRUEBAS RAPIDAS

ONE STEP / UN SOLO PASO

4120020	B-hCG strip 20 Tests	Kit
4120050	B-hCG strip 50 Tests	Kit
4120070	B-hCG strip 70 Tests	kit
4130020	B-hCG cassette 20 Tests	kit
4130040	B-hCG cassette 40 Tests	kit
4130050	B-hCG cassette 50 Tests	Kit
4245120	Helicobacter Pylori Ag cassette 20 Tests (1 x 25 mL Buffer)	kit
4245122	Helicobacter Pylori Ag cassette 25 Tests (20 x 1 mL Buffer)	Kit
4242550	Helicobacter Pylori Ag strip 50 Tests (50 x 1 mL Buffer)	Kit
4260220	Helicobacter Pylori Ab cassette 20 Tests	Kit
4260240	Helicobacter Pylori Ab cassette 40 Tests	Kit
4242550	Helicobacter Pylori Ab strip 50 Tests	Kit
4270220	Infectious Mononucleosis cassette 20 Tests	Kit
4270240	Infectious Mononucleosis cassette 40 Tests	Kit
4275220	Treponema pallidum cassette 20 Tests	Kit
4275240	Treponema pallidum cassette 40 Tests	Kit
4200225	Rota-Adeno virus cassette 25 Tests	Kit
4275540	Malaria cassette 40 Tests	kit
4280225	Strep-A Cassette 25 Tests	Kit
4275540	Malaria cassette 40 Tests	kit
4256040	Dengue cassette 40 Tests	kit
4325220	Faecal Occult Blood cassette 20 Tests	Kit
4325225	Faecal Occult Blood cassette 25 Tests	Kit
4410120	AMP Amphetamine strip 20 Tests	Kit
4410150	AMP Amphetamine strip 50 Tests	Kit
4410240	AMP Amphetamine cassette 40 Tests	kit
4415120	BAR Barbiturates strip 20 Tests	Kit
4415150	BAR Barbiturates strip 50 Tests	Kit
4415240	BAR Barbiturates cassette 40 Tests	kit
4420120	BZO Benzodiazepines strip 20 Tests	Kit
4420150	BZO Benzodiazepines strip 50 Tests	Kit
4420240	BZO Benzodiazepines cassette 40 Tests	kit
4430120	COC Cocaine strip 20 Tests	kit
4430150	COC Cocaine strip 50 Tests	kit
4430240	COC Cocaine cassette 40 Tests	kit
4431120	MDMA Ecstasy strip 20 Test	Kit
4431150	MDMA Ecstasy strip 50 Test	Kit
4435120	MET Methamphetamine strip 20 Tests	Kit
4435150	MET Methamphetamine strip 50 Tests	Kit
4435240	MET Methamphetamine cassette 40 Tests	Kit
4440120	MTD Methadone strip 20 Tests	Kit
4440150	MTD Methadone strip 50 Tests	Kit
4440220	MTD Methadone cassette 40 Tests	kit
4450120	MOP Morphine strip 20 Tests	Kit
4450150	MOP Morphine strip 50 Tests	Kit
4450240	MOP Morphine cassette 40 T	kit
4451120	OPI Opiate strip 20 Test	Kit
4451150	OPI Opiate strip 50 Test	Kit
4451240	OPI Opiate cassette 40 Test	Kit
4452120	PCP Phencyclidine strip 20 Test	Kit
4452150	PCP Phencyclidine strip 50 Test	Kit
4452040	PCP Phencyclidine cassette 40 T	Kit
4452220	TCA Tricyclic Antidepressant strip 20 T.	Kit
4452250	TCA Tricyclic Antidepressant strip 50 Tests	Kit
4465120	THC Marijuana strip 20 Tests	Kit
4465150	THC Marijuana strip 50 Tests	Kit
4465240	THC Marijuana cassette 40 Tests	kit
4463310	MDP Screen 12 Cassette 10x12 Test	kit
4463325	MDP Screen 12 Cassette 25x12 Test	kit
4463210	MDP Screen 12 Panel 10x12 Test	kit
4463225	MDP Screen 12 Panel 25x12 Test	kit

