

# **Annex to the accreditation certificate: N° 1/038 According to standard ISO 15189:2022 For a medical laboratory**

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## **Accredited organisation:**

### **BioneXt S.A.**

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<https://www.bionext.lu/en/centres>

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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)
<b>General Domain: MED1 – Clinical Biochemistry</b>			
<b>Technical Domain: MED1.1 – General Biochemistry</b>			
Serum (or plasma)	Antistreptolysin ASLO C-Reactive Protein (CRP) Hypersensitive C-Reactive Protein (CRPhs) Lipoprotein a	Turbidimetry (automated system, COBAS 503)	Latex immunoturbidimetric method
	Albumin	Colorimetry (automated system, COBAS 503)	Bromocresol Green method
	T4L T3L Estradiol Progesterone Thyroglobulin	ECLIA Electrochemiluminescence (automated system, COBAS E801)	ECL method / competition
	Alanine amino transferases Aspartate amino transferase	Colorimetry (automated system, COBAS 503)	IFCC method, without pyridoxal phosphate
	Protéines totales	Colorimétrie (automatique, COBAS 503)	Méthode colorimétrique dite du Biuret
	HDL cholesterol LDL cholesterol Total cholesterol Triglycerides	Spectrophotometry (automated system, COBAS 503)	Enzymatic, colorimetric method
	Alkaline phosphatase	Colorimetry (automated system, COBAS 503)	IFCC Method
	Iron	Colorimetry (automated system, COBAS 503)	Ascorbate / FerroZine method
	Cholinesterase	Colorimetry	Colorimetric method / Butyrylthiocholine

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
		(automated system, COBAS 503)	
	Direct bilirubin Total Bilirubin	Colorimetry (automated system, COBAS 503)	Diazo Method
	Apolipoprotein A1 Apolipoprotein B IgA IgG IgM Transferrin	Immunoturbidimetry (automated system, COBAS 503)	Immunoturbidimetric method
	PSA PSAL HcG FSH LH TSH ACE CA 15-3 CA 19-9 CA 125 AFP NT-proBNP	ECLIA Electrochemiluminescence (automated system, COBAS E801)	ECL method / sandwich
	Creatine kinase CKNAC Creatine kinase CKMB Lactate dehydrogenase	Colorimetry (automated system, COBAS 503)	Immunological UV method
	Vitamin B12	ELISA and related immunoassays (automated system, COBAS 503)	ECLIA (electrochemiluminescence)
	Vitamin D 25OH, Vitamin B9	ELISA and related immunoassays (automated system, COBAS 503)	Electrochemiluminescence by competition
	Ferritin	ELISA and related immunoassays (automated system, COBAS 503)	Immunoturbidimetric
	P1NP	ELISA and related immunoassays (automated system, COBAS PRO)	Sandwich
Stool	Fecal occult blood test	Immunoturbidimetry automated system, Sentifit	Immunochemistry by absorbance

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Serum	Lipase	Colorimetry (automated system, COBAS 503)	Colorimetric method
	γ-Glutamyl Transferase	Colorimetry (automated system, COBAS 503)	Carboxy-GLUPA / Szasz-Persijn / Tris method
	Rheumatoid factor Haptoglobin Transferrin saturation	Turbidimetry (automated system, COBAS 503)	Immunoturbidimetric method
	Pancreatic amylase	Spectrophotometry (automated system, COBAS 503)	Colorimetric method
	Troponin T hs	ELISA and related immunoassays (automated system, COBAS 801)	ECLIA
	Alkaline reserve	Spectrophotometry (automated system, COBAS PRO)	Absorption spectrometry
	Procalcitonin	ELISA and related immunoassays (automated system, COBAS PRO)	Electrochemiluminescence ECLIA
	Myoglobin Prolactin Testosterone SHBG ACTH Insulin C-Peptide Parathormone CTX - CrossLaps	ELISA and related immunoassays (automated system, COBAS PRO)	Sandwich
	Homocysteine	Spectrophotometry (automated system, COBAS PRO)	Enzymatic method
	SDHEA Cortisol	ELISA and related immunoassays (automated system, COBAS PRO)	Competition
	Androstenedione	Direct immunoassay (automated system, LIAISON)	Chemiluminescence competition
	Beta-2 Microglobulin Complement C3 Complement C4	Spectrophotometry (automated system, COBAS PRO)	Immunoturbimetry

