

Anexa 1 la formularul Specificatii Tehnice Anexa 23

Lotul nr. 1 Analizator biochimic automat 100 teste sistem de tip deschis

Nr.	Denumire produs	Analizator biochimic automat 100 teste sistem de tip deschis		Specificații tehnice oferite
	Analizator biochimic automat 100 teste sistem de tip deschis	Descriere	Analizator biochimic automat 100 teste sistem de tip deschis	Analizator biochimic automat 100 teste sistem de tip deschis, model Selectra ProS (Elitech/Olanda)
		Parametru	Specificația	
		Sistem analitic	Automat, cu calculator integrat sau exterior (procesor, monitor, tastatura+mouse.	Automat, cu calculator integrat (procesor, monitor, tastatura+mouse)
		Tip de lucru	continuu	continuu
		Tip sistem	deschis	deschis
			random acces	Random acces
		Capacitatea (teste/oră)	≥ 100 (teste fotometrice, fără modulul ISE)	133 (teste fotometrice, fără modulul ISE)
		Posibilitatea efectuării analizelor urgente	da	da
		Tipul dispozitivului	staționar	staționar
		Tip probă	Ser și plasmă	Ser și plasmă
			urină	urină
			sînge integru / hemolizat	sînge integru / hemolizat
			CSF (lichid cefalo-rahidian)	CSF (lichid cefalo-rahidian)
		Tip diluare	automat	automat
		Sistem de spălare	TOTAL Automat (cuvă, ac, sistem de dozare)	TOTAL Automat (cuvă, ac, sistem de dozare)
		Program control al calității	da	da
		Compartiment reactivi cu racire	da	da
		Rotor cu răcire pentru mentinerea probelor	cu termostat la 37 grade C	cu termostat la 37 grade C
		Rotor cu încălzire pentru probe cu termostat la 37 grade C	da	da
		Cuva pentru probe reutilizabil, (indicati ciclurile posibile de reutilizare)	da	Cuva pentru probe reutilizabil - 10 000 cicluri.

		Regimuri de masurare	Cinetic	da	da
			mono și bi-cromatic	da	da
			imunoturbidimetrc (Turbidity)	da	da
			Cantrolul cantitatii de reagent ramas	da	da
		Semnalizare	Lipsa reagent si proba	da	da
		Sistem de dozare	Reagenti: utilizarea a minim 2 metodici	Metodici: mono si bireagent	da
			Volumul reagentului programabil cu pasul de 1 µl.	da	da
			Cu sensor de obstacole	da	da
		Alimentarea		220 V, 50 Hz	220 V, 50 Hz
		Reactive biochimice pentru analizatorul biochimic automat cu system deschis		2500 buc	Reactive biochimice pentru analizatorul biochimic automat cu system deschis 2500 buc. inclusi in costul analizatorului.



Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra ProS - Periodic Maintenance and Configuration

02/04/2022

Issued date

A handwritten signature in black ink, appearing to read 'M. Verdaasdonk'.

Maurice Verdaasdonk
Vice President Clinical Systems

A logo icon for ELITechGroup, consisting of three overlapping hexagons in green, blue, and grey.

ELITechGroup
EMPOWERING IVD



Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra ProS - Introduction and Overview

17/03/2022

Issued date

A handwritten signature in black ink, appearing to read 'M. Verdaasdonk'.

Maurice Verdaasdonk
Vice President Clinical Systems

A logo icon for ELITechGroup, consisting of three green hexagons of varying sizes arranged in a triangular pattern.

ELITechGroup
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Clinical Systems

CLINICAL CHEMISTRY REAGENTS CATALOGUE



Clinical Chemistry Reagents

ELITechGroup is an established global manufacturer and distributor, with over 30 years of expertise in clinical laboratory instrumentation and reagents for In-Vitro Diagnostic (IVD) applications. ELITechGroup features a full range of clinical chemistry assays, benchmarked to industry standards, and available in dedicated system packs or generic format. ELITechGroup is committed to ongoing product development to expand the menu offering for all ELITechGroup systems.

Selectra Solutions

The Selectra Family of bench top systems provide an efficient and cost effective solution for small to mid-sized laboratories. Selectra Pro and Selectra Mach®5 systems, combined with the Selectra reagents, calibrators and controls will deliver results that the laboratory can trust.



Selectra reagents

The Selectra reagent line, consisting of liquid stable ready-to-use reagents, calibrators, controls and consumables are an integral part of the Selectra Pro & Mach5 systems. The reagent line forms the foundation of consistent, accurate and reliable results and, through an ongoing commitment to product development, test menu continues to broaden.

◆ RELIABILITY

Ready-to-use, liquid stable, barcoded reagents to minimize errors

◆ CONSISTENCY

Reproducible performance across the Selectra Family

◆ QUALITY

European design and manufacture (CE Marked)

Quality matters

The system pack reagents are based on proven methodologies, referenced and traceable to industry standards for assured quality and laboratory peace of mind. ELITechGroup Clinical Systems maintains a quality management system certified according to ISO 13485:2016.

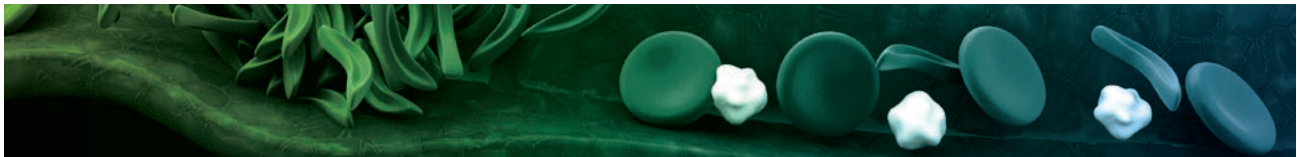
Reagents, calibrators, controls and solutions are CE-marked, and compliance with European In Vitro Diagnostic Medical Device Regulations (IVDR) is pending

Complete System

ELITechGroup recommends ELITech Calibrator and Controls be used with ELITechGroup reagents. Refer to each Item for recommended Calibrator and /or Control. If no specific Calibrator and/or Control is listed for a specific item, ELICAL (Calibration); and ELITROL I and ELITROL II (Controls) are recommended.