URINANALYSIS / URIANALISIS

REAGENTS AND INSTRUMENTS / REACTIVOS E INSTRUMENTOS

7031005	Urine Strips 3 parameters 100 Tests	kit
7101005	Urine Strips 10 parameters 100 Tests (for use in DARA)	kit
7101010	Urine Strips 10 parameters 100 Tests	kit
7810010	DARA (Urine Strip Reader)	unit

ESR / VSG

TUBS-INSTRUMENTS-CONTROLS / TUBOS-INSTRUMENTS-CONTROLES

5211000	Plus-Sed (Tubes Westergren) 6x100	Box
5215000	Plus-Sed micro (Tubes Westergren) 6x100	Box
5220060	Plus-Sed auto 6x100	Box
5231050	Vacused for Linear (vacuum plastic) 5x100	Box
5310010	Visualsed ESR Rack 10 Posiciones	unit
5810005	IRIA (ESR Instrument 5 positions)	unit
5810030	IRIA NE (ESR Instrument)	unit
5810010	Lena (ESR Instrument 16 positions)	unit
5810035	Lena NE (ESR Instrument 20 positions)	unit
5810020	Eriline AR (ESR Instrument 60 positions)	unit
5810025	THERMA NE (ESR Instrument 100 positions)	unit
5910005	ESR control 2 x 10 mL	kit
5920005	QC1: ESR 2 x 2 mL	kit
5930005	QC2: ESR 2 x 2 mL	kit
5310005	Erix Orbital sampler mixer	Un.
5310015	Linear thermal printer for Lena/Iria	un.
5310020	Code Bar reader	Un.
5320005	Eriline printer paper 12x1 Rollos	Un.
5320010	Lena/Iria thermal Printer Paper	un.

ELISAS

REAGENTS AND INSTRUMENTS / REACTIVOS E INSTRUMENTOS

6107205	T3 96 Tests	kit
6107210	Free T3 96 Tests	kit
6107215	T4 96 Tests	kit
6107220	Free T4 96 Tests	kit
6107225	TSH 96 Tests	kit
6107230	U-TSH 96 Tests	kit
6107305	Prolactin 96 Tests	kit
6107310	hCG 96 Tests	kit
6107315	Free beta-hCG 96 Tests	kit
6107320	LH 96 Tests	kit
6107325	FSH 96 Tests	kit
6107330	Visual hCG 96 Tests	kit
6107505	HGH 96 Tests	kit
6107605	Estradiol 96 Tests	kit
6107610	Estriol 96 Tests	kit
6107615	Testosterone 96 Tests	kit
6107620	Progesterone 96 Tests	kit
6207100	Brucella IgG 96 Tests	kit
6207105	Anti-H. Pylori IgG 96 Tests	kit
6207110	Anti-H. Pylori IgM 96 Tests	kit
6207115	Anti-H. Pylori IgA 96 Tests	kit
6207130	Brucella IgM 96 Test	kit
6208035	HSV 1 IgG 96 Tests	kit
6208040	HSV 1 IgM 96 Tests	kit
6208045	HSV 2 IgG 96 Tests	kit
6208050	HSV 2 IgM 96 Tests	kit
6208055	HSV 1/2 IgM 96 Tests	kit
6407405	AFP 96 Tests	kit
6407410	CEA 96 Tests	kit
6407415	CA 15-3 96 Tests	kit
6407420	CA 19-9 96 Tests	kit
6407425	CA 125 96 Tests	kit
6407440	Troponin I 96 Tests	kit
6407445	Myoglobin 96 Tests	kit
6507505	Ferritin 96 Tests	kit
6507510	IgE 96 Tests	kit
6507515	HS CRP 96 Tests	kit
6507520	B2MG 96 Tests	kit
6802000	GEA (Microplate Reader)	unit
6802050	SAGA (Microplate Washer)	unit