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	CDT	Electrokinetic separation CAPILLARYS	Absorption spectrophotometry
	Protein electrophoresis	Capillary electrophoresis CAPILLARYS	Electrokinetic separation technique
Urine	Urine dipstick analysis: glucose, bilirubin, blood, leukocytes, nitrite, pH	Urine dipstick, UC3500 (Sysmex)	Semi-quantitative method
	Urine analysis with sediment: testing for glucose, acetone, protein, urobilin, bilirubin, blood, leukocytes, nitrite, determination of pH and specific gravity, examination of the sediment under the microscope	Urine dipstick, fluorocytometry, automated microscopy UC3500, UF4000, UD10 (Sysmex)	Semi-quantitative method, quantitative and qualitative method
	Urinary proteins	Spectrophotometry (automated system, COBAS PRO)	Turbimetry
Serum/ plasma – urine	Glucose	Spectrophotometry (automatique, COBAS 503)	Colorimetric method (hexokinase/G-6-PHD)
Serum/ plasma – urine	Uric acid Alpha-amylase Calcium Creatinine Magnesium Inorganic phosphorus Urea	Spectrophotometry (automated system, COBAS 503)	Colorimetric method
	Microalbumin	Turbidimetry (automated system, COBAS 503)	Turbidimetric method
	Chloride Potassium Sodium	Measurement of electrical potential - Electrochemistry (automated system, COBAS 503)	Indirect potentiometric method

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
<b>Technical domain: MED1.2 – Pharmacology – Toxicology and radio-toxicology</b>			
Urine	Amphetamine Barbiturates Buprenorphine Benzodiazepine Cocaine 3,4-Methylenedioxy-N-methylamphetamin (MDMA) Methamphetamine Morphine / Opiat Methadone Tricyclic antidepressants tetrahydrocannabinol (THC)	Immunochemistry (manual method, Drug-Screen Multi Test)	Rapid immunochemical test
<b>General domain: MED2 – Haematology</b>			
<b>Technical domain: MED2.1 – Hemocytology</b>			
EDTA whole blood	HbA1c	HPLC method (Tosoh Bioscience G11)	HPLC method
	Automated blood count, microscopic blood count	Flow cytometry and diffraction (leukocytes, neutrophils, lymphocytes, monocytes, eosinophils, basophils); impedance (red blood cells, platelets) or PLT-I; photometry (hemoglobin; electrical pulses (hematocrit) XN1, XN2, XN3	Quantitative method
	Reticulocytes	Flow cytometry and impedance XN2, XN3	Quantitative method
	Sedimentation rate	Photometry (automatic measurement, Alifax)	Automated photometric reading of red cell sedimentation kinetics
<b>Technical domain: MED2.2 – Coagulation</b>			
Plasma	D-Dimer	Nephelometry (automated system, Siemens CS5100)	Adapted, nephelometric, quantitative method, 6-point calibration
	Fibrinogen	Chronometry (automated system, Siemens CS5100)	Adapted, chronometric, quantitative method, 5-point calibration

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	APPT	Chronometry (automated system, Siemens CS5100)	Adapted, chronometric, quantitative method, no calibration
	Prothrombin Time (PT) / INR	Chronometry (automated system, Siemens CS5100)	Adapted, chronometric, quantitative method, 6-point calibration
	Protein S	Chronometry (automated system, Siemens CS5100)	Prolongation of coagulation time by inhibition of factor Va
	Protein C ATIII	Chromogenic method (automated system, Siemens CS5100)	OD measurement
	Resistance to activated protein C	Chronometry (automated system, Siemens CS5100)	Quantitative method
<b>Technical domain: MED2.3 – Immunohematology</b>			
Serum (or plasma)	ABO blood grouping, Rhesus, Kell	Agglutination (automated system, ORTHO VISION)	Agglutination column filtration
	IAT	Agglutination (automated system, ORTHO VISION)	Agglutination column filtration
<b>General domain: MED3 – Immunology</b>			
<b>Technical domain: MED3.1 – Allergology</b>			
Serum	Specific IgE Total IgE	Automatic measurement PHADIA	FEIA Sandwich immunoassay
<b>Technical domain: MED3.2 – Autoimmune diagnostics</b>			
Serum	Anti-acetylcholine receptor antibodies Anti-Musk antibodies	ELISA and related immunoassays (automated system, ZENIT UP)	ELISA (Quantitative method)
	anti-LGI1/CASPR2 antibodies Pancreatic islet-cell antibodies (ICA)	Fluorescence microscopy	Immunofluorescence (Qualitative method)
	Anti-phospholipid antibodies IgG Anti-phospholipid antibodies IGM	Fluorescence (automated system, Phadia)	Immunoenzymatic method
	Anti-actin antibodies	Fluorescence microscopy	Immunofluorescence / DOT

