

Azienda certificata
UNI EN ISO
9001 13485

Diagnostics and Reagents for Clinical Laboratories





Clinical Chemistry

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Biolis 50i is an automated Clinical analyzer with higher test performance and operability for Chemical Chemistry tests.

Futura System Group s.r.l. has certified all its reagents line on Biolis 50i and provides dedicated packaging with barcode.

Throughput

480 tests/hour for photometry
580 tests/hour with ISE

Main features

- Automatic Sample's Pre-dilution
- Reagent tray: R1: 36 position; R2: 35 position.
R1: 70 ml – 35 ml R2: 20 ml
- Reagent Tray Refrigeration under 10 degree
- 72 samples on board
- Easy touch screen operation
- Full-featured interface
- STAT sample available
- Clot detector and automatic cleaning of sample probe
- Dedicated ISE sample probe
- Sample kind: Serum, Plasma, Urine, CSF, Blood cells, Dialysis
- Sample and reagents barcode reader
- Reaction volume reduction to 100 µl.. Analysis volume 100-300 µl
- 12 fixed wavelengths (340, 380, 405, 450, 505, 546, 570, 600, 660, 700, 750, 800 nm)
- Tungsten halogen lamp

Dimension

W1050 x D750 x H1145 (mm)

Weight

300 kg

Power input

AC100/115/230V±10%, 50/60Hz
Voltage fluctuation: Less than 10%

Ambient conditions

15°C - 30°C

Fully Automated Clinical Analyzer

Biolis 30i



Biolis 30i is the latest automated analyser for Chemical Chemistry model of Biolis series.

It is a fully automated, bench-top use clinical analyser developed and manufactured in Japan.

New functions has been developed as Sample clot detection, Crash prevention.

Futura System Group s.r.l. has certified all its reagents line on the instrument.

Throughput

270 tests/hour 450 tests/hour with ISE

Main features

- Automatic Sample's Pre-dilution
- Reagent tray: R1: 36 position; R2: 35 position.
- Reagent tray Cooling temperature: 8-12°C
- 30 samples on board for samples and 45 for standards and blank samples
- Space-saving compact desktop design
- Easy-to-use software
- Small and Bench-Top, Air pressure mixing
- Fully featured in compact design
- STAT sample available
- Sample kind: Serum, Plasma, Blood cell, Urine, Dialysis, CSF
- Bar code reader supported
- 13 fixed wavelengths (340 – 800nm)
- Cuvette auto washing with heated water and 2 kinds of washing solutions

New functions:

Sample clot detection
Crash prevention

Dimension

80 x 67 x 55.5 cm

Weight

95 kg

Power input

100/115/230 volt (50-60 Hz)

Ambient conditions

15°C – 30°C

Reagents

Product	Ref	Packaging
Angiotensin Converting Enzyme (ACE) * New Angiotensin converting Enzyme (ACE) quantitative kinetic colorimetric assay FAPGG (N-[3-(2-furyl)acryloyl]-L-phenylalanyl-glycylglycine) method on Serum and Plasma. Lyophilized calibrator and control are separately supplied as respectively REF CS014CAL, CS014CONN and CS014CONP.	CS014	R1 2x 50 ml R2 10x10 ml
Ammonia Ultra New Ammonia quantitative UV assay. Sample: Plasma. Stable, liquid and ready to use monoreagent. Standard (1x5 ml) liquid and ready to use included.	CS008	R1 3x20 ml
Total and Prostatic Acid Phosphatase Increasing kinetic colorimetric method according to Hillmann. Prefilled Buffer in 2 mL vials, Tartrate reagent liquid and ready to use, Substrate Fast Red as tablets to dissolve in the Buffer. Working Solution stability of 2 days at 2-8° C. Specific for serum (avoid plasma).	2077	19 Buffer x 2 ml 1 Substrate x 19 Tablets 1 Tartrate
Total Bile Acids New Total Bile Acids quantitative enzymatic assay. Stable, liquid and ready to use reagents (3+1 ratio). Sample: Serum and Plasma. Ready to use calibrator and lyophilized control are separately supplied as respectively REF CS012CAL and CS012CON.	CS012 CS013	R1 2x60 ml R2 2x20 ml R1 1x60 ml R2 1x20 ml
Albumin Chemical colorimetric method with Bromocresol Green (BCG), reading in end point. Stable, liquid and ready to use monoreagent. Sample: serum or plasma. Standard (1x5 ml) liquid and ready to use included.	2012 2010 HH2013 B24-2013	6x100 ml 2x250 ml 3 x 60 ml 5 x 40 ml
Alkaline Phosphatase Increasing kinetic colorimetric method according to DGKC recommendation. DEA Buffer. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 10 days at 2-8°C). Sample: serum or plasma.	2075 2076 HH2074 B24-2074	R1 5x80 ml + R2 1x100 ml R1 5x40 ml + R2 1 x 50 ml R1 6x60 ml + R2 6 x 15 ml R1 8x24 ml + R2 8 x 6 ml
ALT GPT Decreasing kinetic UV method according to IFCC recommendation. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 10 days at 2-8°C). Sample: serum or plasma.	2615 2616 HH2617 B24-2617	R1 5x80 ml + R2 1x100 ml R1 5x40 ml + R2 1 x 50 ml R1 6x60 ml + R2 6 x 15 ml R1 8x24 ml + R2 8 x 6 ml
AST GOT Decreasing kinetic UV method according to IFCC recommendation. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 10 days at 2-8°C). Sample: serum or plasma.	2515 2516 HH2517 B24-2517	R1 5x80 ml + R2 1x100 ml R1 5x40 ml + R2 1 x 50 ml R1 6x60 ml + R2 6 x 15 ml R1 8x24 ml + R2 8 x 6 ml
Alpha Amylase Increasing kinetic colorimetric method. Substrate CNP-G3. Stable, liquid and ready to use monoreagent. Sample: serum, plasma or diluted urine.	2127 HH2128 B24-2128	10x10 ml 5 x 20 ml 4 x 40 ml
Bicarbonate New Colorimetric method with phosphoenolpyruvate. Stable, liquid and ready to use monoreagent. Sample: serum and plasma. Standard (1x5 ml) liquid and ready to use included.	CS009	6x10 ml
Total Bilirubin Chemical colorimetric, modified Jendrassik and Groff method, reading in end point. Stable, liquid and ready to use reagents (4+1 ratio). Used as two-reagents for automation with sample starter or as monoreagent preparing a working solution (stability of 24 hours at room temperature). Calculation by calibration using multiparametric CHEMISTRY CALIBRATOR. Sample: serum or plasma.	2023 2024	R1 5x40 ml + R2 1 x 50 ml R1 5x80 ml + R2 1x100 ml

Product	Ref	Packaging	
Total Bilirubin			
Chemical colorimetric DPD method, reading in end point sample blank. Stable, liquid and ready to use reagents (4+1 ratio). Dedicated line for automation. Calibration with multiparametric CHEMISTRY CALIBRATOR. Storage at 2-8°C. Sample: serum or plasma.	HH2021 B24-2021	R1 6x60 ml + R2 6x15 ml R1 8x24 ml + R2 8 x 6 ml	
Direct Bilirubin			
Chemical colorimetric, Diazo with Sulphanilic Acid method, reading in end point. Stable, liquid and ready to use reagents (4+1 ratio). Used as two-reagents for automation with sample starter or as monoreagent preparing a working solution (stability of 24 hours at room temperature). Calculation by calibration using multiparametric CHEMISTRY CALIBRATOR. Sample: serum or plasma.	2026	R1 5x40 ml + R2 1x50 ml	
Direct Bilirubin			
Chemical colorimetric, reading in end point sample blank. Stable, liquid and ready to use reagents (4+1 ratio). Dedicated line for automation. Calibration with multiparametric CHEMISTRY CALIBRATOR. Storage at 2-8°C. Sample: serum or plasma.	HH2028 B24-2028	R1 2x60 ml + R2 2x15 ml R1 4x20 ml + R2 4 x 5 ml	
Calcium Arsenazo III			
Chemical colorimetric method with Arsenazo III, reading in end point. Stable, liquid and ready to use monoreagent. Sample: serum, plasma or diluted urine. Standard (1x10 ml) liquid and ready to use included.	2034 2035 HH2036 B24-2036	6x100 ml 2x250 ml 8 x 60 ml 4 x 40 ml	
Chlorides			
Chemical colorimetric method with Mercurious Thiocyanate, reading in end point. Stable, liquid and ready to use monoreagent. Sample: serum, plasma, cerebrospinal fluid (CSF) or diluted urine. Standard (1x10 ml) liquid and ready to use included.	3006 HH3009 B24-3009	6x50 ml 8x60 ml 6x40 ml	
Total Cholesterol			
Enzymatic colorimetric method according to Trinder, reading in end point. Stable, liquid and ready to use monoreagent. Sample: serum or plasma. Standard (1x5 ml) liquid and ready to use included.	2049 2040 HH2047 B24-2047	6x100 ml 6x 50 ml 8x 60 ml 6x 40 ml	
Direct HDL Cholesterol			
Direct enzymatic colorimetric method, reading in end point. Stable, liquid and ready to use reagents (3+1 ratio). For automation. Sample: serum or plasma. Calibrator is separately supplied as HDL-LDL CHOLESTEROL CALIBRATOR (REF 3276 - 2x1 ml).	2061 2060 HH2063 B24-2063	R1 1x90 ml + R2 1x30 ml R1 1x60 ml + R2 1x20 ml R1 1x60 ml + R2 1x20 ml R1 7x24 ml + R2 7x 8 ml	
HDL Cholesterol PEG 6000			
Precipitation by PEG addition. Stable, liquid and ready to use monoreagent. Standard (1x5 ml) liquid and ready to use included. To use with Total Cholesterol kit.	2039	6x50 ml	
Direct LDL Cholesterol			
Direct enzymatic colorimetric method, reading in end point. Stable, liquid and ready to use reagents (3+1 ratio). For automation. Sample: serum or plasma. Calibrator is separately supplied as HDL-LDL CHOLESTEROL CALIBRATOR (REF 3276 - 2x1 ml).	3278 3277 HH3279 B24-3279	R1 1x60 ml + R2 1x20 ml R1 1x30 ml + R2 1x10 ml R1 2x30 ml + R2 2x10 ml R1 7x24 ml + R2 7x 8 ml	
Cholinesterase			
Decreasing kinetic colorimetric method according to DGKC '94 recommendation. Substrate: Butyrylthiocholine and Hexacyanoferrate III. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 7 days at 2-8°C). Sample: serum or plasma.	2105 2104 HH2106 B24-2106	R1 5x40 ml + R2 1x50 ml R1 5x 8 ml + R2 1x10 ml R1 3x40 ml + R2 2x15 ml R1 4x24 ml + R2 4x 6 ml	
Dibucaine			
Auxiliary reagent for Cholinesterase to determine Dibucaine Number. Liquid, stable and ready to use monoreagent.	2661	10x10 ml	

Reagents

Product	Ref	Packaging
CK-NAC Increasing kinetic UV method according to IFCC/DGKC recommendation. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 10 days at 2-8°C). Sample: serum or plasma.	7006 7066 HH7067 B24-7067	R1 5x40 ml + R2 1x50 ml R1 5x 8 ml + R2 1x10 ml R1 3x40 ml + R2 2x15 ml R1 2x24 ml + R2 2x 6 ml
CK-MB Increasing kinetic UV method after immunoinhibition of CK-M monomer. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution. Sample: serum or plasma.	7068 HH7068 B24-7068	R1 5x8 ml + R2 1x10 ml R1 1x48 ml + R2 1x12 ml R1 2x24 ml + R2 2x 6 ml
Copper Chemical colorimetric method with 3,5-di-Br-PAESA, reading in end point. Stable, liquid and ready to use reagents (1+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution. Sample: serum. Standard (1x10 ml) liquid and ready to use included.	5401	R1 6x9 ml + R2 1x6 ml
Creatinine Increasing kinetic colorimetric method according to Jaffé (alkaline picrate), without deproteinization. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 5 hours at 15-25° C). Sample: serum, plasma or diluted urine. Standard (1x10 ml) liquid and ready to use included.	2055 HH2055 B24-2055	R1 5x80 ml + R2 1x100 ml R1 6x60 ml + R2 6x 15 ml R1 8x24 ml + R2 8x 6 ml
Creatinine enzymatic Enzymatic colorimetric method. Stable, liquid and ready to use reagents (3+1 ratio). Two-reagents use, on board stability and calibration stability: 30 days. Sample: serum, plasma or diluted urine.	HH2056 B24-2056	R1 6x60 ml + R2 6x 20 ml R1 6x24 ml + R2 6x 8 ml
Ethanol* Ethanol quantitative UV assay on Serum, Whole Blood and Urine. Standard (1x5 ml) included.	ET8852	R1 1x65 ml R2 20x3 ml R3 1x1.2 ml
Fructosamine Quantitative determination of Fructosamine. Nitrotetrazolium chloride (NBT) colorimetric method. Lyophilized calibrator and control are separately supplied as respectively REF CS015CAL, CS015CONN and CS015CONP.	New CS015	R1 4x10 ml + R2 2x10 ml
Glucose-6-Phosphate Dehydrogenase (G6PDH) Quantitative determination for G-6-PDH activity in erythrocytes.	PD410	R1 1x100 ml R2 1x2 ml R3 1x2 ml R4 1x20 ml
Gamma-GT Increasing kinetic colorimetric method. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 10 days at 2-8°C). Sample: serum or plasma.	3026 3027 HH3028 B24-3028	R1 5X40 ml + R2 1x50 ml R1 5X 8 ml + R2 1x10 ml R1 6X60 ml + R2 6x15 ml R1 8x24 ml + R2 8x 6 ml
Glucose Enzymatic colorimetric method according to Trinder, reading in end point. Stable, liquid and ready to use monoreagent. Sample: serum, plasma or diluted urine. Standard (1x5 ml) liquid and ready to use included.	2092 2089 2088 HH2093 B24-2093	6x500 ml 6x100 ml 2x250 ml 8x 60 ml 6x 40 ml
Glyco Haemoglobin Chemical colorimetric method with ion exchange resin to separate glyco-haemoglobin (A1). Reading in end point. Reaction requires the pre-treatment of samples (hemolyzed and diluted whole blood). Manual testing. Complete kit (prefilled tubes, lysing reagent, calibrator, tubes and separator filters). <i>For HbA1c testing by immunoturbidimetric method, see inside IMT section.</i>	4555	20 tests