LABORATORY EQUIPMENT/EQUIPAMIENTO DE LABORATORIO

SINGLE CHANNEL AJUSTABLE VOLUME PIPETTES PIPETAS DE UN SOLO CANAL VOLUMEN AJUSTABLE
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8000100	Pipette (Range / Rango 0.1-2.5 μ L)	unit
8000105	Pipette (Range / Rango 0.5-10 μ L)	unit
8000110	Pipette (Range / Rango 2-20 μ L)	unit
8000115	Pipette (Range / Rango 5-50 μ L)	unit
8000120	Pipette (Range / Rango 10-100 μ L)	unit
8000125	Pipette (Range / Rango 20-200 μ L)	unit
8000130	Pipette (Range / Rango 50-200 μ L)	unit
8000135	Pipette (Range / Rango 100-1000 μ L)	unit
8000140	Pipette (Range / Rango 200-1000 μ L)	unit
8000145	Pipette (Range / Rango 1000-5000 μ L)	unit
8000300	Pipettes Set (5-50 mL, 10-100 mL, 100-1000 mL)	3 pipettes

SINGLE CHANNEL FIXED VOLUME PIPETTES PIPETAS DE UN SOLO CANAL VOLUMEN FIJO

8000200	Pipette 5 μ L	unit
8000205	Pipette 10 μ L	unit
8000210	Pipette 20 μ L	unit
8000215	Pipette 25 μ L	unit
8000220	Pipette 50 μ L	unit
8000225	Pipette 100 μ L	unit
8000230	Pipette 200 μ L	unit
8000235	Pipette 250 μ L	unit
8000240	Pipette 500 μ L	unit
8000245	Pipette 1000 μ L	unit
8000250	Pipette 2000 μ L	unit
8000255	Pipette 5000 μ L	unit

EIGHT CHANNEL AJUSTABLE VOLUME PIPETTES PIPETAS DE OCHO CANALES VOLUMEN AJUSTABLE
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8000400	Pipette 0.5-10 μ L	unit
8000405	Pipette 5-50 μ L	unit
8000410	Pipette 50-300 μ L	unit

TWELVE CHANNEL AJUSTABLE VOLUME PIPETTES PIPETAS DE DOCE CANALES VOLUMEN AJUSTABLE

8000420	Pipette 0.5-10 μ L	unit
8000425	Pipette 5-50 μ L	unit
8000430	Pipette 50-300 μ L	unit

DISPONSABLE TIPS / PUNTAS DESECHABLES
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8000005	Tips 2-200 μ L (25x1.000 tips / box)	unit
8000010	Tips 100-1000 μ L (10x1.000 tips / box)	unit

