

Annex to the accreditation certificate: N° 1/014 According to standard ISO 15189:2022 For a medical laboratory

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Accredited organisation:

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Medical Biology

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
(e.g. products, materials, samples, matrices, equipment)		(e.g. manual or automatic measurement)	(e.g. published, adapted, checked internally)
Flexible scope analyses *			
General domain: MED1 - Clinical Biochemistry			
Technical domain: MED1.1 - General Biochemistry			
<i>Cobas c502</i>			
Plasma	Lactate	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay
Serum	Homocystein	Spectrophotometry (automated system, Cobas 8000 Roche)	Enzymatic assay
Serum	Apolipoprotein A1	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Apolipoprotein B	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	ASLO	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Haptoglobin	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	IgA	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	IgG	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	IgM	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Lipoprotein(a)	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Rheumatoid factor (RF)	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Soluble Transferrin (STFR)	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Serum	Amylase pancreatic	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay
Serum	Cholinesterase	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay
Serum	Carbamazepine	Spectrophotometry (automated system, Cobas 8000, Roche)	KIMS
Serum	Phenytoin	Spectrophotometry (automated system, Cobas 8000, Roche)	KIMS
Serum	Valproic acid	Spectrophotometry (automated system, Cobas 8000 Roche)	Enzymatic assay
Serum	Prealbumin	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Urine	Micoalbumin (Micral)	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	CRP high sensitive	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Alpha1-Acid Glycoprotein	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Angiotensin converting Enzym	Spectrophotometry (automated system, Cobas 8000 Roche)	Enzymatic assay
Serum	Free Kappa light chain	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Free Lambda light chain	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Urine	Albumin	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum		Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Urine	Total protein	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Phenobarbital	Spectrophotometry (automated system, Cobas 8000, Roche)	KIMS
Serum	Fructosamine	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
<i>Cobas 8000 ISE</i>			
Serum	Chloride	Electrochemical detection of ions (automated system, Cobas 8000, Roche)	ISE
Urine			
Serum	Potassium		
Urine			
Serum	Sodium		
Urine			
<i>Cobas 8000 c701</i>			
Serum	Transferrin (TF)	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	CRP	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Ferritin	Turbidimetry (automated system, Cobas 8000, Roche)	Turbidimetric
Serum	Bilirubin direct	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay
Serum	Bilirubin total	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay
Serum	Calcium	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay (MN Bapta)
Urine		Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay (MN Bapta)
Serum	HDL Cholesterol	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic (colorimetric) assay
Serum	Creatinine	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay
Urine		Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay
Serum	Iron	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay
Serum	Phosphorus	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay (Molybdat UV)