Product	Ref	Packaging	
Iron Ferene			
Chemical colorimetric method with Ferene, reading in end point. Stable, liquid and ready to use reagents (4+1 ratio). Sample: serum. Standard (1x10 ml) liquid and ready to use included.	2909	R1 5x80 ml + R2 1x100 ml	
	2908	R1 5x40 ml + R2 1x 50 ml	
	HH2910	R1 6x60 ml + R2 6x 15 ml	
	B24-2910	R1 8x24 ml + R2 8x 6 ml	
LDH-P			
Decreasing kinetic UV method according to SFBC recommendation (P-->L) . Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 10 days at 2-8°C). Sample: serum or plasma.	3116	R1 5x40 ml + R2 1x50 ml	
	3166	R1 5x 8 ml + R2 1x10 ml	
	HH3167	R1 2x60 ml + R2 2x15 ml	
	B24-3167	R1 4x24 ml + R2 4x 6 ml	
Lactate New			
Enzymatic UV method assay on Plasma and Liquor. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 14 days at 2-8°C).	CS017	R1 4x20 ml R2 2x10 ml	
Lipase Color			
Increasing direct kinetic colorimetric method. Stable, liquid and ready to use reagents (5+1 ratio). Can be used as two-reagents for automation. Sample: serum or plasma. Calibrator (1x1 ml) lyophilized and stable 7 days after reconstitution included.	3254	R1 4x10 ml + R2 1 x 8 ml	
	HH3254	R1 2x50 ml + R2 2x10 ml	
	B24-3254	R1 4x25 ml + R2 4 x 5 ml	
Magnesium			
Chemical colorimetric method with Xylidyl Blue, reading in end point. Stable, liquid and ready to use monoreagent. Sample: serum, plasma, cerebrospinal fluid (CSF) or diluted urine. Standard (1x10 ml) liquid and ready to use included only in the kit HH5104.	HH5104	5x30 ml	
	B24-5103	6x40 ml	
Magnesium UV			
Enzymatic method, kinetic reading in UV. Stable, liquid and ready to use bi-reagent. Sample: serum, plasma and diluted urine.	HH5105	R1 2x60 ml + R2 2x15 ml	
	B24-5105	R1 4x24 ml + R2 4 x 6 ml	
Homocysteine Enzymatic			
Enzyme cycling method, kinetic reading in UV. Stable, liquid and ready to use reagents. Sample: serum or plasma. Calibrators, liquid and ready to use, are included (LIV [μmol/L] 1x3 ml + LIV [28 μmol/L] 1x3 ml). The kit code C7071 includes two calibrators level (1x1,5 ml + 1x1,5 ml) and it is in dedicated package for COBAX instruments.	HH7071	R1 1x30 ml + R2 1x5 ml	
	B24-7071	R1 2x15 ml + R2 1x5 ml	
	C7071	200 Tests	
Potassium			
Chemical turbidimetric method with Tetraphenylborate, reading in end point. Stable, liquid and ready to use monoreagent. Sample: serum or heparinized plasma. Standard (1x5 ml) liquid and ready to use included.	3502	1x50 ml	
	HH3503	4x60 ml	
	B24-3503	6x40 ml	
Phosphorus			
Chemical UV method with Ammonium Molybdate, without deproteinization, reading in end point. Stable, liquid and ready to use monoreagent. Sample: serum, plasma or diluted urine. Standard (1x5 ml) liquid and ready to use included.	2405	6x50 ml	
	HH2406	8x60 ml	
	B24-2406	6x40 ml	
Sodium			
Increasing kinetic enzymatic method by activation of b-Galactosidase enzyme with ONPG (O-nitrophenyl -β-D-galactopyranose) substrate. Liquid and ready to use reagents. Sample: serum. Standard (1x5 ml) liquid and ready to use included.	HH3500	R1 2x28 ml + R2 2x14 ml	
	B24-3500	R1 2x24 ml + R2 2x 12 ml	
Total Protein			
Chemical colorimetric method with Biuret reaction, reading in end point. Stable, liquid and ready to use monoreagent. Sample: serum or plasma. Standard (1x5 ml) liquid and ready to use included.	2091	6x100 ml	
	2090	2x250 ml	
	HH2098	8x 60 ml	
	B24-2098	6x 40 ml	
Proteins in Urine			
Chemical colorimetric method with Pyrogallol Red, reading in end point. Stable, liquid and ready to use monoreagent. Sample: urine or cerebrospinal fluid (CSF). Standard (1x5 ml) liquid and ready to use included.	2097	6x50 ml	
	HH2099	8x60 ml	
	B24-2099	6x40 ml	

Reagents



Product

Ref Packaging

Triglycerides

Enzymatic colorimetric method according to Trinder, reading in end point. Stable, liquid and ready to use monoreagent. Sample: serum or plasma. Standard (1x5 ml) liquid and ready to use included.

2704	6x100 ml
2703	6 x 50 ml
HH2705	8 x 60 ml
B24-2705	6 x 40 ml

TIBC - Total Iron Binding Capacity

Auxiliary reagent for iron assay. Stable, liquid and ready to use monoreagent. Saturation method. Complete kit of adsorbent powder and disposable to dose.(Spoon)

2999	R1 1x110 ml + R2 1x30 gr
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UIBC - Unsaturated Iron Binding Capacity

New

Colorimetric method assay on serum and heparin plasma. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents.

CS016	R1 4x20 ml + R2 2x10 ml
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Urea UV

Decreasing enzymatic kinetic UV method. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 10 days at 2-8°C). Sample: serum, plasma or diluted urine. Standard (1x5 ml) liquid and ready to use included.

2806	R1 5x80 ml + R2 1x100 ml
2805	R1 5x40 ml + R2 1x 50 ml
HH2807	R1 6x60 ml + R2 6x 15 ml
B24-2807	R1 8x24 ml + R2 8x 6 ml

Uric Acid

Enzymatic colorimetric method according to Trinder, reading in end point. Stable, liquid and ready to use reagents (4+1 ratio). Sample: serum, plasma or diluted urine. Standard (1x5 ml) liquid and ready to use included.

2206	R1 5x80 ml + R2 1x100 ml
2207	R1 5x40 ml + R2 1x 50 ml
HH2208	R1 6x60 ml + R2 6x 15 ml
B24-2208	R1 8x24 ml + R2 8x 6 ml

Urinary Stones*

Qualitative Colorimetric determination of Carbonate, Calcium, Magnesium, Ammonium, Oxalate, Phosphate, Uric Acid and Cystine on renal and urinary stones by visual inspection.

URISTONE2	30 Test
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Zinc

Chemical colorimetric method, reading in end point. Stable, liquid and ready to use reagents (4+1 ratio). Can be used as two-reagents for automation or as monoreagent preparing a working solution (stability of 15 days at 2-8°C). Sample: serum, plasma and urine. Standard (1x5 ml) liquid and ready to use included.

5403	R1 5x8 ml + R2 1x10 ml
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*Order minimum 3 kits.

The **REF** that begins with **HH** has the packaging suitable for the most common automatic analyzers and specific barcode for Tokyo Boeki **Biolis 50i** and, on request, the barcodes for **Hitachi 911-912**.


The **REF** with **B24** has the dedicated packaging and barcode for Tokyo Boeki **Biolis 24i** and **Biolis 30i**, with 36 positions plate reagents. The codes **HH** and **B24** don't include Chemical Standard.

Clinical Chemistry Reagents work successfully on all "open System" and on the most common automatic analyzers in the market.


Specific applications are available for the most common clinical chemistry instruments and can be required at info@futura-system.it or to your local distributor.

Product	Ref	Packaging	
Ammonia Controls Liquid controls for determination of ammonia. Three levels.	CS008CON	3x5 ml	
ACE Calibrator Iyo Lyophilized calibrator for Angiotensin converting Enzyme (ACE) quantitative kinetic colorimetric assay FAPGG (N-[3-(2-furyl)acryloyl]-L-phenylalanylglycylglycine) method on Serum and Plasma.	CS014CAL	6x1 ml	
ACE High Control Iyo Lyophilized control for Angiotensin Converting Enzyme (ACE) quantitative Kinetic Colorimetric assay FAPGG (N-[3-(2-furyl)acryloyl]-L-phenylalanylglycylglycine) method on Serum and Plasma.	CS014CONH	6x1 ml	
ACE Normal Control Iyo Lyophilized control for Angiotensin Converting Enzyme (ACE) quantitative Kinetic Colorimetric assay FAPGG (N-[3-(2-furyl)acryloyl]-L-phenylalanylglycylglycine) method on Serum and Plasma.	CS014CONN	6x1 ml	
Total Bile Acids Calibrator Liquid calibrator for Total Bile Acid quantitative enzymatic assay on Serum and Plasma.	CS012CAL	1x2 ml	
Total Bile Acids control Lyophilized controls for Total Bile Acid analysis on Serum and Plasma.	CS012CON	2x1 ml	
CK-MB Control Lyophilized control for CK-MB	8020	1x2 ml	
Chemistry Calibrator Multi parametric calibrator for clinical chemistry (enzymes, substrates and electrolytes). Human matrix. Lyophilized.	6020	10x3 ml	
Chemistry Control N Control sera for clinical chemistry (enzymes, substrates and electrolytes). Human matrix. Normal values. Lyophilized.	4020	10x5 ml	
Chemistry Control P Control sera for clinical chemistry (enzymes, substrates and electrolytes). Human matrix. Abnormal values. Lyophilized.	5020	10x5 ml	
Ethanol High Control liquid Liquid control for ethanol quantitative UV assay on Serum, Whole Blood and Urine.	ETCH258	6x2 ml	
Ethanol Low Control liquid Liquid control for ethanol quantitative UV assay on Serum, Whole Blood and Urine.	ETCL133	6x2 ml	
Fructosamine Calibrator Lyophilized calibrator for determination of fructosamine on serum and plasma. Colorimetric method NBT.	CS015CAL	1x1 ml	
Fructosamine Control N Lyophilized control for determination of fructosamine on serum and plasma. Colorimetric method NBT.	CS015CONN	2x1 ml	
Fructosamine Control P Lyophilized control for determination of fructosamine on serum and plasma. Colorimetric method NBT.	CS015CONP	2x1 ml	
G6PDH Deficient Control Lyophilized control for determination of Glucose-6-Phosphate Dehydrogenase (G6PDH).	PD2617	6x0,5 ml	

Calibrators and Controls

 Product	Ref	Packaging
G6PDH Normal Control Lyophilized control for determination of Glucose-6-Phosphate Dehydrogenase (G6PDH).	PD2618	6x0,5 ml
HDL-LDL Cholesterol Calibrator Lyophilized calibrator for Direct HDL Cholesterol and Direct LDL Cholesterol. Human matrix.	3276	2x1 ml
Homocysteine Control Four levels control for Homocysteine.	8012	4x3 ml
Lipidic Control Three level controls kit for HDL Cholesterol and LDL Cholesterol. Lyophilized, human matrix.	7000	3x3 ml

Wash Solutions

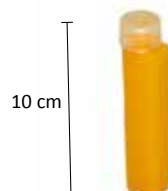
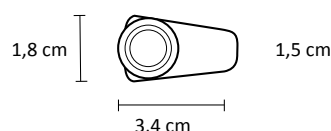
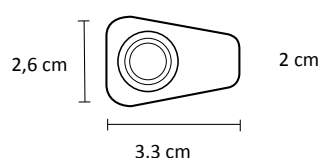
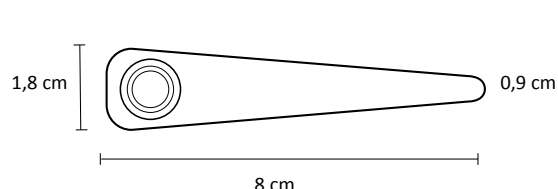
 Product	Ref	Packaging
Washing Solution Daily Cuvettes wash solution, liquid and ready to use: used for the daily washing of both the cuvettes and the flow cells within the automatic instruments.	B001	1x1000 ml
Extra Washing Solution Extra wash solution, liquid and ready to use: used for the extra wash of both the cuvettes and the flow cells within the automatic instruments.	B002	2x100 ml
Surfactant (Concentrated) Surfactant concentrated solution used in order to facilitate a better flow of liquids in the hydraulic circuits.	B003	2x50 ml
Washing Solution for Urine Analyzers Cleaning solution for urine analyzers, liquid and ready to use, best for washing the hydraulic circuits of automatic urine analyzers.	B004	1x1000 ml

Vial / Instrument Reference Table



The Reagents are distributed in standard round vials for general purpose and in special dedicated and barcoded vials for Automatic Analyzers Instruments.

Products with Ref HHxxx :



Vial for:

Biolis 50i

Hitachi

911

912

917

Dirui

T240

CS300

CS400

CS600

Beckman Coulter

Olympus

AU400

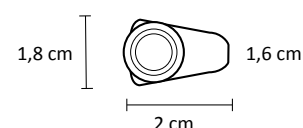
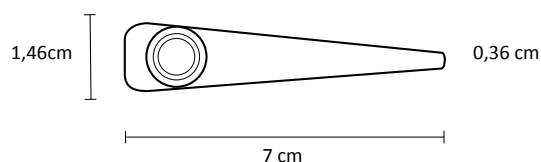
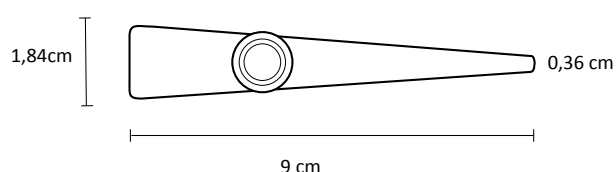
AU480

AU600

AU680

Products with code HH xxxx are barcoded for Biolis 50i and for Hitachi 911 /912 /917 on request

Products with Ref B24xxx :




Vial for:

Biolis 24i

Biolis 30i

Products with code B24-xxxx are barcoded for Biolis 24i and Biolis 30i and fit the reagent plate at 36 positions.