**CLINICAL CHEMISTRY / QUIMICA CLINICA**

Code	Description	
CT10020	Albumin 2x40 mL	kit
CT10022	Albumin 6x40 mL	kit
CT10025	Albumin 10x60 mL	kit
CT10042	Alkaline Phosphatase BR 3x50 mL	kit
CT10045	Alkaline Phosphatase BR 12x50 mL	kit
CT10052	ALT/GPT BR opt. 3x50 mL	kit
CT10055	ALT/GPT BR opt. 12x50 mL	kit
CT10060	Amylase MR 2x40 mL	kit
CT10062	Amylase MR 6x40 mL	kit
CT10072	AST/GOT BR opt. 3x50 mL	kit
CT10075	AST/GOT BR opt. 12x50 mL	kit
CT10082	Direct Bilirubin 3x50 mL	kit
CT10085	Direct Bilirubin 12x50 mL	kit
CT10092	Total Bilirubin 3x50 mL	kit
CT10095	Total Bilirubin 12x50 mL	kit
CT10110	Calcium Arsenazo III Color 2x40 mL	kit
CT10112	Calcium Arsenazo III Color 6x40 mL	kit
CT10140	Cholesterol MR 2x40 mL	kit
CT10142	Cholesterol MR 6x40 mL	kit
CT10145	Cholesterol MR 10x60 mL	kit
CT10160	Creatine Kinase BR 1x50 mL	kit
CT10162	Creatine Kinase BR 3x50 mL	kit
CT10170	Creatine Kinase-MB 1x50 mL	kit
CT10172	Creatine Kinase-MB 3x50 mL	kit
CT10182	Creatinine 6x40 mL	kit
CT10185	Creatinine 16x40 mL	kit
CT10192	GGT BR opt. 3x50 mL	kit
CT10195	GGT BR opt. 12x50 mL	kit
CT10200	Glucose MR 2x40 mL	kit
CT10202	Glucose MR 6x40 mL	kit
CT10205	Glucose MR 10x60 mL	kit
CT10240	HDL-Cholesterol Direct 1x60 mL	kit
CT10242	HDL-Cholesterol Direct 3x60 mL	kit
CT10262	Iron Ferrozine 3x50 mL	kit
CT10265	Iron Ferrozine 12x50 mL	kit
CT10282	LDH BR 3x50 mL	kit
CT10290	LDL-Cholesterol Direct 1x60 mL	kit
CT10300	Magnesium 2x40 mL	kit
CT10310	Magnesium BR 2x80 mL	kit
CT10320	Phosphorus-UV 2x40 mL	kit
CT10322	Phosphorus-UV 6x40 mL	kit
CT10325	Phosphorus-UV 10x60 mL	kit
CT10350	Total Protein 2x40 mL	kit
CT10352	Total Protein 6x40 mL	kit
CT10355	Total Protein 10x60 mL	kit
CT10360	Triglycerides MR 2x40 mL	kit
CT10362	Triglycerides MR 6x40 mL	kit
CT10365	Triglycerides MR 10x60 mL	kit
CT10382	Urea/BUN BR 3x50 mL	kit
CT10385	Urea/BUN BR 12x50 mL	kit
CT10390	Uric Acid MR 2x40 mL	kit
CT10392	Uric Acid MR 6x40 mL	kit
CT10395	Uric Acid MR 10x60 mL	kit

CONTROLS AND CALIBRATORS / CONTROLES Y CALIBRADORES

CT19750	Human Multicalibrator CC/H 10x3 mL	kit
CT19800	Human Multisera Control Normal 10x5 mL	kit
CT19850	Human Multisera Control Abnormal 10x5 mL	kit

**IMMUNOLOGY / INMUNOLOGIA****TURBIDIMETRY / TURBIDIMETRIA**

CT31100	ASLO-Turbidimetric 1x50 mL	kit
CT31112	ASLO-Turbidimetric 3x50 mL	kit
CT31115	ASLO-Turbidimetric 12x50 mL	kit
CT31200	CRP-Turbidimetric 1x50 mL	kit
CT31212	CRP-Turbidimetric 3x50 mL	kit
CT31215	CRP-Turbidimetric 12x50 mL	kit
CT31300	RF-Turbidimetric 1x50 mL	kit
CT31312	RF-Turbidimetric 3x50 mL	kit
CT31315	RF-Turbidimetric 12x50 mL	kit
CT31000	i-FOB-Turbidimetric 1x50 mL	kit
CT31012	i-FOB-Turbidimetric 3x50 mL	kit
CT31350	a1 Glycoprotein 2x40 mL	kit
CT31352	a1 Glycoprotein 6x40 mL	kit
CT31400	C3 at 2x40 mL	kit
CT31402	C3 at 6x40 mL	kit
CT31500	C4 at 2x40 mL	kit
CT31502	C4 at 6x40 mL	kit
CT31600	Ferritin-Turbidimetric 1x50 mL	kit
CT31602	Ferritin-Turbidimetric 3x50 mL	kit
CT31700	IgA at 2x40 mL	kit
CT31702	IgA at 6x40 mL	kit
CT31800	IgG at 2x40 mL	kit
CT31802	IgG at 6x40 mL	kit
CT31900	IgM at 2x40 mL	kit
CT31902	IgM at 6x40 mL	kit
CT32000	Microalbumin-Turbidimetric 1x50 mL	kit
CT32002	Microalbumin-Turbidimetric 3x50 mL	kit
CT32100	Transferrin at 2x40 mL	kit
CT32105	Transferrin at 6x40 mL	kit
CT32500	usCRP-Turbidimetric 1x50 mL	kit
CT18000	iso Cleaning Solution 2x40 mL	kit
CT18002	iso Cleaning Solution 6x40 mL	kit



**EC-Declaration of Conformity
according to Annex III, EC Directive 98/79/EG**

In-vitro-diagnostic medical devices:

RIDA[®] QUICK Clostridium difficile Toxin A/B

Immunochemographic rapid assays for the qualitative detection of the toxins A and B of Clostridium difficile in stool samples and culture broth.