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Urine	Phosphorus	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay (Molybdat UV)
Serum	Total amylase	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay IFCC
Serum	AST/GOT	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay
Serum	GGT	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic (colorimetric) assay
Serum	LDH	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay (UV-Test)
Serum	Triglyceride	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic (colorimetric) assay
Serum	Urea	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay (kinetic)
Urine		Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay (kinetic)
Serum	Uric acid	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic (colorimetric) assay
Urine		Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic (colorimetric) assay
Serum	Magnesium	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay
Urine		Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay
Serum	Total Cholesterol	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay IFCC
Serum	LDL Cholesterol	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic (colorimetric) assay
Serum	Glucose	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Urine	Glucose	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay calculated
Serum	Alkalinephosphatase	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay
Serum	ALT/GPT	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay
Serum	Creatine kinase CK	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic assay (UV Test)
Serum	Lipase	Spectrophotometry (automated system, Cobas 8000, Roche)	Enzymatic (colorimetric) assay
Serum	Total protein	Spectrophotometry (automated system, Cobas 8000, Roche)	Colorimetric assay
<i>Cobas 8000 e801</i>			
Serum	Osteocalcin	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	CK-MB	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	LH	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	FSH	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Prolactin	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Progesterone	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Beta-HCG	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	TSH	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Serum	FT3	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	CEA	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Total PSA	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Free PSA	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Alpha-fetoprotein (AFP)	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	CA 125	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	CA 15-3	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	CA 19-9	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	proBNP	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Thyroglobuline (TG)	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Plasma	PTH	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Beta-crosslaps	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	DHEA-S	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Plasma	ACTH	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Myoglobin	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Serum	CYFRA 21-1	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Sexual hormone binding globulin (SHBG)	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Calcitonin	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Insulin	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	C-peptide	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	P1NP	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	HE4	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	NSE (Neuron specific enolase)	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Testosterone	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Estradiol	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	FT4	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Folate	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Vitamin B12	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Cortisol	Competitive Assay (automated system, Cobas 8000, Roche)	ECLIA
Serum	HS Troponin T	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Serum	Digoxin	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	1,25 OH Vitamin D	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	AMH (Anti-Müllerian hormone)	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Procalcitonin	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
<i>ELEC</i>			
Serum	Monoclonal proteins	Immuno-electrophoresis (IELEC, SEBIA)	Immunotyping
Serum	CDT-IFCC	CAPILLARYS System	Capillary electrophoresis
Serum	Serum proteins	CAPILLARYS System	Capillary electrophoresis
<i>Cobas 8000 e602</i>			
Serum	Ionized Calcium	Electrochemical detection of ions (automated system, Electrolyte Analyzer)	ISE
<i>Chromatography</i>			
Urine	Catecholamines (urine) (noradrenalin, adrenalin, dopamine)	HPLC (Agilent)	HPLC
Urine	VMA/HVA/5-HIAA	HPLC (Agilent)	HPLC
Serum	Vitamin A/E	UHPLC/HPLC(Agilent)	HPLC
Urine	Serotonin	HPLC (Agilent)	HPLC
Serum		HPLC (Agilent)	HPLC
Lithium-Heparin-Plasma	Vitamin C	UHPLC/HPLC(Agilent)	HPLC
EDTA blood	Vitamin B1	UHPLC/HPLC(Agilent)	HPLC
EDTA blood	Vitamin B2	UHPLC/HPLC(Agilent)	HPLC
EDTA blood	Vitamin B6	UHPLC/HPLC(Agilent)	HPLC
<i>Stool tests</i>			
Stool	Faecal haemoglobin	Latex agglutination-automated-QC Sensor (Eiken)	iFOB (iO, Eiken)
Stool	pH – determination in stool	Electrochemical analysis (manual)	Potentiometric
Stool	A1-Antitrypsin	ELISA and related immunoassays (manual test)	ELISA

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Stool	sIgA	ELISA and related immunoassays (manual test)	ELISA
<i>Urine</i>			
Urine	Urinanalysis (glucose, proteins, bilirubin, pH, blood, ketone, nitrite, leukocytes, urobilinogen)	Spectrophotometry (Cobas 6500, Roche)	Colometric
<i>Liaison XL</i>			
Serum	IGF-1	ELISA and related immunoassays (automated system, Liaison/ DiaSorin)	CLIA
Stool	Calprotectin	ELISA and related immunoassays (automated system, Liaison XL / DiaSorin)	CLIA
Serum	1,25-Dihydroxy-Vitamin-D	ELISA and related immunoassays (automated system, Liaison XL / DiaSorin)	CLIA
Serum	Androstenedione	ELISA and related immunoassays (automated system, Liaison XL / DiaSorin)	CLIA
Stool	Elastase	ELISA and related immunoassays (automated system, Liaison XL / DiaSorin)	CLIA
<i>ELISA</i>			
Serum	DHT	ELISA and related immunoassays (manual test)	ELISA
Serum	17-OH-Progesterone	ELISA and related immunoassays (manual test)	ELISA
Saliva	Cortisol	ELISA and related immunoassays (manual test)	ELISA
Serum	Free Testosterone	ELISA and related immunoassays (manual test)	ELISA
Serum	Biotin	ELISA and related immunoassays (manual test)	ELISA
Technical domain: MED1.3 – Calculated parameters			
Serum	Free androgen Index	/	/
Serum	Glomerular filtration rate (GFR)	/	/
Serum	PSA ratio	/	/
Serum	Transferrin Saturation	/	/
Serum	LDL (Friedewald equation)	/	/