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	Anti-LKM antibodies Anti-LC1 antibodies Anti-neuron antibodies Anti-nuclear antibodies ANCA Anti-myelin antibodies Anti-mitochondria antibodies Anti-parietal cell antibodies Anti-liver antibodies Anti-MPO antibodies Anti-PR3 antibodies Anti-kidney antibodies (GBM)	Immunoassay	(Qualitative and quantitative methods)
	Anti-intrinsic factor antibodies Anti-ganglioside antibodies	Immunoassay	DOT (Quantitative method)
	Anti-Gliadine IgA antibodies, Anti-transglutaminase IgA antibodies	Immunoassay Automated system, Profiblot 48	DOT
	Anti-TPO antibodies Anti-Thyroglobulin antibodies Anti-TSHr antibodies	ELISA and related immunoassays (automatic measurement, COBAS PRO)	ECLIA Competition method
<b>General domain: MED4 – Medical microbiology</b>			
<b>Technical domains: MED4.2 – Medical bacteriology / MED4.3 – Medical parasitology / MED4.4 – Medical mycology</b>			
<b>Macro- and microscopic examinations</b>			
<b>URINARY TRACT INFECTION / CYTOBACTERIOLOGICAL EXAMINATION OF URINE</b>			
Urine / Urine sediment	Red blood cells, leukocytes, epithelial cells and crystals	Flow cytometry Automated method UF4000 (Sysmex)	Enumeration of red and white blood cells, epithelial cells and crystals
	Microorganisms	Automated light microscopy UD10 (Sysmex)	Direct examination: Search for bacteria and yeast on a GRAM stained slide



Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	Bacteria and yeast	Automated method Wasp (MLS)	Manual plating Culture and recognition of colonies
	Testing for urinary soluble antigens of Legionella pneumophila and Streptococcus pneumoniae	Immunochromatography (manual method, BinaxNOW Legionella Ag Urinary)	Rapid immuno-chromatographic test
<b>UROGENITAL AND SEXUALLY TRANSMITTED INFECTIONS</b>			
Vaginal swab	Bacteria and yeast	Light microscopy Manual method	Fresh state: Search for microorganisms on the slide
			Direct examination: Search for bacteria and yeast on a GRAM / MGG stained slide
	Bacteria and yeast	Méthode automatisée WASP (MLS)	Automated plating Culture and recognition of colonies by automated method
<b>DIGESTIVE TRACT INFECTION / STOOL CULTURE</b>			
Stool	Microorganisms	Manual or automated slide staining (PREVI Color, Biomérieux) Light microscopy	Direct examination : Search for bacteria on GRAM stained slides
	Bacteria and yeasts	Manual and/or automated technique WASP (MLS)	Manual or automated plating Culture and colony recognition by manual or automated method
	Bacteria	Manual technique Macroscopic characteristics	Manual plating Culture and recognition of colonies by manual method
<b>OTHER TYPES OF INFECTIONS</b>			
Sperm Secretion and exudates of the otorhinolaryngeal sphere Expectoration Puncture fluid Urethral swab Intrauterine device (IUD) Ocular specimen Skin	Microorganisms	Manual or automated slide staining (PREVI Color, BioMérieux) Light microscopy	Direct examination: Search for bacteria and yeast on a GRAM stained slide
	Bacteria and yeast	Manual and/or automated method WASP (MLS)	Manual or automated plating Culture and recognition of colonies by manual or automated methods
	Bacteria	Manual method Macroscopic characteristics	Manual plating