► Mach series
Mach5

Anaemia



Reference	Method	Reagent 1	Reagent 2	Tests / Kit
FEFE-M230	FERENE	2 x 26 mL	2 x 8 mL	372

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IFRT-0230	LATEX IMMUNO-TURBIDIMETRY Needs Calibrator IFRT-0042	2 x 20 mL	2 x 5 mL	200

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
TIBC-M130	DIRECT- CHROMAZUROL B	1 x 26 mL	1 x 9 mL	177

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
TRF2-M230	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043 and control CONT-0060	2 x 26 mL	2 x 7 mL	372

Cardiac



Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CHSL-M690	CHOD - PAP	6 x 90 mL	-	3,126

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CKSL-M230	IFCC	2 x 26 mL	2 x 8 mL	372

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CMSL-0230	IMMUNO-INHIBITION- IFCC Needs Control CKMB-0900	4 x 20 mL	1 x 20 mL	666

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CHDL-M330	SELECTIVE DETERGENT Needs Calibrator HLCA-0041	3 x 22 mL	1 x 24 mL	468

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CLDL-M330	SELECTIVE DETERGENT Needs Calibrator HLCA-0041	3 x 22 mL	1 x 24 mL	468

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
TGML-M690	GPO - PAP	6 x 90 mL	-	3,126

Diabetes

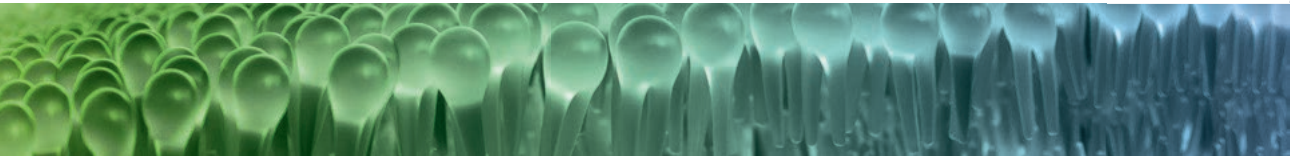


Reference	Method	Reagent 1	Reagent 2	Tests / Kit
GHSL-M490	HEXOKINASE	4 x 89 mL	4 x 26 mL	2,068
GPSL-M690	GLUCOSE OXIDASE - PAP	6 x 90 mL	-	3,126

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
HBAE-M130	ENZYMATIC Needs Calibrator HBAE-0043 and Control HBAC-0049	1 x 26 mL	1 x 13 mL	217
		Reagent 3		
		2 x 53 mL		-

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IMAL-M230	IMMUNO-TURBIDIMETRY Needs Calibrator IMAL-0043 and Controls IMAL-0046 and IMAL-0047	2 x 25 mL	1 x 12 mL	356

General Chemistry



ALBUMIN

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ALBU-M830	BROMOCRESOL GREEN (BCG)	8 x 25 mL	-	792

ALKALINE PHOSPHATASE (ALP)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ALPI-0230	IFCC	8 x 8 mL	4 x 4 mL	380

ALANINE AMINOTRANSFERASE (ALT/GPT)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ALSL-M490	IFCC	4 x 85 mL	4 x 26 mL	2,460

AMYLASE

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
AMSL-M430	CNPG3 Direct/IFCC TRACEABILITY	4 x 25 mL	-	740

ASPARTATE AMINOTRANSFERASE (AST/GOT)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ASSL-M490	IFCC	4 x 85 mL	4 x 26 mL	2,460

URIC ACID

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
AUML-M830	URICASE - PAP	8 x 25 mL	-	1,424

BILIRUBIN DIRECT

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
BIDI-M430	DIAZOTIZED SULPHANILIC ACID	4 x 26 mL	4 x 8 mL	744

BILIRUBIN TOTAL

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
BITO-M430	DIAZO REACTION/SURFACTANT ACCELERATOR	4 x 26 mL	4 x 8 mL	744

CALCIUM

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CALA-M430	ARSENAZO III	4 x 25 mL	-	712

CHOLINESTERASE

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CHEB-0250	DGKC/BUTYRYLTHIOCHOLINE METHOD	2 x 8 mL	1 x 5 mL	118

CREATININE

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CRSL-M490	ENZYMATIC - PAP	4x 69 mL	4 x 26 mL	1,968

GAMMA-GLUTAMYLTRANSFERASE (GAMMA-GT)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
GISL-M230	IFCC-GLUPA-C	4 x 26 mL	4 x 8 mL	372

LACTATE DEHYDROGENASE (LDH)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
LLSL-M230	IFCC LACTATE TO PYRUVATE	2 x 26 mL	2 x 8 mL	372

LIPASE

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
LPSL-0250	COLORIMETRIC, DGGM	2 x 8 mL	2 x 6 mL	98

MAGNESIUM

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
MGXB-M430	XYLIDYL BLUE	4 x 23 mL	-	392

PHOSPHORUS

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
PHOS-M430	PHOSPHOMOLYBDATE	4 x 25 mL	-	444

PROTEIN TOTAL (SERUM)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
PROB-M830	BIURET	8 x 25 mL	-	1,184

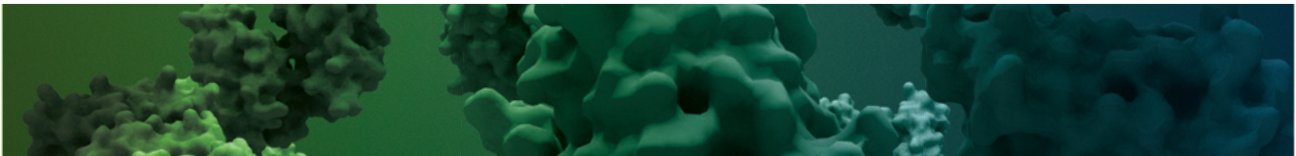
PROTEIN TOTAL (URINE)

Reference	Method	Reagent 1	Standard	Tests / Kit
PRTU-M230	PYROGALLOL RED Standard included	2 x 26 mL	1 x 2 mL	356

UREA

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
URSL-M830	UREASE - GLDH	8 x 25 mL	8 x 8 mL	1,480

Specific Proteins & Special Chemistry



ANTI-STREPTOLYSIN O

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ASLO-0250	LATEX - IMMUNO-TURBIDIMETRY Calibrator included (1x 1mL) Needs Controls IRCT-0046 and IRCT-0047	2 x 25 mL	1 x 6 mL	220

CRP

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ICRP-M230	IMMUNO-TURBIDIMETRY Needs Calibrator ICRP-0043 and IRCT-0046 and 0047	2 x 26 mL	1 x 9 mL	372

HAPTOGLOBIN

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IHAP-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	148