Product number: N0803

Manufacturer: R-Biopharm AG
An der neuen Bergstraße 17
64297 Darmstadt
Germany

Classification according to Annex II, IVDD: common class

These products are not listed in Annex II of the Council Directive 98/79/EC concerning in-vitro-diagnostic medical devices dated 27th October 1998. The products are neither products for self-diagnosis, nor products for performance evaluation.

To fulfil the requirements for CE-mark, Annex III, parts 2 – 5 of the IVDD have been applied.

We, herewith, declare that the products as well as their production fulfil the essential requirements according to Annex I, 98/79/EC concerning in-vitro-diagnostic medical devices dated 27th October 1998 (In Vitro Diagnostic Medical Devices Directive, IVDD). This technical documentation in accordance with Annex III of the Council Directive 98/79/EC allows the assessment of the conformity of the product with the above mentioned requirements.

All concerned devices produced after

2010-07-01

are placed on the market in accordance with this declaration.

The EC declaration of conformity is the procedure whereby the manufacturer or its authorized representative established in the European Community ensures and declares that the products concerned meet the provisions of the Council Directive 98/79/EC which apply to them.

Darmstadt, 2011-08-31

G. Heuschele
Head of Quality Management / Regulatory Affairs





**EC-Declaration of Conformity
according to Annex III, EC Directive 98/79/EG**

In-vitro-diagnostic medical devices:

RIDA[®] QUICK Norovirus

Immunochematographic rapid assays for the detection of norovirus in stool.

Manufacturer: R-Biopharm AG
An der neuen Bergstraße 17
64297 Darmstadt
Germany

Classification according to Annex II, IVDD: common class

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Darmstadt, 2009-04-06

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Variations: RIDA[®] QUICK Rotavirus/Adenovirus Combi Box with strips
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2003-11-24

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Darmstadt, 2009-04-06

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**EC-Declaration of Conformity
according to Annex III, EC Directive 98/79/EG**

In-vitro-diagnostic medical devices:

RIDA[®] QUICK Clostridium difficile Toxin A/B

Immunochemographic rapid assays for the qualitative detection of the toxins A and B of Clostridium difficile in stool samples and culture broth.

Product number: N0803

Manufacturer: R-Biopharm AG
An der neuen Bergstraße 17
64297 Darmstadt
Germany

Classification according to Annex II, IVDD: common class

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Darmstadt, 2009-04-06

G. Heuschele
Head of Quality Management / Regulatory Affairs

Safety Data Sheet

according to 1907/2006/EC, Article 31

Printing date 04.05.2009

Revision: 04.05.2009

1 Identification of the substance/preparation and of the company/undertaking

- **Product details**
- **Trade name:** RIDA Quick Adenovirus/Rotavirus - Kombi
- **Article number:** N1002/03
- **Application of the substance / the preparation:** In vitro Diagnostica
- **Manufacturer/Supplier:**
R-Biopharm AG
An der neuen Bergstraße 17
D-64297 Darmstadt
- **Further information obtainable from:** FE e-mail: info@r-biopharm.de
- **Information in case of emergency:** FE 0049-6161-8102-0

2 Hazards identification

- **Hazard description:** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **GHS label elements** Void

3 Composition/information on ingredients

- **Chemical characterization**
- **Description:** Mixture of substances with nonhazardous additions.

- **Dangerous components:**

cellulose nitrate

F; R 11

50-100%

Warning: 2.7/1

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

4 First-aid measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.

5 Fire-fighting measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Person-related safety precautions:** Wear protective clothing.
- **Measures for environmental protection:** No special measures required.
- **Measures for cleaning/collecting:** Pick up mechanically.