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Serum	Indirect Bilirubin	/	/
Serum	Osmolality	/	/
Serum	Albumin-creatinine-Ratio	/	/
Serum	Creatinine clearance	/	/
Urine	Potassium in 12 / 24h urine	/	/
Urine	Sodium in 12 / 24h urine	/	/
Urine	Chloride in 12 / 24h urine	/	/
Urine	Calcium in 12 / 24h urine	/	/
Urine	Creatinine in 12 / 24h urine	/	/
Urine	Phosphor in 12 / 24h urine	/	/
Urine	Magnesium in 12 / 24h urine	/	/
Urine	Protein total in 12 / 24h urine	/	/
Urine	Urea in 12 / 24h urine	/	/
Urine	Uric acid in 12 / 24h urine	/	/
Serum	ROMA score	/	/
Serum	Corrected calcium	/	/
Serum	HOMA-IR	/	/
Urine	Micralbumin / 24h	/	/
Serum	Glomerular filtration rate (MDRD)	/	/
Serum	URCL Urea clearance	/	/
Serum	GFR K(kinder)	/	/
Serum	Protein/creatinin ratio	/	/
Serum	Calcium/creatinine ratio	/	/
Serum	PINI	/	/
Serum	GFR (CKD-EPI)	/	/
Serum	Vitamin D ratio	/	/
Serum	Kappa/Lambda Ratio	/	/
Serum	NONHDL		
Serum	Quicki Index (Quantitative Insulin Sensitivity Check Index)		
Urine	Catecholamine urinaire (Noradrenalin, Adrenalin, Dopamin) µg /24 Std	/	/
Urine	VMA/HVA/5HIAA mg / 24 Std	/	/

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Urine	Serotonin in Urine µg / 24 Std	/	/
Urine	Catecholamine in urine (noradrenalin, adrenalin, dopamine) µg /g creatinine	/	/
Urine	VMA/HVA/5HIAA mg / g creatinine	/	/
Urine	Serotonin in Urine µg / g creatinine	/	/
Serum	FIB4 (Fibrose Score)	/	/
General domain: MED2 - Haematology			
Technical domain: MED2.1 - Hemocytology			
EDTA whole blood	Sedimentation rate (VS)	Photometry (Alifax Test, BCL Indumed)	Photometrical capillary stopped flow kinetic analysis
EDTA whole blood	HbA1c	HPLC (TOSOH G11)	HPLC
EDTA whole blood	Abnormal blood films (manual differentiation)	Light microscopy (Nikon)	brightfield microscopy after staining
EDTA whole blood	Complete blood count incl Thrombocytes from Citrate	Flow cytometry (XN 9000, Sysmex)	Optical + impedance count
EDTA whole blood	Reticulocytes		
Technical domain: MED2.2 - Coagulation			
Human plasma samples: Citrate	Quick + INR	Electromagnetic (STA_R MAX 3)	Coagulometric
	Thrombin time		Coagulometric
	Fibrinogen		Coagulometric
	D-Dimer	Photometry (STA_R MAX 3)	Latex immunoassay
	PTT (Stago/CK Prest)	Electromagnetic (STA_R MAX 3)	Coagulometric
General domain: MED3 - Immunology			
Technical domain: MED3.1 - Allergy			
Serum	Total IgE	Fluorescent immunoassay (automated system ImmunoCAP, Phadia)	FEIA
Serum	Specific IgE		
Stool	Histamine	ELISA and related immunoassays (manual test)	ELISA

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Technical domain: MED3.2 - Autoimmune diagnostics			
Serum	Euroline Systemic Sclerosis Profile (Ro52, PDGFR, Ku, PM-Scl75, PM-Scl100, Th/To, NOR90, Fibrillarine, RP155, RP11, CENPA, CENPB, Scl-70)	Colorimetric membrane-based immunoassay (EuroblotOne, automated system Euroimmun)	Blot
Serum	ANA differentiation (U1 RNP, SM, SS-A, SS-B Ro-52, SS-B, Scl-70, PM-Scl100, Jo-1, CENP B, PCNA, dsDNS, Nucleosome, Histone, Ribosomal P-protein, AMA-M2, DSF70)		
Serum	Differentiation of liverspecific abs (AMA-M2, M2-3E, Sp100, PML, gp210, LKM-1, LC-1, SLA/LP, Ro-52)		
Serum	Myositis profile (Ro52, Ku, PM-Scl100, PM-Scl75, Jo-1, SRP, PL-7, PL-12, EJ, OJ)		
Serum	Anti-Ganglioside IgM, IgG		
Serum	Anti-MPO, Anti-PR3 (IgG)		
Serum	Anti-GAD (Glutamatedecarboxylase, IgG)	ELISA and related immunoassays (manual test)	ELISA
Serum	Anti-IA2 (Tyrosin-Phosphatase) (IgG)	ELISA and related immunoassays (manual test)	ELISA
Serum	Anti-endomysium IgA	IFT (IF-Sprinter, EUROStar Microscope, half automated processing, Euroimmun)	IFT
Serum	Liver mosaic (anti-mitochondrial, anti-smooth muscle, anti-LKM, anti-F-actin abs.)	IFT (IF-Sprinter, EUROStar Microscope, half automated processing, Euroimmun)	IFT
Serum	ANA		
Serum	Granulocytes mosaic: (cANCA, pANCA)		
Serum	Anti-dsDNA	ELISA and related immunoassays (automated system, Euroimmun)	ELISA