IGA

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IIGA-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	129

IGG

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IIGG-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	114

IGM

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IIGM-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	160

ALPHA-1-ACID GLYCOPROTEIN / OROSOMUCOID

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IORO-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	148

PREALBUMIN

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IPAL-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	144

RHEUMATOID FACTOR

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
RHFA-M130	IMMUNO-TURBIDIMETRY Needs Controls IRCT-0046 and IRCT-0047	1 x 26 mL	1 x 7 mL	185

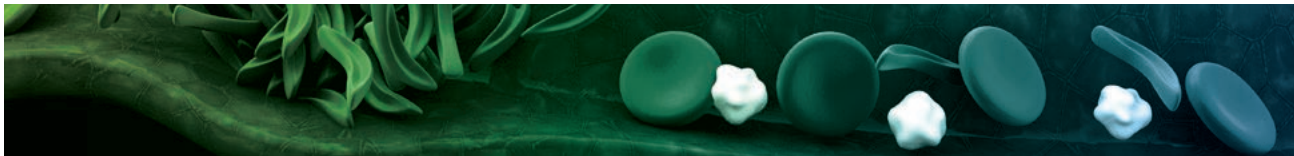
VITAMIN D

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
VITD-0250	LATEX - IMMUNO-TURBIDIMETRY Needs Calibrator VITD-0043 and Control VITD-0049	2 x 21 mL	2 x 5 mL	248



► PRO series
XS, S, M & XL

Anaemia



IRON

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
FEFE-0230	FERENE	4 x 14.6 mL	4 x 3.9 mL	200

FERRITIN

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IFRT-0230	LATEX IMMUNO-TURBIDIMETRY Needs Calibrator IFRT-0042	2 x 20 mL	2 x 5 mL	176

TIBC

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
TIBC-0250	DIRECT- CHROMAZUROL B	2 x 25 mL	2 x 7 mL	194

TRANSFERRIN

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ITRF-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	5 x 25 mL	1 x 5 mL	400

Cardiac



CHOLESTEROL

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CHSL-0250	CHOD-PAP	12 x 20 mL	-	684

CREATINE KINASE (CK NAC)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CKSL-0230	IFCC	4 x 20 mL	4 x 5 mL	320

CREATINE KINASE-MB (CK-MB)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CMSL-0230	IMMUNO-INHIBITION-IFCC	4 x 20 mL	1 x 20 mL	320

CHOLESTEROL HDL

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CHDL-0250	SELECTIVE DETERGENT Needs Calibrator HLCA-0041	4 x 21 mL	2 x 14 mL	316

CHOLESTEROL LDL

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CLDL-0250	SELECTIVE DETERGENT Needs Calibrator HLCA-0041	4 x 21 mL	2 x 14 mL	316

TRIGLYCERIDES

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
TGML-0250	GPO-PAP	12 x 20 mL	-	684

Diabetes



GLUCOSE

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
GHSL-0250	HEXOKINASE	8 x 20 mL	8 x 5 mL	456
GPSL-0250	GLUCOSE OXIDASE-PAP	12 x 20 mL	-	684

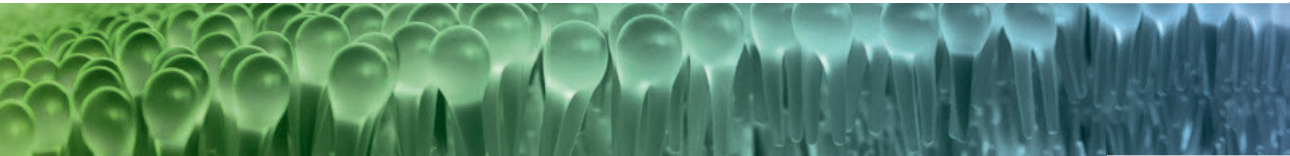
HEMOGLOBIN A1C (HbA1c)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
HBAC-0240	LATEX- IMMUNO-TURBIDIMETRY Needs Calibrator HBAC-0043	1 x 24 mL	1 x 7.6 mL	89
		Reagent 3	Reagent 4	
		1 x 0.4 mL	4 x 25 mL	-

MICROALBUMIN (URINE)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IMAL-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IMAL-0043 and Controls IMAL-0046 and IMAL-0047	2 x 25 mL	1 x 5 mL	100

General Chemistry



ALBUMIN

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ALBU-0250	BROMOCRESOL GREEN (BCG)	12 x 20 mL	-	576

ALKALINE PHOSPHATASE (ALP)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ALPI-0230	IFCC	8 x 8.8 mL	4 x 4.8 mL	328
PASL-0230	DGKC/SCE DEA BUFFER	4 x 20 mL	4 x 5 mL	320

ALANINE AMINOTRANSFERASE (ALT/GPT)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ALSL-0250	IFCC	8 x 20 mL	8 x 5 mL	528

AMYLASE

Reference	Method	Reagent 1		Tests / Kit
AMSL-0230	CNPG3 Direct/IFCC TRACEABILITY	6 x 20 mL	-	342

ASPARTATE AMINOTRANSFERASE (AST/GOT)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ASSL-0250	IFCC	8 x 20 mL	8 x 5 mL	528

URIC ACID

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
AUSL-0250	URICASE-PAP-DUAL REAGENT	8 x 20 mL	8 x 5 mL	512
AUML-0250	URICASE-PAP	12 x 20 mL	-	816

BILIRUBIN DIRECT

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
BIDI-0250	DIAZOTIZED SULPHANILIC ACID	8 x 20 mL	8 x 5 mL	528

BILIRUBIN TOTAL

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
BITO-0250	DIAZO REACTION/SURFACTANT ACCELERATOR	8 x 20 mL	8 x 5 mL	528

CALCIUM

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CALA-0250	ARSENAZO III	12 x 20 mL	-	684

CHOLINESTERASE

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CHEB-0250	DGKC / BUTYRYLTHIOCHOLINE METHOD	1 x 8 mL	1 x 5 mL	68

CREATININE

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
CRSL-0250	ENZYMATIC-PAP	8 x 21 mL	8 x 7 mL	664

GAMMA-GLUTAMYLTRANSFERASE (GAMMA-GT)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
GISL-0250	IFCC-GLUPA-C	8 x 20 mL	8 x 5 mL	576

LACTATE DEHYDROGENASE (LDH)

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
LLSL-0230	IFCC (LACTATE to PYRUVATE)	4 x 20 mL	4 x 5 mL	320