(Contd. on page 2)

GB

Safety Data Sheet

according to 1907/2006/EC, Article 31

Printing date 04.05.2009

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Trade name: RIDA Quick Adenovirus/Rotavirus - Kombi

(Contd. of page 1)

· **Additional information:** No dangerous substances are released.

7 Handling and storage

- **Handling:**
- **Information for safe handling:** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

· General Information

Form:	Solid
Colour:	White
Odour:	Characteristic

· Change in condition

Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.

· **Ignition temperature:** 180°C

(Contd. on page 3)

GB

Safety Data Sheet

according to 1907/2006/EC, Article 31

Printing date 04.05.2009

Revision: 04.05.2009

Trade name: RIDA Quick Adenovirus/Rotavirus - Kombi

(Contd. of page 2)

· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	3.5 Vol %
Upper:	15 Vol %
· Vapour pressure at 20°C:	58.7 hPa
· Density at 20°C:	1.65 g/cm ³
· Bulk density at 20°C:	0.25 kg/m ³
· Solubility in / Miscibility with water:	Insoluble.
· Solvent content:	
Organic solvents:	0.0 %
· Solids content:	100.0 %

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Acute toxicity:**

- **LD/LC50 values relevant for classification:**

26628-22-8 sodium azide

Oral LD50 27 mg/kg (rat)

Dermal LD50 20 mg/kg (rabbit)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

- **General notes:** Generally not hazardous for water

13 Disposal considerations

- **Product:**
- **Recommendation**
Autoclave or dispose as hazardous waste.
Disposal must be made according to official regulations.

(Contd. on page 4)

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Safety Data Sheet

according to 1907/2006/EC, Article 31

Printing date 04.05.2009

Revision: 04.05.2009

Trade name: RIDA Quick Adenovirus/Rotavirus - Kombi

(Contd. of page 3)

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **Land transport ADR/RID (cross-border)**
- **ADR/RID class:** -

- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No

- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

- **UN "Model Regulation":** -
- **Transport/Additional information:** Not dangerous according to the above specifications.

15 Regulatory information

- **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).
- **National regulations:**
- **Waterhazard class:** Generally not hazardous for water.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant R-phrases**
11 Highly flammable.
- **Department issuing MSDS:** QS 0049-6151-8102-0
- **Contact:** QS 0049-6151-8102-0
- **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises Dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement internationale concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
- *** Data compared to the previous version altered.**

GB

SAUGOS DUOMENŲ LAPAI

SE 301 SDS
Rev 01 05/08/04 1 / 3**1. INFORMACIJA APIE PRODUKTĄ IR KOMPANIJĄ****Prekės pavadinimas:** RPR - CARBON**Nuorodos – dydžiai:** Visos nuorodos ir dydžiai susiję.**Produkto aprašymas:** Reagentas greitam plazmos reagentų RPR nustatymui.**Gamintojas:** LINEAR CHEMICALS, S.L.

Joaquim Costa, 18 – 08390 MONTGAT (SPAIN)

Tel.: + 34 – 93 469 49 90 Fax: + 34 – 93 469 34 35

El. paštas : info@linear.es**2. SUDĖTIS/INFORMACIJA APIE SUDEDAMĄSIAS DALIS**

Informacija apie produkto pavojus ES

Komponentas	Koncentracija	R frazės	Klasifikacija
Natrio azidas	0.95 g/L	-	-

3. FIZINĖS IR CHEMINĖS SAVYBĖS

Fizinis būvis	Skystas
Spalva	Juodas
Kvapapas	Bekvapis
pH reikšmė	7.0 (± 0.1)
Virimo taškas	-
Tirpimo taškas	-
Pliūpsnio temperatūra	-
Užsiliepsnojimo temperatūra	-
Sprogimo ribos	-
Garų slėgis	-
Tankis	-
Tirpumas vandenyje	Labai tirpus
Klampa	-

4. PAVOJŲ IDENTIFIKAVIMAS

Perspėjimas: Dirbant su biologinėmis medžiagomis būtina laikytis įprastų higienos reikalavimų. Medžiaga paprastai nekenksminga nuotekoms. Būtina laikytis Geros Laboratorinės Praktikos reikalavimų.