Reagents, Calibrators and Controls Reference Table

 Product	Ref	Packaging	Liq. STD in the kit	CAL	CTR
ACE - Angiotensin Converting Enzyme	CS014	R1 2x50 ml + R2 10x10 ml	NA	CS014CAL	CS014CONN- CS014CONH
Ammonia Ultra	CS008	R1 3x20 ml	1x5 ml	NA	CS008CON 4020 or
Total & Prostatic Acid Phosphatase	2077	19 Buffer x 2 ml 1 Substrate x 19 Tablets 1 Tartrate	NA	6020	4020-5020
Total Bile Acids	CS012 CS013	R1 2x60 ml + R2 2x20 ml R1 1x60 ml + R2 1x20 ml	NA NA	CS012CAL CS012CAL	CS012CON CS012CON
Albumin	2012 2010 HH2013 B24-2013	6x100 ml 2x250 ml 3x60 ml 5x40 ml	1 x 5 ml 1 x 5 ml Not included in the kit Not included in the kit	6020 6020 6020 6020	4020-5020 4020-5020 4020-5020 4020-5020
Alkaline Phosphatase	2075 2076 HH2074 B24-2074	R1 5x80 ml + R2 1x100 ml R1 5x40 ml + R2 1x50 ml R1 6x60 ml + R2 6x15 ml R1 8x24 ml + R2 8x6 ml	NA NA NA NA	6020 6020 6020 6020	4020-5020 4020-5020 4020-5020 4020-5020
ALT GPT	2615 2616 HH2617 B24-2617	R1 5x80 ml + R2 1x100 ml R1 5x40 ml + R2 1x50 ml R1 6x60 ml + R2 6x15 ml R1 8x24 ml + R2 8x6 ml	NA NA NA NA	6020 6020 6020 6020	4020-5020 4020-5020 4020-5020 4020-5020
AST GOT	2515 2516 HH2517 B24-2517	R1 5x80 ml + R2 1x100 ml R1 5x40 ml + R2 1x50 ml R1 6x60 ml + R2 6x15 ml R1 8x24 ml + R2 8x6 ml	NA NA NA NA	6020 6020 6020 6020	4020-5020 4020-5020 4020-5020 4020-5020
Alpha Amylase	2127 HH2128 B24-2128	10x10 ml 5x20 ml 6x40 ml	NA NA NA	6020 6020 6020	4020-5020 4020-5020 4020-5020
Bicarbonate	CS009	6 x 10 ml	1x5 ml	use STD in the kit	NA
Total Bilirubin	2023 2024	R1 5x40 ml + R2 1x50 ml R1 5x80 ml + R2 1x100 ml	NA NA	6020 6020	4020-5020 4020-5020
Total Bilirubin	HH2021 B24-2021	R1 6x60 ml + R2 6x15 ml R1 8x24 ml + R2 8x6 ml	NA NA	6020 6020	4020-5020 4020-5020
Direct Bilirubin	2026	R1 5x40 ml + R2 1x50 ml	NA	6020	4020-5020
Direct Bilirubin	HH2028 B24-2028	R1 2x60 ml + R2 2x15 ml R1 4x20 ml + R2 4x5 ml	NA NA	6020 6020	4020-5020 4020-5020
Calcium Arsenazo III	2034 2035 HH2036 B24-2036	6x100 ml 2x250 ml 8x60 ml 4x40 ml	1 x 10 ml 1 x 10 ml Not included in the kit Not included in the kit	6020 6020 6020 6020	4020-5020 4020-5020 4020-5020 4020-5020
Chlorides	3006 HH3009 B24-3009	6x50 ml 8x60 ml 6x40 ml	1 x 10 ml Not included in the kit Not included in the kit	6020 6020 6020	4020-5020 4020-5020 4020-5020
Total Cholesterol	2049 2040 HH2047 B24-2047	6x100 ml 6x 50 ml 8x 60 ml 6x40 ml	1 x 5 ml 1 x 5 ml Not included in the kit Not included in the kit	6020 6020 6020 6020	4020-5020 4020-5020 4020-5020 4020-5020
Direct HDL Cholesterol	2061 2060 HH2063 B24-2063	R1 1x90 ml + R2 1x30 ml R1 1x60 ml + R2 1x20 ml R1 1x60 ml + R2 1x20 ml R1 7x24 ml + R2 7x 8 ml	NA NA NA NA	3276 or 6020 3276 or 6020 3276 or 6020 3276 or 6020	7000 / 4020-5020 7000 / 4020-5020 7000 / 4020-5020 7000 / 4020-5020
HDL Cholesterol PEG 6000	2039	6x50 ml	1 x 5 ml	use STD in the kit	NA
Direct LDL Cholesterol	3278 3277 HH3279 B24-3279	R1 1x60 ml + R2 1x20 ml R1 1x30 ml + R2 1x10 ml R1 2x30 ml + R2 2x10 ml R1 7x24 ml + R2 7x 8 ml	NA NA NA NA	3276 or 6020 3276 or 6020 3276 or 6020 3276 or 6020	7000 / 4020-5020 7000 / 4020-5020 7000 / 4020-5020 7000 / 4020-5020

Reagents, Calibrators and Controls Reference Table

Product	Ref	Packaging	Liq. STD in the kit	CAL	CTR
Cholinesterase	2105	R1 5x40 ml + R2 1x50 ml	NA	6020	4020-5020
	2104	R1 5x 8 ml + R2 1x10 ml	NA	6020	4020-5020
	HH2106	R1 3x40 ml + R2 2x15 ml	NA	6020	4020-5020
	B24-2106	R1 4x24 ml + R2 4x 6 ml	NA	6020	4020-5020
Dibucaine	2661	10x10 ml	NO (Against factor CHE)	NO (Against factor CHE)	NA
CK-NAC	7006	R1 5x40 ml + R2 1x50 ml	NA	6020	4020-5020
	7066	R1 5x 8 ml + R2 1x10 ml	NA	6020	4020-5020
	HH7067	R1 3x40 ml + R2 2x15 ml	NA	6020	4020-5020
	B24-7067	R1 2x24 ml + R2 2x 6 ml	NA	6020	4020-5020
CK-MB	7068	R1 5x8 ml + R2 1x10 ml	calib against fact or ctr	calib against fact or ctr	8020
	HH7068	R1 1x48 ml + R2 1x12 ml	calib against fact or ctr	calib against fact or ctr	8020
	B24-7068	R1 2x24 ml + R2 2x 6 ml	calib against fact or ctr	calib against fact or ctr	8020
Copper	5401	R1 6x9 ml + R2 1x6 ml	1 x 10 ml	use STD in the kit	4020-5020
Creatinine	2055	R1 5x80 ml + R2 1x100 ml	1 x 10 ml	6020	4020-5020
	HH2055	R1 6x60 ml + R2 6x 15 ml	Not included in the kit	6020	4020-5020
	B24-2055	R1 8x24 ml + R2 8x 6 ml	Not included in the kit	6020	4020-5020
Creatinine Enzymatic	HH2056	R1 6x60 ml + R2 6x 20 ml	Not included in the kit	6020	4020-5020
	B24-2056	R1 6x24 ml + R2 6x 8 ml	Not included in the kit	6020	4020-5020
Ethanol	ET8852	R1 1x65 ml + R2 20x3 ml R3 1x1.2 ml	1 x 5 ml	NA	ETCL133- ETCH258
Fructosamine	CS015	R1 4x10 ml + R2 2x10 ml	Not included in the kit	CS015CAL	CS015CONN - CS015CONP
G6PDH	PD410	R1 1x100 ml + R2 1x2 ml + R3 1x2 ml + R4 1x20 ml	1 x 1 ml	NA	PD2617 - PD2618
Gamma-GT	3026	R1 5X40 ml + R2 1x50 ml	NA	6020	4020-5020
	3027	R1 5X 8 ml + R2 1x10 ml	NA	6020	4020-5020
	HH3028	R1 6X60 ml + R2 6x15 ml	NA	6020	4020-5020
	B24-3028	R1 8x24 ml + R2 8x 6 ml	NA	6020	4020-5020
Glucose	2092	6x500 ml	2 x 5 ml	6020	4020-5020
	2089	6x100 ml	1 x 5 ml	6020	4020-5020
	2088	2x250 ml	1 x 5 ml	6020	4020-5020
	HH2093	8x 60 ml	NA	6020	4020-5020
	B24-2093	6x 40 ml	NA	6020	4020-5020
Glyco Haemoglobin	4555	20x1 test	1 x 1 ml	use STD in the kit	NA
Iron Ferene	2909	R1 5x80 ml + R2 1x100 ml	10 ml	6020	4020-5020
	2908	R1 5x40 ml + R2 1x 50 ml	10 ml	6020	4020-5020
	HH2910	R1 6x60 ml + R2 6x 15 ml	Not included in the kit	6020	4020-5020
	B24-2910	R1 8x24 ml + R2 8x 6 ml	Not included in the kit	6020	4020-5020
LDH-P	3116	R1 5x40 ml + R2 1x50 ml	NA	6020	4020-5020
	3166	R1 5x 8 ml + R2 1x10 ml	NA	6020	4020-5020
	HH3167	R1 2x60 ml + R2 2x15 ml	NA	6020	4020-5020
	B24-3167	R1 4x24 ml + R2 4x 6 ml	NA	6020	4020-5020
Lactate	CS017	R1 1x50 ml + R2 5x10 ml	NA	6020	4020-5020
Lipase Color	3254	R1 4x10 ml + R2 1x8 ml	NA	Included in the kit	4020-5020
	HH3254	R1 2x50 ml + R2 2x10 ml	NA	Included in the kit	4020-5020
	B24-3254	R1 4x25 ml + R2 4x5 ml	NA	Included in the kit	4020-5020
Magnesium	HH5104	6x60 ml	1 x 10 ml	6020	4020-5020
	B24-5103	6x40 ml	Not included in the kit	6020	4020-5020
Magnesium UV	HH5105	R1 2x60 ml + R2 2x15 ml	1 x 10 ml	6020	4020-5020
	B24-5105	R1 4x24 ml + R2 4x6 ml	Not included in the kit	6020	4020-5020
Homocysteine Enzymatic	HH7071	R1 1x30 ml + R2 1x5 ml	Cal. 0 3ml + Cal. 28 3ml	use CAL in the kit	8012 (Liq)
	B24-7071	R1 2x15 ml + R2 1x5 ml	Cal. 0 3ml + Cal. 28 3ml	use CAL in the kit	8012 (Liq)
	C7071	200 Tests	Cal.0 1,5ml +Cal.28 1,5ml	use CAL in the kit	8012 (Liq)
Potassium	3502	1x50 ml	1 x 5 ml	6020	4020-5020
	HH3503	4x60 ml	Not included in the kit	6020	4020-5020
	B24-3503	6x40 ml	Not included in the kit	6020	4020-5020

Reagents, Calibrators and Controls Reference Table

 Product	Ref	Packaging	Lip. STD in the kit	CAL	CTR
Phosphorus	2405	6x50 ml	1 x 5 ml	6020	4020-5020
	HH2406	8x60 ml	1 x 5 ml	6020	4020-5020
	B24-2406	6x40 ml	Not included in the kit	6020	4020-5020
Sodium	HH3500	R1 2x28 ml + R2 2x14 ml	1 x 5 ml	6020	4020-5020
	B24-3500	R1 2x24 ml + R2 2x12 ml	1 x 5 ml	6020	4020-5020
Total Protein	2091	6x100 ml	1 x 5 ml	6020	4020-5020
	2090	2x250 ml	1 x 5 ml	6020	4020-5020
	HH2098	8x60 ml	Not included in the kit	6020	4020-5020
	B24-2098	6x40 ml	Not included in the kit	6020	4020-5020
Proteins in Urine	2097	6x50 ml	1 x 5 ml	use STD in the kit	NA
	HH2099	8x60 ml	1 x 5 ml	use STD in the kit	NA
	B24-2099	6x40 ml	1 x 5 ml	use STD in the kit	NA
Triglycerides	2704	6x100 ml	1 x 5 ml	6020	4020-5020
	2703	6x50 ml	1 x 5 ml	6020	4020-5020
	HH2705	8x60 ml	Not included in the kit	6020	4020-5020
	B24-2705	6x40 ml	Not included in the kit	6020	4020-5020
TIBC - Total Iron Binding Capacity	2999	R1 1x110 ml + R2 1x30 gr	NA	NA	NA
UIBC - Unsaturated Iron Binding Cap.	CS016	R1 4x20 ml + R2 2x10 ml	NA	6020	4020-5020
Urea UV	2806	R1 5x80 ml + R2 1x100 ml	1 x 5 ml	6020	4020-5020
	2805	R1 5x40 ml + R2 1x 50 ml	1 x 5 ml	6020	4020-5020
	HH2807	R1 6x60 ml + R2 6x 15 ml	Not included in the kit	6020	4020-5020
	B24-2807	R1 8x24 ml + R2 8x 6 ml	Not included in the kit	6020	4020-5020
Uric Acid	2206	R1 5x80 ml + R2 1x100 ml	1 x 5 ml	6020	4020-5020
	2207	R1 5x40 ml + R2 1x 50 ml	1 x 5 ml	6020	4020-5020
	HH2208	R1 6x60 ml + R2 6x 15 ml	Not included in the kit	6020	4020-5020
	B24-2208	R1 8x24 ml + R2 8x 6 ml	Not included in the kit	6020	4020-5020
Urinary Stones	URISTON E2	30 tests	NA	NA	NA
Zinc	5403	R1 5x8 ml + R2 1x10 ml	1 x 5 ml	use STD in the kit	4020-5020


Drugs of Abuse (DOA) Liquid Reagents for Urine

Product	Ref	Packaging
Amphetamine EIA Urine	930008	R1 2x21 ml + R2 2x8 ml - 200 tests
Barbiturates EIA Urine	930098	R1 2x21 ml + R2 2x8 ml - 200 tests
Benzodiazepines EIA Urine	930018	R1 2x21 ml + R2 2x8 ml - 200 tests
Cannabinoid EIA Urine	930028	R1 2x21 ml + R2 2x8 ml - 200 tests
Cocaine EIA Urine	930038	R1 2x21 ml + R2 2x8 ml - 200 tests
Ecstasy EIA Urine	930058	R1 2x21 ml + R2 2x8 ml - 200 tests
EDDP EIA (Methadone Metabolite) Urine	MD930078	R1 2x21 ml + R2 2x8 ml - 200 tests
Methadone EIA Urine	930068	R1 2x21 ml + R2 2x8 ml - 200 tests
Opiates EIA Urine	930088	R1 2x21 ml + R2 2x8 ml - 200 tests