LIPASE

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
LPSL-0250	COLOURIMETRIC DGGM SUBSTRATE	2 x 8 mL	2 x 6 mL	98

MAGNESIUM

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
MGXB-0250	XYLIDYL BLUE	6 x 24 mL	-	420

PHOSPHORUS

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
PHOS-0230	PHOSPHOMOLYBDATE -UV	6 x 20 mL	-	342

TOTAL PROTEIN

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
PROB-0250	BIURET	12 x 20 mL	-	684

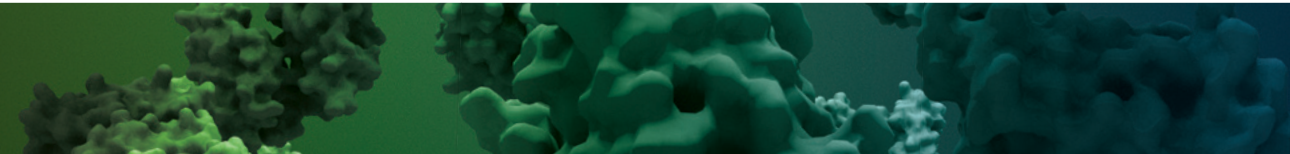
TOTAL PROTEIN-URINE

Reference		Reagent 1	Reagent 2	Standard
PRTU-0600	PHOSPHOMOLYBDATE-UV Standard included	2 x 125 mL		1 x 5 mL

UREA

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
URSL-0250	UREASE-GLDH	8 x 20 mL	8 x 5 mL	528

Specific Proteins & Special Chemistry



ANTI-STREPTOLYSIN O

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ASLO-0250	LATEX-IMMUNO-TURBIDIMETRY calibrator included (1 x 1 mL) Needs Controls IRCT-0046 and IRCT-0047	2 x 25 mL	1 x 6 mL	212

CRP

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
ICRP-0400	IMMUNO-TURBIDIMETRY Needs Calibrator ICRP-0043 and Controls ICRP-0046 and ICRP-0047	2 x 25 mL	1 x 5 mL	160

HAPTOGLOBIN

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IHAP-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	100

IGA

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IIGA-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	80

IGG

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IIGA-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	160

IGM

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IIGM-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	100

ALPHA-1-ACID GLYCOPROTEIN / OROSOMUCOID

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IORO-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	100

PREALBUMIN

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IPAL-0400	IMMUNO-TURBIDIMETRY Needs Calibrator IPRO-0043	2 x 25 mL	1 x 5 mL	194

RHEUMATOID FACTOR

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
IRFA-0230	IMMUNO-TURBIDIMETRY Calibrator IRFA-0042 and Controls IRCT-0046 and IRCT-0047	2 x 20 mL	2 x 5 mL	144

VITAMIN D

Reference	Method	Reagent 1	Reagent 2	Tests / Kit
VITD-0250	LATEX-IMMUNO-TURBIDIMETRY Needs Calibrator VITD-0043 and Control VITD-0049	2 x 21 mL	2 x 5 mL	202

Ion Selective Electrode Consumables

ISE CALIBRATORS

Reference	Description	Configuration		
ISCA-0250	CAL L	6 x 20 mL	6 x 20 mL	
	CAL H	6 x 20 mL		

ISE CONTROL

Reference	Description	Configuration		
ISCT-0046	ISE CONTROL I	10 x 5 mL		
ISCT-0047	ISE CONTROL II	10 x 5 mL		

ISE CONSUMABLES

Reference	Description	Configuration		
ISRS-0800	ISE REFERENCE SOLUTION	1 x 500 mL	-	
ISDI-0250	ISE DILUENT	12 x 25 mL	-	
ISCC-0280	ISE CLEANER/CONDITIONER	6 x 8 mL	3 x 25 mL	

► System Solutions & Consumables

System Solutions



Reference	Description	Configuration		
SLHC-5900	ACID SOLUTION	1 x 1 L		
SLSY-5905	SYSTEM SOLUTION	1 x 1 L		

Reagent Containers

PRO SERIES

Reference	Description	Configuration		
CVTL-1010	ECS VIALS / CAPS 10 mL	1x 10 units		
CVTL-2530	ECS VIALS / CAPS 25 mL	1x 30 units		
CVTL-5010	ECS VIALS / CAPS 50 mL	1x 10 units		

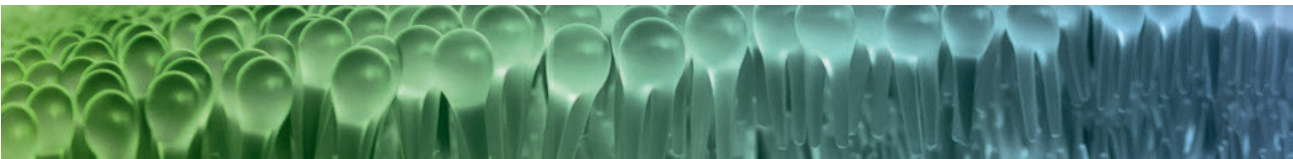
MACH SERIES

Reference	Description	Configuration		
CMAC-1084	ECS LARGE WEDGE/CAP	4 UNITS / pack		
CMAC-3010	ECS SMALL WEDGE/CAP	10 UNITS / pack		



General Clinical Chemistry Reagents

General Chemistry



ALBUMIN

Reference	Method	Reagent 1	Reagent 2	Standard
ALBU-0600	BROMOCRESOL GREEN (BCG) Standard included	2 x 125 mL	-	1 x 2 mL

ALKALINE PHOSPHATASE (ALP)

Reference	Method	Reagent 1	Reagent 2	Standard
PASL-0400	DGKC/SCE DEA BUFFER	2 x 50 mL	1 x 26 mL	-
PASL-0420	DGKC/SCE DEA BUFFER	4 x 50 mL	2 x 26 mL	-

ALANINE AMINOTRANSFERASE (ALT/GPT)

Reference	Method	Reagent 1	Reagent 2	Standard
ALSL-0410	IFCC	2 x 50 mL	1 x 26 mL	-
ALSL-0430	IFCC	4 x 50 mL	2 x 26 mL	-
ALSL-0510	IFCC	5 x 100 mL	1 x 127 mL	-

AMYLASE

Reference	Method	Reagent 1	Reagent 2	Standard
AMSL-0390	CNPG3 DIRECT/IFCC TRACEABILITY	1 x 50 mL	-	-
AMSL-0400	CNPG3 DIRECT/IFCC TRACEABILITY	6 x 50 mL	-	-