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Wound Pus			Culture and recognition of colonies by manual method
Skin and appendages	Filamentous fungi and yeasts	Light microscopy (manual measurement)	Microscopic examination
		Manual plating	Culture in solid medium Macroscopic and microscopic examination in the fresh state and after culture
Whole blood	Malaria	Light microscopy (manual method)	Light microscopy slide reading after MGG staining
		Immunochromatography (manual method)	Rapid immuno-chromatographic test
<b>Antibiograms and additional tests</b>			
<b>Culture from matrices :</b> Urine Vaginal swab Sperm Secretion and exudates of the otorhinolaryngeal sphere Expectoration Puncture fluid Urethral swab Intrauterine device (IUD) Ocular specimen Skin Wound Pus Stool	Antibiotic susceptibility	Diameter measurement Agar diffusion (manual technique)	ANTIMICROBIAL SUSCEPTIBILITY TESTING MIC and complementary tests in solid media: diffusion in agar media
	Antibiotic susceptibility	Spectrophotometry Diffusion in liquid media (automated method, Vitek2, BioMérieux)	ANTIMICROBIAL SUSCEPTIBILITY TESTING MIC and complementary tests: Measurement of growth inhibition in liquid medium in the presence of antibiotics
Swabs (armpits, nose, inguinal folds, throat, wound)	MRSA	Manual method	Qualitative method on specific chromogenic media
Swabs (rectal, nasal, inguinal folds, armpits, wound, throat) Stool	ESBL	Manual method	Qualitative method on specific chromogenic media

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
<b>Identification</b>			
<b>Culture from matrices :</b> Urine Vaginal swab Sperm Secretion and exudates of the otorhinolaryngeal sphere Expectoration Puncture fluid Urethral swab Intrauterine device (IUD) Ocular specimen Skin Wound Pus Stool	Bacteria and yeast Search for MRSA Search for ESBL	Automated method Mass spectrometry Maldi-Tof (Bruker)	Automated identification by mass spectrometry
<b>Technical domain: MED4.6 - Infectious molecular biology</b>			
Stool	Testing for parasites : <i>Giardia lamblia</i> <i>Entamoeba histolytica</i> <i>Cryptosporidium spp.</i> <i>Blastocystis hominis</i> <i>Dientamoeba fragilis</i> <i>Cyclospora cayetanensis</i> <i>Enterocytozoon spp.</i> <i>Encephalitozoon spp.</i> <i>Strongyloides spp.</i> <i>Hymenolepis spp.</i> <i>Ascaris spp.</i> <i>Taenia spp.</i> <i>Trichuris trichiura</i> <i>Ancylostoma spp.</i> <i>Enterobius vermicularis</i> <i>Necator americanus</i>	DNA/RNA detection and amplification (gene hybridization with amplification) (STAR/STARLET/CFX96)	Quantitative and qualitative methods
Stool	Testing for viruses: Norovirus GI Norovirus GII Rotavirus Adenovirus Astrovirus		

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	Sapovirus		
Stool	Testing for bacteria : <i>Campylobacter</i> spp. <i>Salmonella</i> spp. <i>Shigella</i> spp. <i>E. coli</i> entéro-invasif <i>Yersinia enterocolitica</i> <i>Escherichia coli</i> O157		
Stool	Testing for bacterial toxin : <i>Clostridium difficile</i> (toxine B) (stx1/stx2) toxine (A/B) de <i>Clostridium difficile</i>		
Vaginal swab	<i>G. vaginalis</i> (quantitatif) <i>A. vaginae</i> (quantitatif) <i>Mobiluncus</i> spp <i>Lactobacillus</i> spp (quantitatif) <i>Trichomonas vaginalis</i> <i>Candida albicans</i> <i>Candida</i> spp		
Genital swabs, urine, oropharyngeal swabs, rectal swabs and semen	Sexually transmitted diseases <i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i> <i>Trichomonas vaginalis</i> <i>Mycoplasma genitalium</i> <i>Ureaplasma urealyticum</i> <i>Mycoplasma hominis</i> <i>Ureaplasma parvum</i>		
Respiratory samples	Testing for SARS-COV-2 Coronavirus Influenza A - Influenza B - RSV -		