Drugs of Abuse (DOA) Calibrators

Product	Ref	Packaging
Multilevel Calibrators		
Multidrug Calibrator for urine including concentrations of AMP / COC / MTD / COT / OPI / BAR	933020	5x10 ml
ECSTASY calibrator (5 levels) for urine	933030	5x10 ml
EDDP calibrator (5 levels) for urine	933040	5x10 ml
CANNABINOID calibrator (5 levels) for urine	933070	5x4 ml
BENZODIAZEPINES calibrator (5 levels) for urine	933080	5x10 ml
Single level Calibrators		
Human urine matrix (Negative)	933010	1x10 ml
Human urine matrix (Negative)	933015	4x10 ml
EDDP calibrator (Cut-off 300 ng/ml)	932955	1x10 ml
ECSTASY calibrator (Cut-off 500 ng/ml)	932935	1x10 ml
CANNABINOID calibrator Low Cut-off (20 ng/ml)	933071	1x4 ml
CANNABINOID calibrator High Cut-off (50 ng/ml)	933072	1x4 ml
BENZODIAZEPINES calibrator Low Cut-off (200 ng/ml)	933081	1x10 ml
BENZODIAZEPINES calibrator High Cut-off (300 ng/ml)	933082	1x10 ml
Multidrug Calibrator for urine High Cut-offs AMP / COC / MTD / COT / OPI / BAR	932915	1x10 ml
Multidrug Calibrator for urine Low Cut-offs AMP / COC / MTD / COT / OPI / BAR	932910	4x10 ml

Drugs of Abuse (DOA) Controls

 Product	Ref	Packaging
Multidrug Control for urine Low Cut-offs AMP / COC / MTD / COT / OPI / BAR	935910	4x10 ml
Multidrug Control for urine High Cut-offs AMP / COC / MTD / COT / OPI / BAR	935915	4x10 ml
BENZODIAZEPINES control Low Cut-off (200 ng/ml)	936081	4x10 ml
BENZODIAZEPINES control High Cut-off (300 ng/ml)	936082	4x10 ml
CANNABINOID control Low Cut-off (20 ng/ml)	936071	4x4 ml
CANNABINOID control High Cut-off (50 ng/ml)	936072	4x4 ml
ECSTASY control (Cut-off 500 ng/ml)	935935	4x10 ml
EDDP control (Cut-off 300 ng/ml)	935955	4x10 ml

Product	Ref	Packaging	
Anti Streptolysin O (ASO) IMT			
Quantitative immunoturbidimetric test, reading in fixed time, one point calibration curve. Stable, liquid and ready to use reagents (R1= Diluent, R2=Latex), 9+1 ratio. Sample: serum. Can be used as two-reagents for automation or as monoreagent preparing a working solution (9+1, stability of 30 days at 2-8°C). Calibrator is included. Multiparametric Controls are separately supplied (ASO/CRP/RF Control, Low Values, REF LTCON01 and ASO/CRP/RF Control, High Values, REF LTCON02).	LT001	R1 1x 45 ml + R2 1x 5 ml	
	LT111	R1 2x115 ml + R2 1x25 ml	
C Reactive Protein (CRP) IMT			
Quantitative immunoturbidimetric test, reading in fixed time, one point calibration curve. Stable, liquid and ready to use reagents (R1= Diluent, R2=Latex), 9+1 ratio. Sample: serum. Can be used as two-reagents for automation or as monoreagent preparing a working solution (9+1, stability of 30 days at 2-8°C). Calibrator is included. Multiparametric Controls are separately supplied (ASO/CRP/RF Control, Low Values, REF LTCON01 and ASO/CRP/RF Control, High Values, REF LTCON02).	LT002	R1 1x 45 ml + R2 1x 5 ml	
	LT222	R1 2x115 ml + R2 1x25 ml	
Rheumatoid Factors (RF) IMT			
Quantitative immunoturbidimetric test, reading in fixed time, one point calibration curve. Stable, liquid and ready to use reagents (R1= Diluent, R2=Latex). Lyophilized calibrator is included. Sample: serum or plasma. Multiparametric controls are separately supplied (ASO/CRP/RF Control Low Values REF LTCON01 and ASO/CRP/RF Control High Values REF LTCON02).	LT003	R1 1x 45 ml + R2 1x 5 ml	
	LT333	R1 2x115 ml + R2 1x25 ml	
Direct HbA1c IMT			
Determination of Glyco-Haemoglobin HbA1c. Procedure provides for direct testing of percentage of specific HbA1c fraction (by immunoturbidimetric method using a monoclonal antibody latex coated). Liquid, stable and ready to use reagents can work on the most common clinical chemistry instrument. Sample: whole blood subject to pre-treatment before use (hemolysis). Lyophilized HbA1c Direct Calibration Set and HbA1c Direct Controls Set (whole blood) are separately supplied as respectively REF 4582 and REF 4583.	HH4580	R1 1x35 ml + R2 1x7 ml	
	B24-4580	R1 1x25 ml + R2 1x5 ml	
Hemolysis Reagent			
Reagent used for hemolyze erythrocytes to determine HbA1c.	4581	3x100 ml	
Microalbumin IMT			
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Diluent, R2= Antiserum). Urinary testing. Ready to use calibrator and control are separately supplied as respectively REF MALCAL, REF MALCON and MALCON LOW.	IM012	R1 1x50 ml + R2 1x5 ml	
Apolipoprotein A1 IMT			
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Diluent, R2= Antiserum). Sample: serum. Ready to use calibrator and control are separately supplied as respectively REF APOCAL and REF APOCON.	IM013	R1 1x50 ml + R2 1x5 ml	
Apolipoprotein B IMT			
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Diluent, R2= Antiserum). Sample: serum. Ready to use calibrator and control are separately supplied as respectively REF APOCAL and REF APOCON.	IM014	R1 1x50 ml + R2 1x5 ml	
Lipoprotein (a) IMT			
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Diluent, R2= Antiserum). Sample: serum. Liquid and ready to use Calibrator and Control are separately supplied as respectively REF LPACAL and LPACON.	IM020	R1 1x50 ml + R2 1x5 ml	
C3 Complement IMT			
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Diluent, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.	IM004	R1 1x50 ml + R2 1x5 ml	

	Product	Ref Packaging
C4 Complement IMT		
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Diluent, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.		IM005 R1 1x50 ml + R2 1x5 ml
Immunoglobulin A IMT (IgA)		
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Diluent, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.		IM002 R1 1x50 ml + R2 1x5 ml
Immunoglobulin G IMT (IgG)		
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Diluent, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.		IM001 R1 1x50 ml + R2 1x5 ml
Immunoglobulin M IMT (IgM)		
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Diluent, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.		IM003 R1 1x50 ml + R2 1x5 ml
Immunoglobulin E IMT (IgE)		
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Diluent, R2= Latex). Sample: serum. Liquid and ready to use calibrator and control are separately supplied as respectively REF LTCAL06 and REF LTCON06.		LT006 R1 1x20 ml + R2 1x10 ml
Kappa Light Chain IMT		
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Buffer, R2= Antiserum). Sample: urine (Bence Jones Protein) or serum, on depending of calibration system used. Serum research requires liquid and ready to use Multicalibrator IMT and Multiparametric Control, separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW. Urinary research requires liquid and ready to use Pediatric Calibrator and Pediatric Control separately supplied as respectively REF IMPED and REF PEDCON.		IM011 R1 1x50 ml + R2 1x5 ml
Lambda Light Chain IMT		
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Buffer, R2= Antiserum). Sample: urine (Bence Jones Protein) or serum, on depending of calibration system used. Serum research requires liquid and ready to use Multicalibrator IMT and Multiparametric Control, separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW. Urinary research requires liquid and ready to use Pediatric Calibrator and Pediatric Control separately supplied as respectively REF IMPED and REF PEDCON.		IM010 R1 1x50 ml + R2 1x5 ml
Antithrombin III IMT		
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Buffer, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.		IM008 R1 1x50 ml + R2 1x5 ml
Fibrinogen IMT		
Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Buffer, R2= Antiserum). Sample: plasma. Lyophilized calibrator and control are separately supplied as respectively REF FIBCAL and REF FIBCON.		IM009 R1 1x50 ml + R2 1x5 ml

Product	Ref	Packaging
Alpha 1 Acid Glycoprotein IMT Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Buffer, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.	IM007	R1 1x50 ml + R2 1x5 ml
Alpha 1 Antitrypsin IMT Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Buffer, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.	IM016	R1 1x50 ml + R2 1x5 ml
Ceruloplasmin IMT Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Buffer, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.	IM017	R1 1x50 ml + R2 1x5 ml
Ferritin IMT Quantitative immunoturbidimetric test, multipoint calibration curve. Stable, liquid and ready to use reagents (R1= Diluent, R2=Latex). Sample: serum. Liquid and ready to use set of calibration included (SET CAL 5x1 ml). Liquid, stable and ready to use controls, are separately supplied as REF IMCON and REF IMCONLOW.	LT009	R1 1x30 ml + R2 1x10 ml
Transferrin IMT Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Buffer, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.	IM006	R1 1x50 ml + R2 1x5 ml
Haptoglobin IMT Quantitative immunoturbidimetric test, reading in fixed time, multipoint calibration curve. Stable, liquid and ready to use reagents (R1=Buffer, R2= Antiserum). Sample: serum. Liquid and ready to use Multicalibrator and Multiparametric Control are separately supplied as respectively REF IMCAL01 and REF IMCON and IMCONLOW.	IM015	R1 1x50 ml + R2 1x5 ml
EZ Vitamin D Quantitative determination of 25-(OH) D levels in serum or plasma, on automated chemistry analyzers, and for the assessment of Vitamin D sufficiency. The kit contains 2 liquid stable reagents. Calibrator set DZ888A-CAL 5x1 ml are sold separately.	DZ888A	R1 1x40 ml + R2 1x10 ml

The REF that begins with **HH** has the packaging suitable for the most common automatic analyzers and specific barcode for Tokyo Boeki **Biolis 50i** and, on request, the barcodes for **Hitachi 911-912**.

The REF with **B24** has the dedicated packaging and barcode for Tokyo Boeki **Biolis 24i** and **Biolis 30i**, with 36 positions plate reagents.

Futura System Group Immunoturbidimetry Reagents work successfully on all "Open System" and on the most common automatic analyzers in the market.

Specific applications are available for the most common clinical chemistry instruments and can be required at info@futuresystem.it or to your local distributor.

Product	Ref	Packaging
ASO-CRP-RF Control low values IMT Multiparametric control, human matrix, low levels. Standardized against: - International Standard from NIBSC 97/662 for ASO. - ERM-DA 472/IFCC Reference Material for CRP. - International Reference Standard from NIBSC 64/002 for RF.	LTCON01	2x1 ml
ASO-CRP-RF Control high values IMT Multiparametric control, human matrix, high levels. Standardized against: - International Standard from NIBSC 97/662 for ASO. - ERM-DA 472/IFCC Reference Material for CRP. - International Reference Standard from NIBSC 64/002 for RF.	LTCON02	2x1 ml
HbA1c Direct Calibration Set IMT Set of calibrators for HbA1c Direct by immunoturbidimetric methods (REF 4580). Five scaled concentrations (as percentage), lyophilized human whole blood (stability: 1 month after rehydration), referred to NGSP/DCCT standard.	4582	1x2 ml Liquid + 4x0,5 ml Liophilized
HbA1c Direct Control Set IMT Set of controls for HbA1c Direct by immunoturbidimetric methods (REF 4580). Two levels, high and low (as percentage), lyophilized human whole blood (stability: 1 month after rehydration), referred to NGSP/DCCT standard.	4583	2x0,5 ml
Microalbumin Calibrator IMT Defibrinated human plasma. Stable, liquid and ready to use, high concentration to dilute (scaled values). Referred to RPPHS/CRM 470 International Standard.	MALCAL	1x1 ml
Microalbumin Control IMT Defibrinated human plasma. Stable, liquid and ready to use. Referred to RPPHS/CRM 470 International Standard.	MALCON	1x1 ml
Microalbumin Control Low IMT New Defibrinated human plasma. Stable, liquid and ready to use. Referred to RPPHS/ERM-DA470 International Standard.	MALCONLOW	1x1 ml
Apolipoprotein Calibrator IMT Stabilized and buffered human plasma, liquid and ready to use, high concentration to dilute (scaled values). Referred to IFCC SSRM Apo A1 Reference and to IFCC SSRM Apo B Reference.	APOCAL	1x1 ml
Apolipoprotein Control IMT Stabilized and buffered human plasma, liquid and ready to use. Referred to IFCC SSRM Apo A1 Reference and to IFCC SSRM Apo B Reference.	APOCON	1x1 ml
Lipoprotein (a) Calibrator IMT Stabilized and buffered human plasma, liquid and ready to use, high concentration to dilute (scaled values). Referred to WHO/IFCC SSRM 2B International Standard.	LPACAL	1x1 ml
Lipoprotein (a) Control IMT Stabilized and buffered human plasma, liquid and ready to use. Referred to WHO/IFCC SSRM 2B International Standard.	LPACON	1x1 ml
Multicalibrator IMT Set of multiparametric calibrators for specific plasma proteins (C3, C4, IgA, IgG, IgM, Antithrombin III, a1-Acid Glycoprotein, a1- Antitrypsin, Ceruloplasmin, Transferrin, Haptoglobin, a2-Macroglobulin, serum Kappa Light Chain, serum Lambda Light Chain). Five scaled concentrations, liquid and ready to use, human matrix. Referred to International Standard CRM 470 for each protein and to Dade Behring Standard Material for Kappa/Lambda Light Chain.	IMCAL01	5x1 ml