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
<i>Phadia</i>			
Serum	Anti-gliadin IgG	Fluoreszenz-Enzym-Immuno-Assay (automated system, Phadia 250, thermo scientific)	EliA
Serum	Anti-gliadin IgA		
Serum	Anti-transglutaminase IgG		
Serum	Anti-transglutaminase IgA		
Serum	Anti-cardiolipin IgG		
Serum	Anti-Beta 2 Glycoprotein		
Serum	ACCP		
Serum	Anti-Saccharomyces cerevisiae IgG (ASCA)		
<i>Cobas 8000 e801</i>			
Serum	TRAb	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Anti-TPO		
Serum	Anti-TG		
<i>Stool tests</i>			
Stool	Anti-Gliadin IgA	ELISA and related immunoassays (manual test)	ELISA
Stool	Anti-Transglutaminase sIgA	ELISA and related immunoassays (manual test)	ELISA
Stool	Zonulin	ELISA and related immunoassays (manual test)	ELISA
General domain: MED4 - Medical microbiology			
Technical domain: MED4.2 – Medical bacteriology/ MED4.3- Medical parasitology/ MED4.4- Medical mycology			
Macro- and microscopic examinations			
URINARY TRACT INFECTION/CYTOBACTERIOLOGICAL EXAMINATION OF URINE			
Urine/Urine sediment	Red blood cells, white blood cells, epithelial cells, bacteria, yeasts, cylinders, crystals, sperm	Light microscopy	Brightfield microscopy
		Automated microscopy -Cobas 6500 (Roche)	Cell / particle counting
	Testing for urinary soluble antigen Legionella	Immunochromatography manual method, BinaxNOW (Abbott)	Immunochromatographic assay
	Bacteria and yeasts	Manual or automated method, Wasp (MLS)	Manual or automated plating Culture and recognition of colonies

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
UROGENITAL AND SEXUALLY TRANSMITTED INFECTIONS			
Genital swabs (female)	Bacteria, yeasts and microorganisms	Light microscopy	Direct examination: Search for bacteria, yeasts and microorganisms on a slide
Genital swabs Intrauterine device (IUD) Sperm	Bacteria and yeasts	Light microscopy Staining manual or automated – Borealys Duo (Biocentric)	GRAM stained: Search for bacteria and yeast on a slide
Genital swabs, Sperm Intrauterine device (IUD) Rectal/ anal swabs	Bacteria and yeasts	Manual and/or automated method- Wasp (MLS)	Manual or automated plating Culture and recognition of colonies
Vaginal swabs	Nugent Score	Gram stained Light microscopy	Gram stained Calculation
DIGESTIVE TRACT INFECTION/ STOOL CULTURE			
Stool	Identification of parasites, worms and eggs in stool	Light microscopy	Brightfield microscopy
	Cryptosporidia	Kinyoun Staining (Electrochemical analysis) manual or automated – Borealys Duo (Biocentric)	Microscopy
	Bacteria and yeasts	Manual method	Manual plating culture and recognition of colonies
OTHER TYPES OF INFECTIONS			
Respiratory tract samples ORL, Ears Wounds Eye, Skin and appendages	Bacteria and yeasts	Light microscopy Staining manual or automated – Borealys Duo (Biocentric)	GRAM stained: Search for bacteria and yeast on a slide
	Bacteria and yeasts	Manual and/or automated method- Wasp (MLS)	Manual or automated plating Culture and recognition of colonies
Skin and appendages	Moulds, yeasts, dermatophytes	Manual Light microscopy	Microscopy with potassium hydroxide solution
		Manual plating	Culture in solid medium macroscopic and microscopic examination in the fresh state and after culture