ASPARTATE AMINOTRANSFERASE (AST/GOT)

Reference	Method	Reagent 1	Reagent 2	Standard
ASSL-0410	IFCC	2 x 50 mL	1 x 26 mL	-
ASSL-0430	IFCC	4 x 50 mL	2 x 26 mL	-
ASSL-0510	IFCC	5 x 100 mL	1 x 127 mL	-

BILIRUBIN DIRECT

Reference	Method	Reagent 1	Reagent 2	Standard
BIDI-0600	DIAZOTIZED SULPHANILIC ACID	2 x 100 mL	1 x 50 mL	-

BILIRUBIN TOTAL

Reference	Method	Reagent 1	Reagent 2	Standard
BITO-0600	DIAZO REACTION/SURFACTANT ACCELERATOR	2 x 100 mL	1 x 50 mL	-

CALCIUM

Reference	Method	Reagent 1	Reagent 2	Standard
CALA-0600	ARSENAZO III Standard included	2 x 125 mL	-	1 x 5 mL

CHOLESTEROL HDL

Reference	Method	Reagent 1	Reagent 2	Standard
CHDL-0600	SELECTIVE DETERGENT	2 x 90 mL	1 x 60 mL	

CHOLESTEROL

Reference	Method	Reagent 1	Reagent 2	Standard
CHSL-0507	CHOD-PAP Standard included	6 x 100 mL	-	1 x 5 mL
CHSL-0707	CHOD-PAP Standard included	4 x 250 mL	-	1 x 5 mL

CREATINE KINASE (CK NAC)

Reference	Method	Reagent 1	Reagent 2	Standard
CKSL-0410	IFCC	2 x 50 mL	1 x 26 mL	
CKSL-0430	IFCC	4 x 50 mL	2 x 26 mL	

CREATINE KINASE-MB (CK-MB)

Reference	Method	Reagent 1	Reagent 2	Standard
CMSL-0410	IMMUNOINHIBITION-IFCC	2 x 50 mL	1 x 26 mL	-

CREATININE

Reference	Method	Reagent 1	Reagent 2	Standard
CRCO-0600	KINETIC JAFFE Standard included	1 x 125 mL	1 x 125 mL	1 x 5 mL
CRSL-0630	ENZYMATIC-PAP	2 x 100 mL	1 x 70 mL	-

GAMMA-GLUTAMYLTRANSFERASE (GAMMA-GT)

Reference	Method	Reagent 1	Reagent 2	Standard
GISL-0400	IFCC-GLUPA-C	2 x 50 mL	1 x 26 mL	-
GISL-0420	IFCC-GLUPA-C	4 x 50 mL	2 x 26 mL	-

GLUCOSE

Reference	Method	Reagent 1	Reagent 2	Standard
GPSL-0507	GLUCOSE OXIDASE Standard included	6 x 100 mL	-	1 x 5 mL
GPSL-0707	GLUCOSE OXIDASE Standard included	4 x 250 mL	-	1 x 5 mL

IRON

Reference	Method	Reagent 1	Reagent 2	Standard
FEFE-0600	FERENE Standard included	2 x 100 mL	1 x 50 mL	1 x 5 mL

General Chemistry (Cont'd)

LACTATE DEHYDROGENASE (LDH)

Reference	Method	Reagent 1	Reagent 2	Standard
LLSL-0400	IFCC (LACTATE TO PYRUVATE)	2 x 50 mL	1 x 26 mL	-
LLSL-0420	IFCC (LACTATE TO PYRUVATE)	4 x 50 mL	2 x 26 mL	-

MAGNESIUM

Reference	Method	Reagent 1	Reagent 2	Standard
MGXB-0600	XYLIDYL BLUE Standard included	2 x 100 mL	-	1 x 5 mL

TOTAL PROTEIN (URINE)

Reference	Method	Reagent 1	Reagent 2	Standard
PRTU-0600	PYROGALLOL RED Standard included	2 x 125 mL	-	1 x 2 mL

PHOSPHORUS

Reference	Method	Reagent 1	Reagent 2	Standard
PHOS-0600	PHOSPHOMOLYBDATE-UV Standard included	2 x 125 mL	-	1 x 5 mL

TOTAL PROTEIN (SERUM)

Reference	Method	Reagent 1	Reagent 2	Standard
PROB-0600	BIURET Standard included	2 x 125 mL	-	1 x 5 mL

TRIGLYCERIDES

Reference	Method	Reagent 1	Reagent 2	Standard
TGML-0427	GPO-PAP Standard included	6 x 50 mL	-	1 x 5 mL
TGML-0517	GPO-PAP Standard included	6 x 100 mL	-	1 x 5 mL
TGML-0707	GPO-PAP Standard included	4 x 250 mL	-	1 x 5 mL

UREA

Reference	Method	Reagent 1	Reagent 2	Standard
URSL-0427	UREASE/GLDH Standard included	4 x 50 mL	2 x 26 mL	1 x 5 mL
URSL-0507	UREASE/GLDH Standard included	5 x 100 mL	1 x 127 mL	1 x 5 mL

URIC ACID

Reference	Method	Reagent 1	Reagent 2	Standard
AUML-0427	URICASE-PAP Standard included	6 x 50 mL	-	1 x 5 mL
AUML-0507	URICASE-PAP Standard included	6 x 100 mL	-	1 x 5 mL



► Calibrators, Controls & Standards

Calibrators (Human Based)

Reference	Description	Configuration
CALI-0550	ELICAL 2 MULTIPARAMETRIC	4 x 3 mL
HLCA-0041	LIPID CALIBRATOR (HDL & LDL CHOL)	2 x 1 mL
VITD-004	Vit D Calibrator set 5 Levels	5 x 1 mL

Controls (Human Based)

Reference	Description	Configuration
CONT-0060	ELITROL I MULTIPARAMETRIC	10 x 5 mL
CONT-0160	ELITROL II MULTIPARAMETRIC	10 x 5 mL
CKMB-0900	CK-MB	4 x 3 mL