5. PIRMOSIOS PAGALBOS PRIEMONĖS

Akių kontaktas	Nedelsiant gausiai praplauti vandeniu
Odos kontaktas	Gausiai nuplauti vandeniu
Nurijus	Reikalinga medicininė konsultacija
Įkvėpus	Kvėpavimo apsauga nereikalinga

6. PRIEŠGAISRINĖS PRIEMONĖS

Gaisro gesinimo priemonės: nėra apribojimų

SAUGOS DUOMENŲ LAPAI

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Rev 01 05/08/04 2 / 3

7. AVARIJŲ LIKVIDAVIMO PRIEMONĖS

Išpylus (atsargumo priemonės personalui):	Galima nuplauti dideliu kiekiu vandens. Naudokite pirštines ir apsauginius drabužius.
Absorbentas:	Nebūtinas. Nebūtinos priemonės žalai apriboti.

8. DARBAS IR LAIKYMAS

Darbas:	Dėvėkite gumines pirštines ir apsauginius drabužius
Laikymas:	Laikykite sandariai uždarytuose konteineriuose šaltai. Laikymo temperatūra turi būti 2 ... 8 °C.
Nelaikyti kartu su:	Be apribojimų

9. APSAUGOS KONTROLĖ/ PERSONALO APSAUGA

Kvėpavimo apsauga: Nėra
Rankų apsauga: Vienkartinės pirštines

10. STABILUMAS IR REAKTYVUMAS

Stabilumas:	Stabilus <u>24 mėnesius</u> nuo pagaminimo dienos, jei laikoma 2-8 °C temperatūroje.
Vengtinios medžiagos:	Stiprios rūgštys, stipriai besioksiduojančios medžiagos
Pavojingos reakcijos:	Tinkamai naudojant nežinomos

11. TOKSIKOLGINĖ INFORMACIJA

LD50 oralinis:	Nežinoma
LD50 dermalinis:	Nežinoma
LD50 odos:	Nežinoma
LD50 įkvėpimo:	Nežinoma
Toksikologinė informacija:	Nežinoma

12. EKOLOGINĖ INFORMACIJA

Mobilumas:	Produktas gerai maišosi su vandeniu
Patvarumas – degradacija:	Kai kurių produktų atsparumo biodegradacijai nelaukiama
Pavojaus vandeniui klasė:	Nereikšminga

13. ATLIEKŲ ŠALINIMAS

Specialios atliekų šalinimo procedūros nereikalingos, išskyrus vietinius reglamentus.

14. TRANSPORTAVIMO INFORMACIJA

Šis produktas nėra pavojingų prekių transportavimo reglamento objektas.

SAUGOS DUOMENŲ LAPAISE 301 SDS
Rev 01 05/08/04 3 / 3**15. REGULIAVIMO INFORMACIJA**

R frazės: nėra

S frazės: nėra

Pagal 88/379 EEB direktyvą nereikalingas specialus ženklimas

16. KITA INFORMACIJA

Šis produktas skirtas naudoti tik *in vitro* diagnostikai. **Skirtas specialistams.**

Reikalaujama, kad klientai užtikrintų visišką produkto tinkamumą jų tikslams.

Klientai turi prisiimti atsakomybę už tinkamą šio produkto naudojimą ir pakankamai įvertintą su tuo susijusią riziką.

Aukščiau pateikta informacija laikoma teisinga, tačiau neturi visa apimančio tikslo ir turi būti naudojama tik kaip vadovavimosi principas. *Linear Chemicals, S. L.* neatsako už žalą, padarytą dėl neteisingo aukščiau minėtų produktų naudojimo.

17. SKUBI PAGALBA

Nacionalinis Toksikologijos institutas (34-91-317 44 00)