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Whole blood	Plasmodium species and Microfilariae	Light microscopy, manual method	Light microscopy reading after MGG staining
Antibiograms and additional tests			
Culture from matrices: Urine Genital samples Stool Respiratory tract samples, Ears, Wounds Eye, Punctate Skin	Antibiotic susceptibility	Diameter measurement Agar diffusion- manual technology	Antimicrobial susceptibility testing zone diameter and complementary tests in solid media: diffusion in agar media
	Antibiotic susceptibility	Turbidimetry, Spectralphotometry Vitek 2XL/Compact (BioMérieux)	Antimicrobial susceptibility testing MIC and complementary tests: measurement of growth inhibition in liquid medium in the presence of antibiotics
Urine Swabs- armpits, nose, inguinal folds, throat	MRSA- Screening	Manual or automated method- Wasp (MLS)	Qualitative method on specific chromogenic media
Swabs- rectal/anal, nasal, inguinal folds, armpits, throat	ESBL- Screening	Manual method	Qualitative method on specific chromogenic media
Swabs- rectal/anal, stool, nasal, inguinal folds, armpits, throat	CARBA- Screening	Manual method	Qualitative method on specific chromogenic media
		Carbapenemase inactivation method	Inhibition test / Agar diffusion
Swabs- rectal/anal, nasal, inguinal folds, armpits, throat	VRE- Screening	Manual method	Qualitative method on specific chromogenic media
Culture from matrices: Urine Genital samples Stool Respiratory tract samples, Ears Wounds Eye, Punctate Skin	Bacteria	Catalase, Oxydase, Indol- Manual tests (BD, BioMérieux) Coagulase -manual test (Pastorex Staph.(BioRad)	Biochemical rapid test Rapid latex agglutination test

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Swabs: armpits, nose, inguinal folds, throat, wound, urine	PBP2A Culture Colony Test	Immunochromatographic Membrane- rapid test (Abbott)	Qualitative enzymatic assay
Culture from matrices: Stool	Salmonella, E.coli	Agglutination assay, manual test (SSI Diagnostic)	Slide agglutination test
Identification			
Culture from matrices: Urine Genital samples Stool Respiratory tract samples, Ears Wounds Eye, Punctate Skin	Bacteria and yeasts	Automated method Mass spectrometry MalDI-TOF (Bruker)	Automated identification by mass spectrometry
Culture from matrices: Urine Genital samples Stool Respiratory tract samples, Ears Wounds Eye, Punctate Skin	Bacteria and yeasts	Fluorescence Automated method using biochemical tests Vitek 2XL/Compact (BioMérieux)	Automated identification using biochemical tests
Culture from matrices: Skin and appendages	Moulds, dermatophytes	Light microscopy	macroscopic and microscopic identification after culture
Technical domain: MED4.6 - Infectious molecular biology			
Stool	Giardia lamblia	Extraction of nucleic acids (Starlet Hamilton, Seegene, EMag, Biomérieux) Amplification (CFX96, Bio-Rad) Detection (Seegene)	Multiplex, hydrolysis probe based real-time PCR DNA / RNA testing
	Cryptosporidium parvum		
	Entamoeba histolytica		
	Blastocystis hominis		
	Dientamoeba fragilis		
	Cyclospora cayetanensis		

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Stool	Adenovirus F (Serotype 40/41)	Extraction of nucleic acids (Starlet Hamilton, Seegene, EMag, Biomérieux) Amplification (CFX96, Bio-Rad) Detection (Seegene)	Multiplex, hydrolysis probe based real-time PCR DNA / RNA testing
	Norovirus G1		
	Norovirus G2		
	Astrovirus		
	Rotavirus		
	Sapovirus		
Swab, Sputum	Parainfluenza 1	Extraction EMag (Biomérieux) or Starlet Hamilton (Seegene) / Amplification Seegene / Thermocycler CFX96 (Bio-Rad) Detection (Seegene)	Multiplex, hydrolysis probe based real-time PCR
	Parainfluenza 2		
	Parainfluenza 3		
	Parainfluenza 4		
	Rhinovirus		
	Adenovirus		
	Human Metapneumo Virus (HuMPV)		
	Influenza A		
	Influenza B		
	RSV A/B		
	SARS-CoV-2		
Swab, urine, Thinprep	Herpes Simplex Virus 1 (HSV1)	Extraction of nucleic acids (Starlet, Seegene / EMag, Biomérieux) Detection (Seegene) Amplification (CFX96, Bio-Rad)	Real-Time PCR
	Herpes Simplex Virus 2 (HSV2)		
	Varicella Zoster Virus (VZV)		
	Treponema pallidum		
Stool	Salmonella spp	Extraction of nucleic acids (Starlet Hamilton, Seegene / EMag, Biomérieux) Amplification (CFX96, Bio-Rad) Detection (Seegene)	Multiplex, hydrolysis probe based real-time PCR DNA / RNA testing
	Yersinia spp		
	Shigella spp		
	Campylobacter spp		
	Escherichia coli verotoxin (EHEC)		
	Clostridium difficile Toxin A/B		
	Shiga toxin – producing E-coli (stx 1/2)		