Specific Proteins Calibrators & Controls

CRP CALIBRATOR SET

Reference	Configuration
ICRP-0043	5 LEVELS

CRP CONTROL

Reference	Configuration
ICRP-0046	CRP CONTROL I
ICRP-0047	CRP CONTROL II

FERRITIN CALIBRATOR

Reference	Configuration
IFRT-0042	FERRITIN CALIBRATOR

HbA1c CALIBRATORS

Reference	Configuration
HBAC-0043	FOR USE WITH HBAC-0240 4 LEVELS
HBAE-0043	FOR USE WITH HBAE-M130 2 LEVELS

HbA1c CONTROLS

Reference	Configuration
HBAC-0049	FOR USE WITH HBAC-0043 & HBAE-0043

MICROALBUMIN (URINE) CALIBRATOR SET

Reference	Configuration
IMAL-0043	5 LEVELS

MICROALBUMIN (URINE) CONTROL I

Reference	Configuration
IMAL-0046	CONTROL I
IMAL-0047	CONTROL II

PROTEIN CALIBRATOR SET

Reference	Configuration
IPRO-0043	5 LEVELS

RF CALIBRATOR

Reference	Configuration
IRFA-0042	RF CALIBRATOR

RHEUMATOLOGY CONTROL I

Reference	Configuration
IRCT-0046	CONTROL I
IRCT-0047	CONTROL II

VITAMIN D CONTROL

Reference	Configuration
VITD-0049	BI-LEVEL CONTROLS

ELITECHGROUP

ELITechGroup is a global leader in Clinical Chemistry, with over 50,000 systems delivered. Our scalable systems are designed around the laboratory's most important needs – reliability and consistency.

ELITechGroup Clinical Systems have performance and quality designed into the complete system across all key components:

- Analyzers
- Liquid stable reagents
- Calibrators & controls
- ISE (Ion-Selective Electrode)
- Service and training

With a strong heritage of reliability and performance, with Selectra Family solutions your laboratory can grow with confidence.



ELITech Clinical Systems SAS (France)

ELITechGroup B.V. (The Netherlands)

For In Vitro diagnostics medical devices: read carefully information available on labelling and/or on the instructions for use and/or in the user manual.

©2021, Selectra Mach is a registered Trademark of ELITechGroup B.V. Availability may be subject to regulatory requirements. Please contact your local representative or email sales.ecsnl@elitechgroup.com for information on the availability of these products in your area.



ELITechGroup

EMPOWERING IVD

www.elitechgroup.com
info@elitechgroup.com

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...									
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
		Selectra ProS							
DM000422656	ANALIZATOR BIOCHIMIC	Selectra ProS™	[LITE]	6003-548	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023
DM000422652	ANALIZATOR BIOCHIMIC	Selectra ProS™	[O/PSID/ISE]	6003-500	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023
DM000422653	ANALIZATOR BIOCHIMIC	Selectra ProS™	[O/PSID]	6003-541	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023
DM000422655	ANALIZATOR BIOCHIMIC	Selectra ProS™	[O]	6003-543	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023
DM000422657	ANALIZATOR BIOCHIMIC	Selectra ProS™	[C/PSID/ISE/US]	6003-600	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023
DM000422654	ANALIZATOR BIOCHIMIC	Selectra ProS™	[O/ISE]	6003-542	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages), conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to *in vitro* diagnostic medical devices and to the public health code.

These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.

This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th, 2023).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico *in vitro* y el código de salud pública.

Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.

Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).

Sées, le 23 Novembre 2021

Valérie LAMBERT,

Responsable des Affaires Réglementaires

Regulatory Affairs Manager

Responsable de los Asuntos Reglementarios

ELITech Clinical Systems SAS

Zone Industrielle

61500 SEES - France

Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51

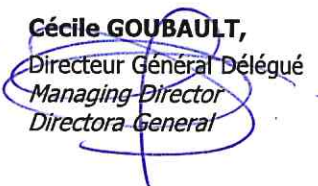
SIRET 318 365 228 00036

Cécile GOUBAULT,

Directeur Général Délégué

Managing Director

Directora General



Société par actions simplifiée au capital de 1.688.392,33 € – SIREN : 318 365 228 – RCS ALENCON

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Metabolites divers / Miscellaneous metabolites		
ALBUMIN	ALBU-0600/0700/0250/M830	53597
BILIRUBIN DIRECT	BIDI-0500	53233
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	
BILIRUBIN TOTAL 4+1	BITO-0600/0250	53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600	53229/53233
CREATININE JAFFE	CRCO-0600/0700	53251
CREATININE PAP	CRSL-M490	53250
CREATININE PAP SL	CRSL-0630/0250	
DIRECT BILIRUBIN	BIDI-M430	53233
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE HK	GHSL-M490	53301
GLUCOSE HK SL	GHSL-0600/0250	
GLUCOSE PAP	GPSL-M690	
GLUCOSE PAP SL	GPSL-0507/0500/0707/0700/0250/0455/0497	
LACTATE	LACT-0100/LACI-0250	53342
MICROPROTEIN PLUS	PRTU-0600/0250	53481
PHOSPHORUS	PHOS-0600/0230/M430	59123
TOTAL BILIRUBIN	BITO-M430	53229
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN	PROB-M830	53985
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA	URSL-M830	53587
UREA UV SL	URSL-0427/0420/0500/0507/0250/0455	
URIC ACID	AUML-M830	53583
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	
URIC ACID SL	AUSL-0250	
URINE PROTEIN	PRTU-M230	53481
Enzymes / Enzymes		
ALP (DEA) SL	PASL-0400/0420/0230	52928
ALP ENVOY	PIVD-0850	
ALP IFCC	ALPI-0230	52923
ALT/GPT	ALSL-M490	
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	52940
AMYLASE	AMSL-M430	
AMYLASE SL	AMSL-0390/0400/0230	52954
AST/GOT	ASSL-M490	
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	52971
CHOLINESTERASE	CHES-0053/CHEB-0250	52994
CK-MB SL / CK-MB	CMSL-0410/0230	53003
CK NAC	CKSL-M230	
CK NAC SL	CKSL-0410/0430/0230	53027
GAMMA-GT	GISL-M230	
GAMMA-GT PLUS SL	GISL-0400/0420/0250	53072
LDH IFCC	LLSL-M230	
LDH-L SL	LLSL-0400/0420/0230	53108
LIPASE	LPSL-0250	
LIPASE ENVOY	LPSL-0850	
LIPASE SL	LPSL-0230	
Electrolytes / Oligo-éléments / Electrolytes / Trace-elements		
CALCIUM ARSENAZO	CALA-0600/0250/M430	45789
CHLORIDE	CHLO-0600/0250	60037
Direct TIBC	TIBC-0250/M130	53904
IRON ENVOY	FEFE-0850	54758
IRON FERENE	FEFE-0230/0600/M230	
MAGNESIUM ENVOY	MAGX-0850	46795
MAGNESIUM XB	MGXB-0250/0600/M430	
MAGNESIUM XYLIDYL	MAGX-0230/0600	
Lipides / Lipids		
CHOLESTEROL	CHSL-M690	53359
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	53359
HDL CHOLESTEROL	CHDL-0250/0600/M330	53391
LDL CHOLESTEROL	CLDL-0250/M330	53395
TRIGLYCERIDES	TGML-M690	53460
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	
TRIGLYCERIDES SL	TGML-0250/0455	