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	Coronavirus SARS-Cov2		
<b>General domain: MED5 – Sérologie</b>			
<b>Technical domain: MED5.1 – Sérologie infectieuse</b>			
Serum	Chlamydia pneumonia serology (IgG, IgM)	ELISA and related immunoassays (automated system, Etimax)	ELISA (Quantitative method)
	Borrelia burgdorpi serology (IgG, IgM); screening serology Chlamydia trachomatis serology (IgG, IgA) Mycoplasma pneumoniae serology (IgG, IgM) Epstein Barr virus serology (EBNA IgG, VCA IgG, VCA IgM) Herpes simplex virus serology (HSV2 IgG, HSV 1 IgG, HSV 1 et 2 IgM) Parvovirus B19 serology (IgG, IgM) Varicella Zoster virus serology (IgG, IgM)	ELISA and related immunoassays (automated system, Liaison XL)	Chemiluminescence (Quantitative method)
	Cytomegalovirus serology (IgG) Rubella IgG Toxoplasmosis IgG	Electrochemiluminescence ECLIA (automated system, COBAS E801)	ECL method / sandwich
	Cytomegalovirus serology (IgM) Rubella IgM Toxoplasmosis IgM	Electrochemiluminescence ECLIA (automated system, COBAS E801)	ECL method / $\mu$ -Capture
	Interferon- $\gamma$ (Quantiferon)	Immunoluminometric technology (automated system, LIAISON)	Chemiluminescence sandwich
Sérum humain (ou plasma)	HIV, Anti HAV total antibodies, Anti HAV IgM antibodies,	ELISA and related immunoassays (automated system, COBAS E801)	ECLIA (electrochemiluminescence)

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	HBs antigen, Anti HBc antibodies HCV, HBs antigen confirmation by neutralisation		
	HBs antibodies Syphilis	ELISA and related immunoassays (automated system, COBAS E801)	ECLIA/Sandwich
	COVID serology	ELISA and related immunoassays (automated system, COBAS E801)	ECLIA / Dual antigen sandwich method
	Rubella IgM, IgG Toxoplasmosis IgM, IgG	ELISA and related immunoassays (automated system, VIDAS)	Enzyme-linked immunosorbent assay with final fluorescence detection (ELFA)
	VDRL (Syphilis)	Agglutination test Manual technique	Indirect haemagglutination
	TPHA (Syphilis)	Agglutination test Manual technique	Agglutination reaction
<b>General domain : MED7 – Reproductive biology</b>			
<b>Technical domain: MED7.1 – Spermiology</b>			
Sperm	Sperm detection and identification, volume, pH, viscosity, agglutination, motility, concentration, round cells	Manual method Direct macro- and microscopic examination, with or without treatment (centrifugation, gradient,...) on fresh sample or after thawing	WHO Standard 2021 Bioforma 42 Spermogram / TMS / Post- vasectomy control
	Morphological examination and identification of cells (round cells, spermatozoa, etc.) and/or vitality	Manual method Staining (Papanicolaou, Eosin-Nigrosin, Harris- Schorr, ...) and/or microscopic examination (MSOME...)	WHO Standard 2021Bioforma 42 Spermogram / Spermocytogram / TMS
	Detection, identification and determination of the concentration of anti- spermatozoa antibodies	Latex agglutination	WHO Standard 2021 Bioforma 42 MAR-Test

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
<b>Technical domain: MED7.2 – Medically assisted procreation</b>			
Sperm	Sperm preparation for MAP: Sperm detection and identification, volume, motility, concentration	Manual method Direct macro- and microscopic examination, with or without treatment (centrifugation, gradient,...) on fresh or thawed samples	WHO Standard 2021 Bioforma 42
<b>General domain : MED9 – Collection of biological samples</b>			
<b>Technical domain: MED9.1 – Collection of biological samples, carried out by the laboratory or under its responsibility</b>			
Venipuncture	/	Venipuncture	Sampling manual D_PREA_002
Microbiological samples: Skin Phanera ENT Mucous membrane	/	Other samples and collections	Sampling manual D_PREA_002