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Swab, Skin particles, Hair, Nails	Trichophyton rubrum/soudanense	Extraction of nucleic acids (EMag, Biomérieux) Amplification (LightCycler480, Roche, CFX96, Bio-Rad) Detection (PathoNostics)	Multiplex, hydrolysis probe, real-time PCR, DNA / RNA testing
	Trichophyton mentagrophytes/interdigitale		
	Trichophyton tonsurans/equinum		
	Trichophyton schoenleinii/quinckeanum		
	Trichophyton benhamiae/concentricum/erinacei		
	Trichophyton verrucosum		
	Trichophyton violaceum		
	Microsporum canis / ferrugineum		
	Microsporum audouinii		
	Dermatophytes spp		
	Scopulariopsis brevicaulis		
	Nannizzia gypsea		
	Epidermophyton floccosum		
	Candida albicans		
Candida parapsilosis			
Swab, EDTA Plasma, Urine	Measles virus	Extraction of nucleic acids (EMag, Biomérieux) Amplification (CFX96, Bio-Rad; LightCycler480, Roche) Detection (Anatolia geneworks)	Real Time PCR
Blood	Plasmodium spp.	Extraction of nucleic acids (EMag, Biomérieux) Amplification (CFX96, Bio-Rad, LightCycler480, Roche) Detection (Altona Diagnostics)	Multiplex, hydrolysis probe, real-time PCR, DNA / RNA testing
	Plasmodium falciparum		
	Plasmodium vivax		
	Plasmodium malariae		
	Plasmodium ovale		
Plasmodium knowlesi			
Urine, Swab, Thinprep, Semen	Mycoplasma hominis		Multiplex, hydrolysis probe based real-time PCR DNA / RNA testing
	Mycoplasma genitalium		
	Trichomonas vaginalis		
	Ureaplasma urealyticum		

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	Ureaplasma parvum Neisseria gonorrhoeae Chlamydia trachomatis	Extraction of nucleic acids (Starlet Hamilton, Seegene, EMag, Biomérieux) Amplification (CFX96, Bio-Rad) Detection (Seegene)	
Thinprep	HPV High Risk Screening	Real-Time PCR (GeneXpert, Cepheid)	DNA / RNA testing
Thinprep Swab Urine	HPV High Risk / Low Risk	Extraction of nucleic acids (EMag, Biomérieux) Amplification (CFX 96, BioRad) Detection: Seegene	Real-Time PCR
Sputum Swab	Influenza A Influenza B RSV A/B SARS-CoV-2	Extraction of nucleic acids (Starlet Hamilton, Seegene EMag, Biomérieux) Amplification (CFX96, Bio-Rad) Detection (Seegene)	Multiplex, hydrolysis probe based real-time PCR DNA / RNA testing
Swab, sputum	Legionella pneumophila Mycoplasma pneumoniae Chlamydia pneumoniae Bordetella pertussis Bordetella parapertussis	Extraction of nucleic acids (Starlet Hamilton, Seegene EMag, Biomérieux) Detection (Seegene) Amplification (CFX96, Bio-Rad)	Real-Time PCR
General domain : MED5 - Serology			
Technical domain : MED5.1 - Infectious Serology			
<i>Cobas 8000 e602</i>			
Serum	Anti-HAV total	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Anti-HAV IgM	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	HBsAg/Confirmation	Chemiluminescent immunoassay (automated system, Cobas 8000, Roche)	ECLIA
Serum	Anti-HBs	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Anti-HBc	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	HCV- Antibodies	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Serum	HIV-Antibodies and p24 antigen	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
Serum	Rubella IgG/IgM	ELISA and related immunoassays (automated system, Cobas 8000 , Roche)	ECLIA
Serum	Toxoplasma gondii IgG, IgM	Chemiluminescent immunoassay (automated system, Cobas 8000, Roche)	ECLIA
Serum	CMV IgG/IgM	ELISA and related immunoassays (automated system, Cobas 8000 , Roche)	ECLIA
Serum	Treponema pallidum (Syphilis)	ELISA and related immunoassays (automated system, Cobas 8000 , Roche)	ECLIA
Serum	Anti-SARS-CoV-2 S (Anti-Spike Protein)	ELISA and related immunoassays (automated system, Cobas 8000, Roche)	ECLIA
VIDAS 3			
Serum	Toxoplasma gondii IgG Avidity	ELISA and related immunoassays (automated system, Vidas 3, Bio-Mérieux)	ELFA
Serum	CMV IgG Avidity	ELISA and related immunoassays (automated system, Vidas 3, Bio-Mérieux)	ELFA
Serum	Toxoplasma gondii IgG - confirmation test	ELISA and related immunoassays (automated system, Vidas 3, Bio-Mérieux)	ELFA
Serum	Toxoplasma gondii IgM-confirmation test	ELISA and related immunoassays (automated system, Vidas 3, Bio-Mérieux)	ELFA
Serum	Rubella IgG- confirmation test	ELISA and related immunoassays (automated system, Vidas 3, Bio-Mérieux)	ELFA
Serum	Rubella IgM-confirmation test	ELISA and related immunoassays (automated system, Vidas 3, Bio-Mérieux)	ELFA
Serum	CMV IgG-confirmation test	ELISA and related immunoassays (automated system, Vidas 3, Bio-Mérieux)	ELFA
Serum	CMV IgM-confirmation test	ELISA and related immunoassays (automated system, Vidas 3, Bio-Mérieux)	ELFA