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Contrôles-Calibrants-Standards / Controls-Calibrators-Standards		
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	44698
CK-MB CONTROL	CKMB-0900	44693
ELICAL 2	CALI-0550	47868
ELITROL I	CONT-0060	47869
ELITROL II	CONT-0160	
GLUCOSE Standard 100 mg/dL	GLUP-0055	41818
HDL LDL CALIBRATOR	HLCA-0041	47868
ISE CONTROL I	ISCT-0046	47869
ISE CONTROL II	ISCT-0047	
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	44702
UREA Standard 50 mg/dL	URUV-0055	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	44704
Protéines spécifiques / Specific proteins		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400/M230	53705
CRP IP CALIBRATOR SET	ICRP-0043	41838
CRP IP CONTROL I	ICRP-0046	41839
CRP IP CONTROL II	ICRP-0047	
CRP WR	CRPW-0230	53705
CRP WR CALIBRATOR SET	CRPW-0043	41838
CRP WR CONTROL	CRPW-0045	41839
CRP WR ENVOY	CRPW-0850	53705
FERRITIN	IFRT-0230	53718
FERRITIN CALIBRATOR	IFRT-0042	41927
HAPTOGLOBIN IP	IHAP-0400	53737
HbA1c	HBAC-0240	59090
HbA1c CALIBRATOR SET	HBAC-0043	53315
HbA1c CONTROL L + H	HBAC-0049	44435
HbA1c Enzymatic	HBAE-M130	63151
HbA1c Enzymatic Calibrator Set	HBAE-0043	53315
IgA IP	IIGA-0400	53760
IgG IP	IIGG-0400	53787
IgM IP	IIGM-0400	53795
MICROALBUMIN IP	IMAL-M230	53475
μALBUMIN IP	IMAL-0400	
μALBUMIN IP CALIBRATOR SET	IMAL-0043	53477
μALBUMIN IP CONTROL I	IMAL-0046	53478
μALBUMIN IP CONTROL II	IMAL-0047	
OROSOMUCOID IP	IORO-0400	53606
PREALBUMIN IP	IPAL-0400	53957
PROTEIN IP CALIBRATOR SET	IPRO-0043	53593
RF CALIBRATOR	IRFA-0042	42230
RHEUMATOID FACTOR	IRFA-0230/RHFA-M130	55111
RHEUMATOLOGY CONTROL I	IRCT-0046	47869
RHEUMATOLOGY CONTROL II	IRCT-0047	
TRANSFERRIN	TRF2-M230	59041
TRANSFERRIN IP	ITRF-0400	
Vitamines/Vitamins		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes		
ISE CALIBRATORS	ISCA-0250	52867
ISE CLEANER/CONDITIONER	ISCC-0280	59058
ISE DILUENT	ISDI-0250	58237
ISE REFERENCE SOLUTION	ISRS-0800	59238
Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments		
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900	59058
SYSTEM SOLUTION	SLSY-5905	58236
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900	
WASH SOLUTION A	SOLA-M163	59058
WASH SOLUTION B	SOLB-M830	59058
Tests d'agglutination / Agglutination tests		
CRP LATEX	LXCR-0112	53707

Vlo
CG



EU Declaration of Conformity



ELITechGroup B.V.
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

declares under sole responsibility that the IVD medical devices specified below (including the listed accessories) and to which this declaration relates, conform to the provisions of:

- **Regulation (EU) 2017/746** of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU ("IVDR")
- **Directive 2011/65/EU** of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, including Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances ("RoHS").

These IVD medical devices carry the CE-marking and are notified in accordance with the IVDR.

Catalogue number	Description	GTIN
6003-500	Selectra ProS™ [O/PSID/ISE]	3661540 60032 6
6003-541	Selectra ProS™ [O/PSID]	3661540 60490 4
6003-542	Selectra ProS™ [O/ISE]	3661540 60491 1
6003-543	Selectra ProS™ [O]	3661540 60492 8
6003-548	Selectra ProS™ [LITE]	3661540 60493 5
6003-600	Selectra ProS™ [C/PSID/ISE/US]	3661540 60041 8

Product	Chemistry analyzers
EMDN code	W02010101
GMDN code	56676
Intended purpose	Automated clinical chemistry analyzer, to be used in combination with specific reagents, for in vitro diagnostic measurement of analytes in samples of serum, plasma, urine, and aqueous standard solutions.
Risk Class	A
Accessories	See Annex I
SRN of manufacturer	NL-MF-000021018
Basic UDI-DI	3661540Pro-series8A

Spankeren, December 2022

Adriaan Intveld

Person Responsible for Regulatory Compliance (PRRC)

	EU Declaration of Conformity	 ELITechGroup EMPOWERING IVD
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List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	DEKRA
	IEC 61010-2-010:2014	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	
	IEC 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
EMC	IEC 61326-1:2006	Electrical equipment for measurement, control, and laboratory use - EMC requirements – Part 1: General requirements	DEKRA
	IEC 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA

Annex I – List of IVD accessories

Catalogue number	Description	EMDN	GMDN	GTIN
3201-019	Precision Test Solution	W0201010185	58048	3661540 60042 5
6002-706	Cuvette Rotor Set	W0201010180	61033	3661540 60057 9

Certificate of Approval

This is to certify that the Management System of:

ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.



Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited



001

Certificate Schedule

Location	Activities
ELITechGroup B.V. Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	ISO 13485:2016 Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.
ELITechGroup B.V. Kanaaldijk 90, 6956 AX Spankeren, The Netherlands	ISO 13485:2016 Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.