Product	Ref	Packaging	
Control High IMT Multiparametric controls for specific plasma proteins (C3, C4, IgA, IgG, IgM, Antithrombin III, a1-Acid Glycoprotein, a1- Antitrypsin, Ceruloplasmin, Transferrin, Ferritin, Haptoglobin, a2-Macroglobulin, serum Kappa Light Chain, serum Lambda Light Chain). Liquid and ready to use, human matrix. Referred to International Standard CRM 470 for each protein and to Dade Behring Standard Material for Kappa/Lambda Light Chain.	IMCON	2x1 ml	
Control Low IMT Multiparametric controls for specific plasma proteins (C3, C4, IgA, IgG, IgM, Antithrombin III, a1-Acid Glycoprotein, a1- Antitrypsin, Ceruloplasmin, Transferrin, Ferritin, Haptoglobin, a2-Macroglobulin, serum Kappa Light Chain, serum Lambda Light Chain). Liquid and ready to use, human matrix. Referred to International Standard CRM 470 for each protein and to Dade Behring Standard Material for Kappa/Lambda Light Chain.	IMCONLOW	2x1 ml	
Pediatric Calibrator IMT Stabilized and buffered human plasma, liquid and ready to use, high concentration to dilute (scaled values). To calibrate serum Immunoglobulins (IgA, IgG and IgM) and serum Transferrin in pediatric samples. Also, to calibrate Kappa/ Lambda Light Chain in urine testing (Bence Jones Protein). Referred to International Standard CRM 470 for each protein and to Dade Behring Standard Material for urinary Kappa/Lambda Light Chain.	IMPED	1x1 ml	
Pediatric Control IMT Stabilized and buffered human plasma, liquid and ready to use. To Quality Control for specific plasma proteins (serum IgA, IgG and IgM and serum Transferrin in pediatric samples), also for Kappa/ Lambda Light Chain in urinary testing (Bence Jones Protein). Referred to International Standard CRM 470 for each serum protein and to Dade Behring Standard Material for urinary Kappa/ Lambda Light Chain.	PEDCON	1x1 ml	
IgE Calibrator IMT Stabilized and buffered human plasma, liquid and ready to use, high concentration to dilute (scaled values). Referred to International Reference Preparation of Human IgE (75/502) (2nd IRP, 1981).	LTCAL06	1x1 ml	
IgE Control IMT Stabilized and buffered human plasma, liquid and ready to use. Referred to International Reference Preparation of Human IgE (75/502) (2nd IRP, 1981).	LTCON06	1x1 ml	
Fibrinogen Calibrator IMT Stabilized and buffered human plasma, lyophilized, high concentration to dilute (scaled values).	FIBCAL	1x0,5 ml	
Fibrinogen Control IMT Stabilized and buffered human plasma, lyophilized.	FIBCON	1x1 ml	
EZ Vitamin D Calibrator Set IMT Five levels liquid, stable and ready to use.	DZ888A-CAL	5x1 ml	
EZ Vitamin D Control IMT Two levels liquid, stable and ready to use.	DZ888A-CON	2x1 ml	

Reagents, Calibrators and Controls Reference Table



Product	Ref	Packaging	CAL	CTR
Anti Streptolysin O (ASO) IMT	LT001 LT111	R1 1x 45 ml + R2 1x 5 ml R1 2x115 ml + R2 1x25 ml	Inside the kit	LTCON01 - LTCON02
C Reactive Protein (CRP) IMT	LT002 LT222	R1 1x 45 ml + R2 1x 5 ml R1 2x115 ml + R2 1x25 ml	Inside the kit	LTCON01 - LTCON02
Rheumatoid Factors (RF) IMT	LT003 LT333	R1 1x 45 ml + R2 1x 5 ml R1 2x115 ml + R2 1x25 ml	Inside the kit	LTCON01 - LTCON02
Direct HbA1c IMT	HH4580 B24-4580	R1 1x35 ml + R2 1x7 ml R1 1x25 ml + R2 1x5 ml	4582 (Lyo) 4582 (Lyo)	4583 (Lyo) 4583 (Lyo)
Microalbumin IMT	IM012	R1 1x50 ml + R2 1x5 ml	MALCAL	MALCON - MALCONLOW
Apolipoprotein A1 IMT	IM013	R1 1x50 ml + R2 1x5 ml	APOCAL	APOCON
Apolipoprotein B IMT	IM014	R1 1x50 ml + R2 1x5 ml	APOCAL	APOCON
Lipoprotein (a) IMT	IM020	R1 1x50 ml + R2 1x5 ml	LPACAL	LPACON
C3 Complement IMT	IM004	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
C4 Complement IMT	IM005	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Immunoglobulin A IMT (IgA)	IM002	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Immunoglobulin G IMT (IgG)	IM001	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Immunoglobulin M IMT (IgM)	IM003	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Immunoglobulin E IMT (IgE)	LT006	R1 1x20 ml + R2 1x10 ml	LTCAL06	LTCON06
Kappa Light Chain IMT(Serum)	IM011	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Lambda Light Chain IMT(Serum)	IM010	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Kappa Light Chain IMT(Urine)	IM011	R1 1x50 ml + R2 1x5 ml	IMPED	PEDCON
Lambda Light Chain IMT(Urine)	IM010	R1 1x50 ml + R2 1x5 ml	IMPED	PEDCON
Antithrombin III IMT	IM008	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Fibrinogen IMT	IM009	R1 1x50 ml + R2 1x5 ml	FIBCAL (Lyo)	FIBCON (Lyo)
Alpha 1 Acid Glycoprotein IMT	IM007	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Alpha 1 Antitrypsin IMT	IM016	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Ceruloplasmin IMT	IM017	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Ferritin IMT	LT009	R1 1x30 ml + R2 1x10 ml	Inside the kit	IMCONLOW - IMCON
Transferrin IMT	IM006	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
Haptoglobin IMT	IM015	R1 1x50 ml + R2 1x5 ml	IMCAL01	IMCONLOW - IMCON
EZ Vitamin D IMT	DZ888A	R1 1x40 ml + R2 1x10 ml	DZ888A-CAL	DZ888A-CON


Liquid Coagulation Line: Reagents, Calibrators and Controls

Product	Ref	Packaging	
Thromboplastin "L" Liquid rabbit brain Thromboplastin to determine Prothrombin Time (PT). Reagent stability is of 60 days at 2-8 °C. Highly sensible to the deficiency of "extrinsic" pathway Factors II,V,VII,X. Assigned ISI and MNPT for a wide range of coagulometers (Coatron A4, Sysmex series, ACL, CoaDATA, KSELMED, Behnk).	CH111	10x5 ml	
PT Calibration curve Lyophilized human plasma (4 levels of PT Calibrans) to rehydrate with distilled water. Stability: 1 hours after reconstitution. Intended for establish a % PT Calibration Curve, generating an INR Reference Curve for the direct INR determination of a patient sample; generating specific ISI and MNPT values for the system, reagent and instrument combination used by the laboratory.	CH021	4x1 ml	
Coagulation Calibrator Lyophilized human plasma to rehydrate with distilled water. Stability: 2 hours at 2-8°C. Calibration Plasma may be used as a reference plasma when assaying for Factors II, V, VII, VIII, IX, X1, XI, XII2, fibrinogen, von Willebrand Factor, antigenic and functional Protein C and Protein S (total and free), Antithrombin (AT) III, Protein C, Factor VIII, Plasminogen and PT on instruments that require one point calibration.	CH022	5x1 ml	
APTT SI + CALCIUM CHLORIDE Activated Partial Thromboplastin Time reagents. Liquid, stable and ready to use reagents. The kit includes APTT reagent containing phospholipids and silica contact activator and Calcium Chloride 0.025 M.	CH224	10x4 ml + 10x4 ml	
Clauss Fibrinogen 100 NIH/ml Fibrinogen quantitative assay according to Clauss. Lyophilized Thrombin reagent and Imidazole Buffer in the kit. Stability of reconstituted thrombin: 8 hours at 15-20°C, 7 days at 2-8°C, 2 months at -20°C in the original vial. Depending on used coagulometer, could be need to reconstitute the Thrombin Reagent with the Kaolin (REF CH008) instead of distilled water, separately supplied. The Imidazole Buffer (4x25 ml) is need to make dilution of the calibrator, controls and samples.	CH100A	10x2 ml + 4x25 ml	
Kaolin Suspension Auxiliary reagent for manual assays of according to Clauss Fibrinogen 100 NIH/ml (REF CH100) when it is required from coagulometer type. Liquid, stable and ready to use reagent.	CH008	1x50 ml	
Fibrinogen Calibrator Lyophilized human plasma to rehydrate with distilled water. To dilute forming scaled concentrations to calibrate exclusively Clauss Fibrinogen 100 NIH/ml assay.	CH020	10x1 ml	
Clauss Fibrinogen 35 NIH/ml Fibrinogen quantitative assay according to Clauss. Lyophilized Thrombin reagent and Imidazole Buffer in the kit. Stability of reconstituted thrombin: 8 hours at 15-20°C, 7 days at 2-8°C, 2 months at -20°C in the original vial. Reconstitute the reagent with distilled water. The Imidazole Buffer (1x25 ml) is need to make dilution of the calibrator, controls and samples. Dedicated calibrator included (1x1 ml).	CH035A	5x2 ml + 1x25 ml + 1x1 ml	
Clauss Fibrinogen 50 NIH/ml Fibrinogen quantitative assay according to Clauss. Lyophilized Thrombin reagent and Imidazole Buffer in the kit. Stability of reconstituted thrombin: 8 hours at 15-20°C, 7 days at 2-8°C, 2 months at -20°C in the original vial. Reconstitute the reagent with distilled water. The Imidazole Buffer (2x25 ml) is need to make dilution of the calibrator, controls and samples. Dedicated calibrator included (2x1 ml).	CH050A	5x4 ml + 2x25 ml + 2x1 ml	
Thrombin Time The Thrombin Time reagent is intended to give a qualitative indication of abnormal Fibrinogen levels or the presence of interfering substances such as Fibrin Degradation Products or Heparin.	CH030	10x2 ml	
Normal Control Plasma Lyophilized human plasma to rehydrate with distilled water. Stability: 24 hours at 2-8°C. PT, APTT, Fibrinogen, TT, Derived Fibrinogen, Antithrombin Xa reference values and ranges for a wide range of coagulometers (Coatron A4, Sysmex series, ACL, CoaDATA, Amelung, Behnk).	CH004	10x1 ml	
Abnormal Control Plasma Lyophilized human plasma to rehydrate with distilled water. Stability: 24 hours at 2-8°C. PT, APTT, Fibrinogen, TT, Derived Fibrinogen, Antithrombin Xa reference values and ranges for a wide range of coagulometers (Coatron A4, Sysmex series, ACL, CoaDATA, Amelung, Behnk).	CH005	10x1 ml	

Reagents, Calibrators and Controls Reference Table

 Product	Ref	Packaging	CAL	CTR
Thromboplastin "L"	CH111	10x5 ml	CH021-CH022	CH004-CH005
APTT SI + Calcium Chloride	CH224	10x4 ml + 10x4 ml	NA	CH004-CH005
Clauss Fibrinogen 100 NIH/ml	CH100A	10x2 ml + 4x25 ml	CH020	CH004-CH005
Clauss Fibrinogen 50 NIH/ml	CH050A	5x4 ml + 2x25 ml + 2x1 ml	incluso nel kit	CH004-CH005
Clauss Fibrinogen 35 NIH/ml	CH035A	5x2 ml + 1x25 ml + 1x1 ml	incluso nel kit	CH004-CH005
Kaolin Suspension (auxiliary reagent for FIBRINOGEN)	CH008	1x50 ml	NA	NA
Thrombin Time	CH030	10x2 ml	NA	CH004-CH005

Reagents Coagulometers Compatibility Matrix

 Product	Ref	ACL series	Coatron AC-4	Sysmex series KG500 Rayto RAC-050	Behnk Systems	ACF (Opto-mechanical)	Manual Coagulometer
Thromboplastin "L"	CH111	■	■	■	■	■	■
APTT SI + Calcium Chloride	CH224	■	■	■	■	■	■
Clauss Fibrinogen 100 NIH/ml	CH100A			■	■	■	■
Clauss Fibrinogen 50 NIH/ml	CH050A		■				
Clauss Fibrinogen 35 NIH/ml	CH035A	■					
Kaolin Suspension	CH008					■	■
PT Calibration Curve	CH021		■	■	■	■	■
Coagulation Calibrator	CH022	■					
Normal Control Plasma	CH004	■	■	■	■	■	■
Abnormal Control Plasma	CH005	■	■	■	■	■	■
Thrombin Time	CH030	■	■	■	■	■	■

Product	Ref	Packaging
Immunoglobulin G (IgG) RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR103	1x15 Tests
Immunoglobulin A (IgA) RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR104	1x15 Tests
Immunoglobulin M (IgM) RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR105	1x15 Tests
Alpha 1 Acid Glycoprotein RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR116	1x15 Tests
Antithrombin III RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR123	1x15 Tests
Apolipoprotein A1 RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR113	1x15 Tests
Apolipoprotein B RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR114	1x15 Tests
C3 Complement RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR106	1x15 Tests
C4 Complement RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR107	1x15 Tests
Fibrinogen RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR122	1x15 Tests
Transferrin RID Quantitative method according to Mancini. Rectangular plate with 15 wells.	IR109	1x15 Tests

Urinary Proteins

Product	Ref	Packaging
Bence Jones Protein RID Qualitative method by double immunodiffusion reaction according to Ouchterlony. Complete kit containing 15 plates, anti kappa and lambda chain antisera and control. Each plate performs simultaneously both kappa and lambda chain for every urinary sample.	IR021	15x2 Tests

Controls

Product	Ref	Packaging
Control High IMT Multiparametric controls for specific plasma proteins (C3, C4, IgA, IgG, IgM, Antithrombin III, a1-Acid Glycoprotein, a1- Antitrypsin, Ceruloplasmin, Transferrin, Ferritin, Haptoglobin, a2-Macroglobulin, serum Kappa Light Chain, serum Lambda Light Chain). Liquid and ready to use, human matrix. Referred to International Standard CRM 470 for each protein and to Dade Behring Standard Material for Kappa/Lambda Light Chain.	IMCON	2x1 ml

Controls

Product	Ref	Packaging
Control Low IMT		
Multiparametric controls for specific plasma proteins (C3, C4, IgA, IgG, IgM, Antithrombin III, a1-Acid Glycoprotein, a1- Antitrypsin, Ceruloplasmin, Transferrin, Ferritin, Haptoglobin, a2-Macroglobulin, serum Kappa Light Chain, serum Lambda Light Chain). Liquid and ready to use, human matrix. Referred to International Standard CRM 470 for each protein and to Dade Behring Standard Material for Kappa/Lambda Light Chain.	IMCONLOW	2x1 ml
Apolipoprotein Control IMT		
Stabilized and buffered human plasma, liquid and ready to use. Referred to IFCC SSRM Apo A1 Reference and to IFCC SSRM Apo B Reference.	APOCON	1x1 ml
Fibrinogen Control IMT		
Stabilized and buffered human plasma, lyophilized.	FIBCON	1x1 ml