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
<i>Liaison XL</i>			
Serum	Mumps virus IgG	ELISA and related immunoassays (automated system, Liaison XL / DiaSorin)	CLIA
Serum	Measles virus IgG		
Serum	Varicella Zoster virus IgG		
Serum	HSV-1 IgG		
Serum	HSV-2 IgG		
Serum	HSV-1/2 IgM		
Serum	Chlamydia trachomatis IgG		
Serum	Chlamydia trachomatis IgA		
Serum	Varicella Zoster virus IgM		
Serum	Mycoplasma pneumoniae IgG		
Serum	Mycoplasma pneumoniae IgM		
Serum	Borrelia burgdorferi IgG		
Serum	Borrelia burgdorferi IgM		
Serum	Mumps virus IgM		
Serum	Measles virus IgM		
Serum	Parvovirus B19 IgG		
Serum	Parvovirus B19 IgM		
Stool	Helicobacter pylori antigen		
Serum	EBNA-1-IgG (EBV)		
Serum	VCA-IgG (EBV)		
Serum	VCA-IgM (EBV)		
<i>Euroimmun</i>			
Serum	Chlamydia pneumoniae IgG	ELISA and related immunoassays (automated system, Euroimmun)	ELISA
Serum	Chlamydia pneumoniae IgA		
Serum	Helicobacter pylori IgG		
Serum	Helicobacter pylori IgA		
Serum	Bordetella pertussis IgG		
Serum	Borrelia IgG – WB	Colorimetric membrane-based immunoassay (EuroblotOne, automated system Euroimmun)	Immunoblot
Serum	Borrelia IgM – WB		

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Serum	Treponema Pallidum IgG/IgM Immunoblot (Syphilis)	Colorimetric membrane-based immunoassay (manual test)	Immunoblot
Serum	Parvovirus B19 IgM confirmation (Immunoblot)		
Serum	Treponema pallidum hemagglutination assay (TPHA)	Agglutination assay (manual test)	Hemagglutination
Serum	VDRL (=RPR) (Syphilis)	Agglutination assay (manual test)	VDRL flocculation test
Serum	HIV-WB	Colorimetric membrane-based immunoassay (manual test)	Western blot
Serum	Tetanus IgG	ELISA and related immunoassays (manual test)	ELISA
General domain : MED9 - Collection of biological samples			
Technical domain : MED9.1 - Collection of biological samples, carried out by the laboratory or under its responsibility			
Blood	/	Venipuncture	Manual primary sampling
Swab nasopharynx, throat, nose	/	Smear	Manual primary sampling

* Flexible scope:

The laboratory is deemed competent in implementing new test methods, objects submitted for analysis and characteristics or properties measured. The laboratory is responsible for the validation of the methods it implements. It is also responsible for managing the list of methods it uses, objects submitted for analysis and characteristics or properties measured within the framework of this accreditation.

The possibility of introducing new methods does not include the introduction of new measurement principles.

The list of accredited activities is available on request from the laboratory.