001



Clinical Systems

Selectra ProS™

THE SMARTEST CHOICE
FOR LABORATORIES
LOOKING TO AUTOMATE



Selectra Solutions



SPECIFICATIONS

THROUGHPUT

- Up to 133 tests/hour
- Up to 266 ISE tests/hour

REAGENT AND SAMPLE HANDLING

One rotor combining both sample and reagent positions.

- Inner rotor ring:
 - 30 refrigerated reagent positions for 10 mL, 25 mL and 50 mL reagent bottles
 - Cooled to 10°C +/-4°C at normal laboratory conditions
 - All reagent positions can be assigned as R1, R2 and R3
- Outer rotor ring:
 - 25 barcode readable positions
 - All positions fit 13x75 mm primary and secondary tubes and pediatric cups
 - All positions can be used for calibrators, controls, normal, pediatric and STAT samples

PIPETTING SYSTEM

- 1000 µL reagent syringe:
 - R 1 volume 110 - 400 µL
 - R 2 volume 0 - 180 µL
 - R 3 volume 0 - 180 µL
 - Programmable in 1 µL steps
- 100 µL sample syringe:
 - Sample volume 1 - 30 µL
 - Programmable in 0.1 µL steps
- Programmable dilution ratios: 1 : 5 up to 1 : 200 in one step increments with 3 possible diluents
- Pre-heated probe with level detection, collision protection and integrated mixer

CUVETTE ROTOR

- Cost effective, semi-disposable cuvette rotor with 48 cuvettes, path length 7 mm
- >10,000 tests per rotor
- Measuring temperature 37°C, controlled by Peltier elements

LIGHT SOURCE

- Quartz-iodine lamp 12V-20W

WAVELENGTH RANGE

- 340 - 800 nm
- Optical unit with 8 position filter wheel
- Automatic wavelength selection
- 340, 405, 505, 546, 578, 620, 660, 700 nm standard installed
- Other wavelengths available on request

PHOTOMETRIC RANGE

- -0.1 to 3.0 Absorbance
- Resolution 0.001 Abs

ANALYTICAL MODES (SINGLE, DUAL AND TRIPLE REAGENT SYSTEM)

- Kinetic measurement with linearity check
- Mono- and bichromatic end point measurement with or without bichromatic reagent blank and/or sample blank correction
- Two point measurement; with or without slope blank
- Graphic plot of all measuring points
- Predilution, post-dilution and automatic reflex dilution as needed
- Non-linear calibration curves
- Prozone check for immunology tests
- Cut-off declaration
- Calculated tests

QUALITY CONTROL

- Up to 15 different controls can be defined, 3 per test
- Westgard rules
- Levey-Jennings plots
- Quality control statistics

WATER CONSUMPTION

- ~950 mL per hour max, continuous operation

STANDARDS AND REGULATIONS

- CE-IVDR
- USA FDA 510(k)
- CB
- UL

DIMENSIONS & WEIGHT

- 90 cm (36 in) x 75 cm (30 in) x 60 cm (24 in) (W x H x D)
- 75 kg (165 lbs)

INTERFACE

- State of the art Host-Query interface available
- Host: RS232 or Ethernet (TCP/IP) through LIS-2A protocol
- Hand held CCD barcode reader used for reagent identification and automated programming of assays, controls and calibrators

INSTALLATION CONDITIONS

- Temperature: 15 - 32 °C (59 - 90°F)
- Humidity: 15 - 85% RH
- Altitude: up to 2000 m
- Plumbing: no dedicated system water or drain required
- Electrical: Voltage: 100 - 240 Vac; Frequency: 50/60 Hz; Power (max): 400 VA

INTEGRATED PC*

- Touch screen navigation
- Operating System: MS Windows™ Embedded

OPTIONS

ISE MODULE*

- Patented Solid State Dry Electrode Technology
- Indirect measurement
- Dilution 1:14
- Measures Sodium, Potassium, Chloride and Bicarbonate

POSITIVE SAMPLE IDENTIFICATION

- Positive Sample Identification (PSID) via integrated barcode reader
- Reads all popular formats including Codes 39, 128, 11, 93, 4, CODABAR and Interleaved 2/5

PRINTER

- Printer supported by MS Windows™

PROACTIVE MAINTENANCE KIT

- Complete parts kit for annual preventive maintenance

* Please verify the right instrument catalog number for this option from your local representative.



WORLDWIDE OFFICES

Please email sales.ecs@elitechgroup.com or contact your local representative for information on the availability in your area.

Worldwide

Australia

BELUX

Brazil

New Zealand

Serbia

The Netherlands

United States

+61 1800 815 098

+32 92 820 531

+55 27 3025 1415

+64 0800 555 611

+381 11 2467119

+31 313 430 581

+1-800-345-2822

sales.ecs@elitechgroup.com

elitechaustralia@elitechgroup.com

info.be@elitechgroup.com

contato@elitech.com.br

elitechnewzealand@elitechgroup.com

elitechsr@elitechgroup.com

info.nl@elitechgroup.com

infoUS@elitechgroup.com



ELITechGroup

EMPOWERING IVD

www.elitechgroup.com



Certificate of Training

ELITechGroup B.V., hereby declares that:

Participant: **Mr. Negru ION**

Employee of: **GBG-MLD SRL – Moldova**

attended a training course, *dated:* **October 2nd – 6th, 2023**

and is now a certified service engineer for the declared instruments;

SELECTRA Pro-series

The training course included the following:

- Organization of ELITechGroup B.V.
- Repair and warranty
(Use of Malfunction Report)
- Medical Device Reporting/Vigilance
(Reporting of incidents)
- Safety (Biohazard, ESD, etc.)
- Product specifications
- Theory of operation
- Daily use of the device
- Installation and Qualification of the device
(Use of Installation and Qualification Report)
- Preventive maintenance
(Schedule and parts)
- Corrective maintenance
(Qualification after repair)
- Equipment needed for installation and maintenance

Technical Services & System Support Manager:

System Support Engineer/Trainer:



Mr. John van Abeelen

**ELITechGroup B.V.
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands**



Mr. Han Wild



Certificate of Training

ELITechGroup B.V., hereby declares that:

Participant: **Mr. Semeniuc VASILI**

Employee of: **GBG-MLD SRL – Moldova**

attended a training course, *dated:* **October 2nd – 6th, 2023**

and is now a certified service engineer for the declared instruments;

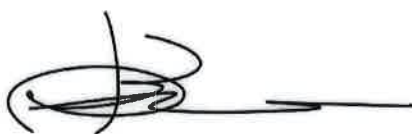
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