Reagents, Calibrators and Controls Reference Table

Special Plasmatic Proteins			
Product	Ref	Packaging	CTR
Immunoglobulin G (IgG) RID	IR103	1x15 Tests	IMCONLOW-IMCON
Immunoglobulin A (IgA) RID	IR104	1x15 Tests	IMCONLOW-IMCON
Immunoglobulin M (IgM) RID	IR105	1x15 Tests	IMCONLOW-IMCON
Alpha 1 Acid Glycoprotein RID	IR116	1x15 Tests	IMCONLOW-IMCON
Antithrombin III RID	IR123	1x15 Tests	IMCONLOW-IMCON
Apolipoprotein A1 RID	IR113	1x15 Tests	APOCON (Liq.)
Apolipoprotein B RID	IR114	1x15 Tests	APOCON (Liq.)
C3 Complement RID	IR106	1x15 Tests	IMCONLOW-IMCON
C4 Complement RID	IR107	1x15 Tests	IMCONLOW-IMCON
Fibrinogen RID	IR122	1x15 Tests	FIBCON
Transferrin RID	IR109	1x15 Tests	IMCONLOW-IMCON
Urinary Proteins			
Product	Ref	Packaging	CTR
Bence Jones Protein RID	IR021	15x2 Tests	IMCONLOW-IMCON

Rheumatology - Slide test

Product	Ref	Packaging
Anti-Streptolysin O (ASO) Latex agglutination slide test. Qualitative and semiquantitative test. Complete kit containing latex reagent, positive and negative controls and disposables.	ND101	100 Tests
Anti-Streptolysin O (ASO) Latex agglutination slide test. Qualitative and semiquantitative test. Only latex reagent.	ND111	100 Tests
C-Reactive Protein (CRP) Latex agglutination slide test. Qualitative and semiquantitative test. Complete kit containing latex reagent, positive and negative controls and disposables.	ND202	100 Tests
C-Reactive Protein (CRP) Latex agglutination slide test. Qualitative and semiquantitative test. Only latex reagent.	ND222	100 Tests
Rheumatoid Factor (RF) Latex agglutination slide test. Qualitative and semiquantitative test. Complete kit containing latex reagent, positive and negative controls and disposables.	ND303	100 Tests
Rheumatoid Factor (RF) Latex agglutination slide test. Qualitative and semiquantitative test. Only latex reagent.	ND333	100 Tests
Waler Rose Haemo-agglutination slide test. Complete kit containing reagent, positive and negative controls and disposables.	SH009	100 Tests
Anti-n-DNA Research of typical auto-antibodies of Lupus Erythematosus. Latex agglutination slide test. Complete kit containing reagent, positive and negative controls and disposables.	SH060	20 Tests

Syphilis Serodiagnosis

Product	Ref	Packaging
RPR Charcoal agglutination slide test. Complete kit containing reagent, positive and negative controls and disposables.	HRPR01 HRPR03	500 Tests 150 Tests
TPHA Indirect haemo-agglutination test on microplates. Complete kit containing reagents, positive and negative controls and disposables.	HRPR02	100 Tests

Infectivity - Slide test

Product	Ref	Packaging
Infectious Mononucleosis Latex agglutination slide test. Complete kit containing reagent, positive and negative controls and disposables.	SH070	50 Tests

Widal Wright Serodiagnosis

Product	Ref	Packaging
Salmonella Typhi AgO Coloured inactive bacterial suspension of antigen O (somatic) Salmonella Typhi for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW10	1x20 ml
Coloured inactive bacterial suspension of antigen O (somatic) Salmonella Typhi for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF10	1x5 ml

Widal Wright Serodiagnosis

Product	Ref	Packaging
Salmonella Typhi AgH Coloured inactive bacterial suspension of antigen H (flagellar) Salmonella Typhi for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW11	1x20 ml
Coloured inactive bacterial suspension of antigen H (flagellar) Salmonella Typhi for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF11	1x5 ml
Salmonella Typhi Total Coloured inactive bacterial suspension of antigens O and H Salmonella Typhi for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW12	1x20 ml
Coloured inactive bacterial suspension of antigens O and H Salmonella Typhi for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF12	1x5 ml
Salmonella Paratyphi A AgO Coloured inactive bacterial suspension of antigen O (somatic) Salmonella Paratyphi A for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW13	1x20 ml
Coloured inactive bacterial suspension of antigen O (somatic) Salmonella Paratyphi A for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF13	1x5 ml
Salmonella Paratyphi A AgH Coloured inactive bacterial suspension of antigen H (flagellar) Salmonella Paratyphi A for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW14	1x20 ml
Coloured inactive bacterial suspension of antigens H (flagellar) Salmonella Paratyphi A for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF14	1x5 ml
Salmonella Paratyphi A Total Coloured inactive bacterial suspension of antigens O and H Salmonella Paratyphi A for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW15	1x20 ml
Coloured inactive bacterial suspension of antigens O and H Salmonella Paratyphi A for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF15	1x5 ml
Salmonella Paratyphi B AgO Coloured inactive bacterial suspension of antigen O (somatic) Salmonella Paratyphi B for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW16	1x20 ml
Coloured inactive bacterial suspension of antigen O (somatic) Salmonella Paratyphi B for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF16	1x5 ml
Salmonella Paratyphi B AgH Coloured inactive bacterial suspension of antigen H (flagellar) Salmonella Paratyphi B for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW17	1x20 ml
Coloured inactive bacterial suspension of antigen H (flagellar) Salmonella Paratyphi B for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF17	1x5 ml
Salmonella Paratyphi B Total Coloured inactive bacterial suspension of antigens O and H Salmonella Paratyphi B for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW18	1x20 ml
Coloured inactive bacterial suspension of antigens O and H Salmonella Paratyphi B for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF18	1x5 ml

Product	Ref	Packaging
Salmonella Paratyphi C AgO		
Coloured inactive bacterial suspension of antigen O (somatic) Salmonella Paratyphi C for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW23	1x20 ml
Coloured inactive bacterial suspension of antigen O (somatic) Salmonella Paratyphi C for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF23	1x5 ml
Salmonella Paratyphi C AgH		
Coloured inactive bacterial suspension of antigen H (flagellar) Salmonella Paratyphi C for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW22	1x20 ml
Coloured inactive bacterial suspension of antigen H (flagellar) Salmonella Paratyphi C for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF22	1x5 ml
Salmonella Paratyphi C Total		
Coloured inactive bacterial suspension of antigen O and H Salmonella Paratyphi C for the quantitative determination of the antibodies by agglutination in tube test , according to Widal.	WW24	1x20 ml
Coloured inactive bacterial suspension of antigens O and H Salmonella Paratyphi C for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal.	WF24	1x5 ml
Proteus OX19		
Coloured inactive bacterial suspension for the quantitative determination of the antibodies associated to Rickettsie by agglutination in tube test .	WW25	1x20 ml
Coloured inactive bacterial suspension for the qualitative determination of the antibodies associated to Rickettsie by agglutination on slide and the quantitative determination on microplates.	WF25	1x5 ml
Proteus OX2		
Coloured inactive bacterial suspension for the quantitative determination of the antibodies associated to Rickettsie by agglutination in tube test .	WW26	1x20 ml
Coloured inactive bacterial suspension for the qualitative determination of the antibodies associated to Rickettsie by agglutination on slide and the quantitative determination on microplates.	WF26	1x5 ml
Proteus OXK		
Coloured inactive bacterial suspension for the quantitative determination of the antibodies associated to Rickettsie by agglutination in tube test .	WW27	1x20 ml
Coloured inactive bacterial suspension for the qualitative determination of the antibodies associated to Rickettsie by agglutination on slide and the quantitative determination on microplates.	WF27	1x5 ml
Brucella Total		
Coloured inactive bacterial suspension of Brucella for the quantitative determination of the antibodies by agglutination in tube test , according to Wright.	WW19	1x20 ml
Coloured inactive bacterial suspension of antigens Brucella for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Wright.	WF19	1x5 ml
Brucella Melitensis		
Coloured inactive bacterial suspension of Brucella Melitensis for the quantitative determination of the antibodies by agglutination in tube test , according to Wright.	WW20	1x20 ml
Coloured inactive bacterial suspension of antigens Brucella Melitensis for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Wright.	WF20	1x5 ml

Widal Wright Serodiagnosis

Product	Ref	Packaging
Brucella Abortus Coloured inactive bacterial suspension of Brucella Abortus for the quantitative determination of the antibodies by agglutination in tube test , according to Wright.	WW28	1x20 ml
Coloured inactive bacterial suspension of antigens Brucella Abortus for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Wright.	WF28	1x5 ml
Brucella Suis Coloured inactive bacterial suspension of Brucella Suis for the quantitative determination of the antibodies by agglutination in tube test , according to Wright.	WW29	1x20 ml
Widal Complete Kit for tube test Bacterial suspension for quantitative determination of the antibodies by agglutination in tube test , according to Widal. Complete kit containing the following bacterial suspensions: Salmonella Typhi AgO, AgH and total. Salmonella Paratyphi A AgO, AgH and total. Salmonella Paratyphi B AgO, AgH and total. Salmonella Paratyphi C AgO, AgH and total.	WW30	12x20 ml
Widal-Wright Kit for tube test Bacterial suspension for quantitative determination of the antibodies by agglutination in tube test , according to Widal and Wright. Multiple kit containing the following bacterial suspensions: Salmonella Typhi AgO, AgH. Salmonella Paratyphi A AgO, AgH. Salmonella Paratyphi B AgO, AgH. Salmonella Paratyphi C total. Brucella total.	WW31	8x20 ml
Widal-Wright Kit minor for rapid slide test Bacterial suspension for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal-Wright. Kit containing the following bacterial suspensions: Salmonella Typhi AgO, AgH. Salmonella Paratyphi A total. Salmonella Paratyphi B total. Brucella total.	WF35	5x5 ml
Widal-Wright Kit maior for rapid slide test Bacterial suspension for the qualitative determination of the antibodies by agglutination on slide and the quantitative determination on microplates, according to Widal-Wright. Kit containing the following bacterial suspensions: Salmonella Typhi AgO, AgH. Salmonella Paratyphi A AgO, AgH. Salmonella Paratyphi B AgO, AgH. Brucella total.	WF37	7x5 ml
WW SERIES (1x20ml) – Bacterial Suspensions for TUBE Tests 40 TESTS (500 µl/test) 16-18h at 37°C. WF SERIES (1x 5ml) – Bacterial Suspensions for SLIDE 100 TESTS (50µl/test) and MICROPLATE 500 Tests (10 µl/test) 24h at 37°C or 4h at 52°C. Controls and consumables available separately.		

Controls and Consumables


Product	Ref	Packaging
Salmonella Control Kit Salmonella positive control and negative control. Use in conjunction with Widal Wright serodiagnosis tests.	WW50	1x0,5 ml + 1x0,5 ml
Brucella Control Kit Brucella positive control and negative control. Use in conjunction with Widal Wright serodiagnosis tests.	WW51	1x0,5 ml + 1x0,5 ml
Proteus Control Kit Proteus positive control and negative control. Use in conjunction with Widal Wright serodiagnosis tests.	WW52	1x0,5 ml + 1x0,5 ml
Slide light background Six area slides. Use in conjunction with Widal Wright serodiagnosis tests REF WF .	WF100	50 pcs
Stirrer Use in conjunction with Widal Wright serodiagnosis tests REF WF for qualitative assay.	WF102	10x25 pcs
Microplate U-well 96 positions microplate. Use in conjunction with Widal Wright serodiagnosis tests REF WF for quantitative assay.	WF101	3 pcs

Product	Ref	Packaging	
Fetal Fibronectin (fFN) Visually interpreted, qualitative immunochromatographic test device for detection of fFN in vaginal secretions during pregnancy.	New	CR533	25 Tests
Insulin-like Growth Factor-Binding Protein 1 (IGFBP-1) Visually interpreted, qualitative immunochromatographic test for detection of IGFBP-1 in vaginal secretions during pregnancy.	New	CR534	25 Tests
Candida Albicans Rapid chromatographic immunoassay for the qualitative detection of Candida albicans antigens from vaginal swabs.	New	CR535	10 Tests
Pregnancy (hCG) Research of hCG in serum, plasma or urine. Chromatographic rapid test in lateral flow. Sensitivity: 20 mIU/mL.		CR507	40 Tests
Vaginal pH Panel Test The Vaginal pH Panel Test (Vaginal Swab) is a rapid dry chemical method for the semi-quantitative detection of pH in female vaginal swab specimens to aid in the diagnosis of bacterial vaginosis.	New	CR536	40 Tests

Infectivity


Product	Ref	Packaging	
Entamoeba Histolytica Ag Rapid chromatographic immunoassay for the qualitative detection of Entamoeba histolytica antigens in human feces.	New	CR518	10 Tests
Helicobacter Pylori Ag Qualitative detection of Helicobacter Pylori antigen in faeces. Chromatographic rapid test in lateral flow. Complete kit including specimen collection vials with buffer and device.		CR202	25 Tests
Helicobacter Pylori Ab Direct research of antibodies Anti-Helicobacter Pylori antigen in whole blood, plasma or serum. Chromatographic rapid test in lateral flow.		CR201-40	40 Tests
Adenovirus Rapid chromatographic immunoassay for the qualitative detection of Adenovirus in human feces specimens.	New	CR537	25 Tests
Norovirus Qualitative, lateral flow immunoassay for the detection of Norovirus in human feces specimens. The kit includes positive and negative controls.	New	CR538	10 Tests
Rotavirus Qualitative, lateral flow immunoassay for the detection of Rotavirus in human feces specimens.	New	CR597	25 Tests
Adenovirus & Rotavirus Qualitative, lateral flow immunoassay for the detection of Rotavirus and Adenovirus in human feces specimens. The kit includes positive and negative controls.	New	CR539	25 Tests
Adenovirus - RSV - Influenza A+B Rapid chromatographic immunoassay for the qualitative detection of Adenovirus antigen, Respiratory Syncytial Virus antigen and Influenza A and B antigens in nasopharyngeal swab specimens. The kit includes positive and negative controls.	New	CR531	10 Tests
Noro - Roto - Adeno virus Qualitative, lateral flow immunoassay for the detection of Norovirus, Rotavirus, Adenovirus in human feces specimens. The kit includes positive and negative controls.	New	CR516	10 Tests
Mononucleosis A rapid test for the diagnosis of Infectious Mononucleosis (IM) to detect Infectious Mononucleosis heterophile antibodies qualitatively in whole blood, serum or plasma. Chromatographic rapid test in lateral flow. The kit includes positive and negative controls.		CR508	25 Tests

Infectivity


 Product	Ref	Packaging
Tuberculosis (TB) A rapid test for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens. Chromatographic rapid test in lateral flow.	CR501	40 Tests
Streptococcus A Qualitative research of Streptococcus A antigen from throat swabs specimens. Chromatographic rapid test in lateral flow. Complete kit including extracting reagents, throat swabs, extraction tubes, positive and negative controls.	CR204	20 Tests
Streptococcus B A rapid test for the qualitative detection of Strep B antigen in specimens taken from vaginal or rectal swabs of pregnant women, or general swabs from newborn. Extraction reagents, swabs and tubes included in the kit.	CR500	20 Tests
Streptococcus Pneumoniae Qualitative detection of Streptococcus Pneumoniae antigen in human urine specimens. Chromatographic rapid test in lateral flow. Complete kit including diluent, positive and negative control and device.	CR100	20 Tests
Adenovirus Pneumonia Qualitative detection of Adenovirus pneumonia antigen in eye conjunctive swab, throat swab and nasal swab. Chromatographic rapid test in lateral flow. Complete kit including extraction reagent, tubes, sterile swabs and device.	CR512	20 Tests
Legionella Pneumophila New Immunochromatographic assay. It is designed for detection of soluble antigen from Legionella pneumophila serogroup 1 in human urine specimen. Complete kit including liquid positive and negative controls.	CR530	25 Tests
Influenza A+B Qualitative detection of influenza type A and type B nucleoprotein antigens in nasopharyngeal swab and nasal swab and nasal aspirate samples. The identification is based on the monoclonal antibodies specific for the nucleoprotein of Influenza virus A. Steril swabs and extraction tubes included. Chromatographic rapid test in lateral flow.	CR213	20 Tests
Clostridium Difficile GDH New Rapid chromatographic immunoassay for the qualitative detection of Clostridium difficile GDH antigen in human feces specimen. The kit includes lyophilized positive control and liquid negative control.	CR594	10 Tests
Clostridium Difficile Toxin A & B New Rapid chromatographic immunoassay for the qualitative detection of Clostridium difficile Toxin A and Toxin B antigens in human feces specimen. The kit includes lyophilized positive control and liquid negative control.	CR595	10 Tests
Clostridium Difficile GDH, Toxin A & B New Rapid chromatographic immunoassay for the qualitative detection of Clostridium difficile GDH, Toxin A and Toxin B in human feces specimen. The kit includes lyophilized positive control and liquid negative control.	CR517	10 Tests
Escherichia Coli 0157 Direct research of Escherichia Coli O157 antigen in faeces. Chromatographic rapid test in lateral flow. Complete kit including specimen collection vials with buffer and device.	CR108	25 Tests
Campylobacter New Rapid chromatographic immunoassay for the qualitative detection of Campylobacter antigen in human feces specimen. The kit includes lyophilized positive control and liquid negative control.	CR593	10 Tests
Giardia Lamblia New Rapid chromatographic immunoassay for the qualitative detection of Giardia Lamblia antigen in human feces specimen. The kit includes lyophilized positive control and liquid negative control.	CR596	10 Tests

Product	Ref	Packaging	
Crypto-Giardia			
Simultaneous qualitative detection of Cryptosporidium and Giardia antigens in human faeces specimens. Chromatographic rapid test in lateral flow. Complete kit including specimen collection vials with buffer and device. Positive control (not included) separately supplied with Ref. CR105-CTR+ and CR106-CTR+.	CR106	25 Tests	
Chlamydia Trachomatis			
A rapid test for the qualitative detection of Chlamydia antigen in female cervical swab and male urethral swab.	1071	20 Tests	
Neisseria Gonorrhoeae	New		
A rapid test for the qualitative detection of Neisseria gonorrhoeae in female cervical swab and male urethral swab specimens. Sterile female cervical swabs included.	CR509	20 Tests	
RSV	New		
A rapid test for the qualitative detection of Respiratory Syncytial Virus Antigen in Nasopharyngeal swab or nasal aspirate specimens. Positive and negative controls included.	CR598	20 Tests	
HBsAg Test			
HBsAg Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human serum or plasma.	LBAG.01	50 Tests	
HCV Hepatitis C Virus Test			
The HCV Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM e IgA) produced against the HCV virus in human serum or plasma.	GCHCV-302a	25 Tests	
HIV 1/2 Rapid Human Immunodeficiency Virus Test			
HIV 1/2 Test is a rapid qualitative immunoassay for the detection of antibodies generated against all subtypes of Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in human serum or plasma.	GCHIV-302a	25 Tests	
HEV IgG/IgM			
A rapid test for the qualitative detection of antibodies (IgG and IgM) to Hepatitis E Virus in human serum or plasma.	CR506	40 Tests	
HAV IgG/IgM Combo			
A rapid test for the qualitative detection of antibodies (IgG and IgM) to Hepatitis A Virus in human serum or plasma.	CR505	25 Tests	
Syphilis Screening			
Research of antibodies anti-Treponema pallidum in whole blood, serum or plasma.	CR203	40 Tests	
Chagas IgG	New		
Lateral flow chromatographic immunoassay for the qualitative detection of IgG anti-Trypanosoma cruzi (T. cruzi) in human serum, plasma or whole blood.	CR532	40 Tests	
Chikungunya IgG & IgM	New		
Rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Chikungunya in human whole blood, serum or plasma.	CR521	40 Tests	
Dengue (IgG & IgM, NS1 Ag) Combo	New		
Rapid chromatographic immunoassay for the qualitative detection of NS1 antigen and IgG and IgM antibodies of Dengue virus in human whole blood, serum, or plasma.	CR522	25 Tests	
Filariasis IgG & IgM	New		
Rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Filariasis parasites (W. Bancrofti and B. Malayi) in whole blood, serum, or plasma.	CR524	40 Tests	
Leishmania IgG & IgM	New		
Rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Leishmania in human whole blood, serum or plasma.	CR527	40 Tests	


Infectivity

 Product	Ref	Packaging
Leptospira IgG & IgM Rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Leptospira interrogans in human whole blood, serum or plasma.	New	CR528 40 Tests
Malaria Pf/Pan Ag Rapid chromatographic immunoassay for the qualitative detection of four kinds of circulating plasmodium falciparum (P. falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.)) in whole blood.	New	CR515 25 Tests
Malaria Pf/Pv Ag Rapid chromatographic immunoassay for the qualitative detection of two kinds of circulating plasmodium falciparum (P. falciparum (P.f.) and P. vivax (P.v.)) in whole blood.	New	CR514 25 Tests
Malaria Pf/Pv & Pf/Pan Ag Rapid chromatographic immunoassay for the qualitative detection of four kinds of circulating Plasmodium falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.) in whole blood.	New	CR529 25 Tests
Typhoid IgG & IgM Rapid chromatographic immunoassay for the simultaneous detection and differentiation of IgG and IgM types of antibodies against Salmonella typhi (S. typhi) in human serum or plasma.	New	CR525 40 Tests
Salmonella Typhi Ag Rapid chromatographic immunoassay for the qualitative detection of Salmonella typhi antigens in human feces specimens. The kit includes lyophilized positive and negative controls.	New	CR526 25 Tests
Vibrio Cholerae O1/O139 Combo Rapid chromatographic immunoassay for the qualitative detection of Vibrio cholerae O1 and Vibrio cholerae O139 in human feces.	New	CR519 10 Tests
Zika (IgG & IgM, NS1 Ag) COMBO Rapid test that utilizes a combination of Zika IgG/IgM antigens and Zika NS1 antibody coated colored particles for the detection of Zika IgG/IgM antibodies and Zika NS1 antigen in human whole blood, serum, or plasma.	New	CR523 10 Tests

Cardiac Markers

 Product	Ref	Packaging
CK-MB Serum research of specific cardiac fraction of Creatine Kinase. Chromatographic rapid test in lateral flow.		CR46 20 Tests
Myoglobin A rapid test for the diagnosis of myocardial infarction (MI) to detect Myoglobin qualitatively in whole blood, serum or plasma. Chromatographic rapid test in lateral flow.		CR504 10 Tests
Troponin I Serum, plasma and whole blood research of Troponin I. Chromatographic rapid test in lateral flow.		CR510 10 Tests

Tumoral Disease

 Product	Ref	Packaging
F.O.B. (Fecal Occult Blood) Research of human haemoglobin in faeces. Highly specific monoclonal antibody, no free meat diet is required before to execute the test. Chromatographic rapid test in lateral flow. Complete kit including set of drawing and pre-treatment of sample.		CR53 40 Tests

Product	Ref	Packaging	
DoA Dip Panel 7 Amphetamine, Cocaine, MOP, Methylenedioxymethamphetamine, Methamphetamine, THC, Methylphenidate.	CR210 CR210-10	25 Tests 10 Tests	
DoA Dip Panel 8+3 Amphetamine, Buprenorphine, Cocaine, THC, Methadone, MOP, Methylenedioxymethamphetamine, Methamphetamine. Anti-adulterants: Creatinine, pH and specific gravity.	CR216	25 Tests	
AB-PINACA (ABP) Research of AB-PINACA in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal AB-PINACA antibody-coupled particles and AB-PINACA-protein conjugate. A goat antibody is employed in the control line system.	New CR540	40 Tests	
Acetaminophen (ACE) Research of acetaminophen in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-acetaminophen antibody-coupled particles and acetaminophen-protein conjugate. A goat antibody is employed in the control line system.	New CR541	40 Tests	
7-aminoclonazepam (ACL) Research of 7-aminoclonazepam in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-7-Aminoclonazepam antibody coupled particles and 7-Aminoclonazepam -protein conjugate. A goat antibody is employed in the control line system.	New CR542	40 Tests	
Alcohol (ALC) Research of alcohol in human urine. Rapid and highly sensitive method. Visual semi-quantitative detection with a color change proportional to the alcohol concentration.	New CR543	40 Tests	
Alprazolam (ALP) Research of alprazolam in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-Alprazolam antibody coupled particles and alprazolam-protein conjugate. A goat antibody is employed in the control line system.	New CR544	40 Tests	
Amphetamine (AMP) Research of amphetamine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-amphetamine antibody coupled particles and amphetamine-protein conjugate. A goat antibody is employed in the control line system.	New CR545	40 Tests	
α-pyrrolidinovalerophenone (α-PVP) Research of alpha-Pyrrolidinovalerophenone in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal alpha-Pyrrolidinovalerophenone antibody-coupled particles and alpha-Pyrrolidinovalerophenone-protein conjugate. A goat antibody is employed in the control line system.	New CR546	40 Tests	
Barbiturate (BAR) Research of barbiturates in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal barbiturates antibody-coupled particles and barbiturates-protein conjugate. A goat antibody is employed in the control line system.	New CR547	40 Tests	
Buprenorphine (BUP) Research of buprenorphine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal buprenorphine antibody-coupled particles and buprenorphine-protein conjugate. A goat antibody is employed in the control line system.	New CR548	40 Tests	

Drug Tests


Product	Ref	Packaging
Benzodiazepine (BZO) Research of benzodiazepines in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal benzodiazepines antibody-coupled particles and benzodiazepines-protein conjugate. A goat antibody is employed in the control line system.	New	CR549 40 Tests
Cathine (CAT) Research of cathine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal cathine antibody-coupled particles and cathine-protein conjugate. A goat antibody is employed in the control line system.	New	CR550 40 Tests
Caffeine (CAF) Research of caffeine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-caffeine antibody coupled particles and caffeine-protein conjugate. A goat antibody is employed in the control line system.	New	CR551 40 Tests
Cannabinol (CNB) Research of cannabinol in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-cannabinol antibody coupled particles and cannabinol-protein conjugate. A goat antibody is employed in the control line system.	New	CR552 40 Tests
Clonazepam (CLO) Research of clonazepam in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-clonazepam antibody coupled particles and clonazepam-protein conjugate. A goat antibody is employed in the control line system.	New	CR553 40 Tests
Cocaine (COC) Research of cocaine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-cocaine antibody coupled particles and cocaine-protein conjugate. A goat antibody is employed in the control line system.	New	CR554 40 Tests
Cotinine (COT) Research of cotinine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-cotinine antibody coupled particles and cotinine-protein conjugate. A goat antibody is employed in the control line system.	New	CR555 40 Tests
Carfentanyl (CFYL) Research of carfentanyl in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-carfentanyl antibody coupled particles and carfentanyl-protein conjugate.	New	CR556 40 Tests
Diazepam (DIA) Research of diazepam in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-benzodiazepine antibody coupled particles and benzodiazepine-protein conjugate. A goat antibody is employed in the control line system.	New	CR557 40 Tests
Ethylenediamine-dimethylphosphinic acid (EDDP) Research of EDDP, an inactive metabolite of methadone, in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-EDDP antibody coupled particles and EDDP-protein conjugate. A goat antibody is employed in the control line system.	New	CR558 40 Tests
Ethyl glucuronide (ETG) Research of ETG in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-ETG antibody coupled particles and ETG-protein conjugate. A goat antibody is employed in the control line system.	New	CR559 40 Tests

Product	Ref	Packaging	
Fentanyl (FYL) Research of fentanyl in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-fentanyl antibody coupled particles and fentanyl-protein conjugate. A goat antibody is employed in the control line system.	New	CR560	40 Tests
Gabapentin (GAB) Research of GAB in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-GAB antibody coupled particles and GAB-protein conjugate. A goat antibody is employed in the control line system.	New	CR561	40 Tests
Ketamine (KET) Research of ketamine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-ketamine antibody coupled particles and ketamine-protein conjugate. A goat antibody is employed in the control line system.	New	CR563	40 Tests
Lysergic acid diethylamide (LSD) Research of LSD in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-LSD antibody coupled particles and LSD-protein conjugate. A goat antibody is employed in the control line system.	New	CR564	40 Tests
6-monoacetylmorphine (6-MAM) Research of 6-MAM in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-6-MAM antibody coupled particles and 6-MAM-protein conjugate. A rabbit antibody is employed in the control line system.	New	CR565	40 Tests
Methcathinone (MCAT) Research of methcathinone in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-methcathinone antibody coupled particles and methcathinone-protein conjugate. A goat antibody is employed in the control line system.	New	CR566	40 Tests
Ecstasy (MDMA) Research of MDMA in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-MDMA antibody coupled particles and MDMA-protein conjugate. A goat antibody is employed in the control line system.	New	CR567	40 Tests
Tenamfetamine (MDA) Research of MDA in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-MDA antibody coupled particles and MDA-protein conjugate. A goat antibody is employed in the control line system.	New	CR568	40 Tests
Methylenedioxypyrovalerone (MDPV) Research of 3,4-methylenedioxypyrovalerone in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-3,4-methylenedioxypyrovalerone antibody coupled particles and 3,4-methylenedioxypyrovalerone-protein conjugate. A goat antibody is employed in the control line system.	New	CR569	40 Tests
Methamphetamine (MET) Research of methamphetamine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-methamphetamine antibody coupled particles and methamphetamine-protein conjugate. A goat antibody is employed in the control line system.	New	CR570	40 Tests
Mescaline (MES) Research of mescaline in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-mescaline antibody coupled particles and mescaline-protein conjugate. A goat antibody is employed in the control line system.	New	CR572	40 Tests

 Product	Ref	Packaging
Morphine (MOP) Research of morphine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-morphine antibody coupled particles and morphine-protein conjugate. A goat antibody is employed in the control line system.	New	CR573 40 Tests
Methylphenidate (MPD) Research of methylphenidate in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-methylphenidate antibody coupled particles and methylphenidate-protein conjugate. A goat antibody is employed in the control line system.	New	CR574 40 Tests
Meperidine (MPRD) Research of meperidine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-meperidine antibody coupled particles and meperidine-protein conjugate. A goat antibody is employed in the control line system.	New	CR575 40 Tests
Methaqualone (MQL) Research of methaqualone in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-methaqualone antibody coupled particles and methaqualone-protein conjugate. A goat antibody is employed in the control line system.	New	CR576 40 Tests
Methadone (MTD) Research of methadone in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-methadone antibody coupled particles and methadone-protein conjugate. A goat antibody is employed in the control line system.	New	CR577 40 Tests
Opiates (OPI) Research of morphine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-morphine antibody coupled particles and morphine-protein conjugate. A goat antibody is employed in the control line system.	New	CR578 40 Tests
Oxycodone (OXY) Research of oxycodone in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-oxycodone antibody coupled particles and oxycodone-protein conjugate. A goat antibody is employed in the control line system.	New	CR579 40 Tests
Phencyclidine (PCP) Research of phencyclidine in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-phencyclidine antibody coupled particles and phencyclidine-protein conjugate. A goat antibody is employed in the control line system.	New	CR580 40 Tests
Pregabalin (PGB) Research of pregabalin in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-pregabalin antibody coupled particles and pregabalin-protein conjugate. A goat antibody is employed in the control line system.	New	CR581 40 Tests
Propoxyphene (PPX) Research of propoxyphene in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-propoxyphene antibody coupled particles and propoxyphene-protein conjugate. A goat antibody is employed in the control line system.	New	CR582 40 Tests
Synthetic marijuana (K2) Research of synthetic marijuana in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-synthetic marijuana antibody coupled particles and synthetic marijuana-protein conjugate. A goat antibody is employed in the control line system.	New	CR583 40 Tests

Product	Ref	Packaging	
Tricyclic antidepressants (TCA) Research of tricyclic antidepressants in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-tricyclic antidepressants antibody coupled particles and tricyclic antidepressants-protein conjugate. A goat antibody is employed in the control line system.	New	CR584 40 Tests	
Marijuana (THC) Research of THC in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-THC antibody coupled particles and THC-protein conjugate. A goat antibody is employed in the control line system.	New	CR585 40 Tests	
Tramadol (TML) Research of tramadol in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-tramadol antibody coupled particles and tramadol-protein conjugate. A goat antibody is employed in the control line system.	New	CR586 40 Tests	
Tropicamide (TRO) Research of tropicamide in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-tropicamide antibody coupled particles and tropicamide-protein conjugate. A goat antibody is employed in the control line system.	New	CR587 40 Tests	
UR-144 Research of UR-144 in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-UR-144 antibody coupled particles and UR-144-protein conjugate. A goat antibody is employed in the control line system.	New	CR589 40 Tests	
Zaleplon (ZAL) Research of zaleplon in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-zaleplon antibody coupled particles and zaleplon-protein conjugate. A goat antibody is employed in the control line system.	New	CR590 40 Tests	
Zolpidem (ZOL) Research of zolpidem in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-zolpidem antibody coupled particles and zolpidem-protein conjugate. A goat antibody is employed in the control line system.	New	CR591 40 Tests	
Zopiclone (ZOP) Research of zopiclone in human urine. Qualitative chromatographic immunoassay based on the principle of competitive binding. The test contains mouse monoclonal anti-zopiclone antibody coupled particles and zopiclone-protein conjugate. A goat antibody is employed in the control line system.	New	CR592 40 Tests	
Urine adulteration test Semi-quantitative color comparison screen for the detection of Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Oxidants and Pyridinium Chlorochromate in human urine.	New	CR600 25 Tests	

Various

 Product	Ref	Packaging
IgE Serum research of IgE. Chromatographic rapid test in lateral flow.	CR27	10 Tests
Microalbumin Semi-quantitative Semi-quantitative test for microalbumin research in urine. Chromatographic rapid test in lateral flow.	CR503	25 Tests
Calprotectin Qualitative detection of Calprotectin protein in human faeces specimens. Chromatographic rapid test in lateral flow. Complete kit including specimen collection vials with extraction buffer and device.	CR502	10 Tests

Orders of all the Rapid Test will be managed on schedule.

Card Control

 Product	Ref	Packaging
Crypto Positive Control Crypto positive control swab.	CR106-CTR+	1x1

Strips

Product	Ref	Packaging	
DIRUI H10 Reagent strips for H-50/100/300/500 with 10 parameters: Urobilinogen, Bilirubine, Ketone, Blood, Proteine, Nitrite, Leucocytes, Glucose, Specific gravity, pH.	231011401001	100 Strips	
DIRUI H11 Reagent strips for H-50/100/300/500 with 11 parameters: Urobilinogen, Bilirubine, Ketone, Blood, Proteine, Nitrite, Leucocytes, Glucose, Ascorbic Acid, Specific gravity, pH.	231010601001	100 Strips	

Consumables

Product	Ref	Packaging	
Fast Read 102 Disposable slide for cells counting under microscope.	BVS100	100 Slides	

Consumables Miscellaneous

Product	Ref	Packaging	
Yellow Tips 5-200 µl	28052	1000 pcs	
Blue Tips 200-1000 µl	28053	500 pcs	
Sample cups 1,5 ml (Technicon)	24053	1000 pcs	
Sample cups 3 ml (Hitachi)	18320	1000 pcs	
Thermic Paper 57x70x12 mm	PH016	5 pcs	
Thermic Paper 57x49x12 mm	PH160	5 pcs	
Thermic Paper 110x49x12 mm	PH018	5 pcs	
Thermic Paper 110x70x12 mm	PH180	5 pcs	



C E R T I F I C A T E

Certificato n. **14-Q-0200538-TIC**
Certificate No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM
OPERATED BY

FUTURA SYSTEM GROUP S.r.l.

Via degli Olmetti 18
00060 Formello RM ITALY

E' CONFORME AI REQUISITI DELLA NORMA
IS IN COMPLIANCE WITH THE REQUIREMENTS OF STANDARD
ISO 9001:2015

QUESTO CERTIFICATO E' VALIDO PER LE SEGUENTI ATTIVITA'
THIS CERTIFICATE IS VALID FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione e commercializzazione di dispositivi medico-
diagnostici in vitro (IVD); commercializzazione di dispositivi medici;
commercializzazione, installazione e servizi di post vendita di
strumentazione per laboratori di analisi cliniche

Design, production and trade of in vitro diagnostic medical devices
(IVD); trade of medical devices; trade, installation and post sales
services of equipment for analysis of clinical laboratories

MEDIANTE UN AUDIT, RAPPORTO n. **RR-0717-Q-TIC-MS-0200538-14**
AN AUDIT WAS PERFORMED, REPORT No.

Data di prima emissione
First issuing

31.07.2014

Data di scadenza
Expiring date

27.07.2020



Deutsche
Akkreditierungsstelle
D-ZM-16012-01-00



Bonn 28.07.2017

L. Lindenblatt

Dipl.- Ing. K. Lindenblatt

TÜV INTERCERT Certification Body



TÜV INTERCERT GmbH - Group of TÜV Saarland - Am Bonner Bogen 2 - 53227 Bonn GERMANY
www.tuv-intercert.org



CERTIFICATO N° SGQ 13485-005/14

Apave Certification Italia S.r.l.

certifica che il sistema di gestione applicato da:
Apave Certification Italia S.r.l. certifies that the management system implemented by:

FUTURA SYSTEM GROUP S.r.l.

Sui seguenti siti:
On the following locations:

Via degli Olmetti, 18 – 00060 Formello – RM - ITALIA

Per le seguenti attività:
For the following activities:

**Progettazione, produzione e commercializzazione di dispositivi medici-diagnostici in vitro (IVD).
Commercializzazione di dispositivi medici. Commercializzazione, installazione e servizi post vendita di
strumentazione per laboratori di analisi cliniche.**

*Design, manufacturing, marketing and sale of in vitro diagnostic (ivd) medical devices. Marketing and sale of medical
devices. Marketing and sale, installation and after sales services of instruments for clinical laboratories.*

IAF: 19 - 29

E' stato valutato conforme ai requisiti richiesti dalla norma:
Has been assessed to meet the requirements of standard:

EN ISO 13485:2016

Prima emissione First issue	25/07/2014
Valido dal Effective date	01/10/2018
Ultima modifica Last modified	01/10/2018
Scadenza Expiring date	24/07/2020

Urbano Strada
Direttore Generale di Apave Certification Italia S.r.l.
General Manager of Apave Certification Italia S.r.l.

Riferirsi alla documentazione del sistema di gestione per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of Management System for details of application to reference standard requirements.
Il presente certificato è soggetto al rispetto dei requisiti contrattuali di Apave Certification Italia S.r.l.
The use and the validity of the certification shall satisfy the contract requirements of Apave Certification Italia S.r.l.
Per informazioni puntuali e aggiornate circa lo stato della presente certificazione si prega di contattare il tel.
+39 0633270123 oppure l'indirizzo e-mail info.certification.it@apave.com.
For precise and updated information regarding any changes in the status of certification as carried in the
present certificate, please call the following phone number +39 0633270123 or send an email to
info.certification.it@apave.com.

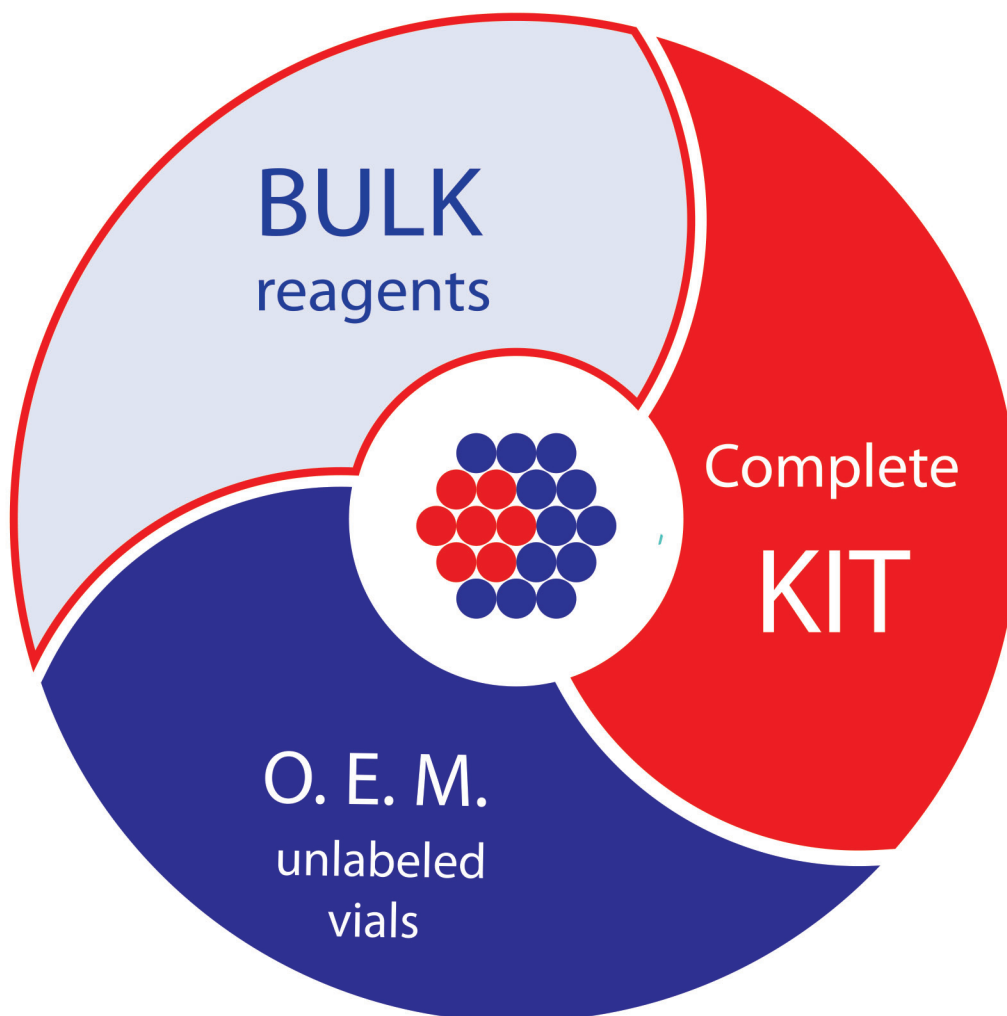
Mod. Certificato SG rev. 00

Warranty, terms and conditions will be specified in the economical proposal.
In accordance with standard MEDDEV 2.12-1 rev. 6 (December 2009) - GUIDELINES ON THE SYSTEM OF
VIGILANCE MEDICAL DEVICES, users are required to report to the manufacturer or to the National Competent
Authorities, depending on the practices in use at the national level, the accidents occurred with medical devices

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