

## Annex to the accreditation certificate: N° 1/017 According to standard e ISO 15189:2012 For a medical laboratory

Version 09 of the technical annex from 15 April 2024 Valid until 07 December 2025

## Accredited organisation:

**KETTERTHILL S.A.** 8, avenue du Swing – B.P. 8 L-4401 Belvaux

The list of collection sites is available at the following link: https://www.ketterthill.lu/en/our-centres/our-locations.html

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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)
General domain: MED	1 - Clinical Biochemistry	/	
Technical domain: ME	D1.1 - General Biochem	istry	
Serum	Alpha 1 antitrypsin Apolipoprotein A1 Apolipoprotein B Beta-2-microglobulin Ceruloplasmin Complement C3, Complement C4 CRP Haptoglobin IgA, IgG, IgM Lp(a) Orosomucoid Transferrin	Turbidimetry (automated system, Abbott Architect-C)	Immunoturbidimetric method
Serum	25-OH vitamin D2-D3 Alpha-fetoprotein Total ß-HCG CA 125, CA 15.3, CA 19.9 CEA C.K. MB Cortisol DHEA-S Ferritin Folate FSH Insulin LH Myoglobin NT-proBNP Estradiol PSA, Free PSA Procalcitonin Progesterone Prolactin SHBG Free T3, Free T4 Total testosterone Thyroglobulin TSH Troponin I hs Vitamin B12	ELISA and related immunoassays (automated system, Abbott Architect-I)	СМІА
Serum	Albumin Amylase Pancreatic amylase Bilirubin	Spectrophotometry (automated system, Abbott Architect-C)	Colorimetric method



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	Conjugated/direct bilirubin H.D.L. cholesterol L.D.L. cholesterol Total cholesterol Cholinesterase Total C.P.K. Iron G.G.T. G.O.T G.P.T L.D.H Lipase Total protein Alkaline phosphatase Triglycerides		
Serum or urine	Uric acid Calcium Creatinine Magnesium Phosphorus Urea	Spectrophotometry (automated system, Abbott Architect-C)	Méthode colorimétrique
	Chloride Potassium Sodium	Electrochemistry (automated system, Abbott Architect-C)	Potentiometric method (indirect ISE)
Plasma or urine	Glucose	Spectrophotometry (automated system, Abbott Architect-C)	Colorimetric method (Hexokinase/G-6-PDH)
Plasma	Homocysteine	ELISA and related immunoassays (automated system, Abbott Architect-I)	СМІА
Serum	Growth Hormone (GH) CTX - CrossLaps Osteoclastin P1NP Calcitonin Intact HCG + beta subunit	ELISA and related immunoassays (automated system, Roche Cobas e801)	ECLIA
Whole blood	Hb A1c	HPLC (automated system, Tosoh Bioscience G8)	HPLC
Urine	Urine chemistry (dipstick) : Testing for glucose, acetone, protein, urobilinogen, bilirubin, blood, leukocytes, nitrites, pH and density	Photometry and Refractometry (automated system, Sysmex UC-3500)	Automated test strip reading
	Albumin, Protein	Turbidimetry (automated system, Abbott Architect-C)	Immunoturbidimetric method



Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Technical domain: M	ED1.2 – Pharmacology –	Toxicology and radio-toxicolo	ogy
	Valproic acid	Turbidimetry (automated system, Abbott Architect-C)	Immunoturbidimetric method
Serum	Ethanol	Spectrophotometry (automated system, Abbott Architect-C)	Colorimetric method (alcohol dehydrogenase)
	Lithium	Spectrophotometry (mesure automatique, Abbott Architect-C)	Colorimetric method
Urine	11-nor-Δ9-THC-9- carboxylic acid (Cannabis), Amphetamine- Methamphetamine, Benzodiazepines, Benzoylecgonine (metabolite of Cocaine), Methadone, Opiates	ELISA and related immunoassays (automated system, Abbott Architect-C)	EIA
General domain: MED	2 - Haematology		
Technical domain: M	ED2.1 - Hemocytology		
Whole blood	Automated blood count	<ul> <li>Impedance measurement, photometry and multi-angular laser diffraction (automated system, Sysmex XN9000)</li> <li>Optical microscopy (automatic measurement, Sysmex DI-60)</li> </ul>	- Blood count - Microscopic reading after staining with MGG
	Reticulocytes	Flow cytometry (automated system, Sysmex XN9000)	Counting after labelling with a specific fluorochrome
	Sedimentation rate	Photometry (automated system, Alifax)	Automated photometric reading of red cell sedimentation kinetics
Technical domain: M	ED2.2 - Coagulation		
Plasma	Antithrombin Protein C	Colorimetry (automated system, Siemens CS5100)	OD measurement
	D-Dimer	Turbidimetry (automated system, Siemens CS5100)	Immunological method
	Fibrinogen	Chronometry (automated system, Siemens CS5100)	Chronometric method
	Protein S	Free turbidimetry (automated system, Siemens CS5100)	Immunological method



Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	Activated partial thromboplastin time	Chronometry (automated system, Siemens CS5100)	Plasma recalcification time in the presence of an activator (cephalin)
	Prothrombin level Prothrombin time - INR	Chronometry (automated system, Siemens CS5100)	Coagulation time of plasma in the presence of calcium thromboplastin
Technical domain: ME	ED2.3 – Immunohematol	ogy	
Whole blood	ABO blood grouping, Rhesus, Kell	Agglutination (automated system, ORTHO VISION, Ortho Clinical Diagnostics)	Haemagglutination and diffusion by centrifugation on glass bead columns
Plasma / Serum	IAT	Agglutination (automated system, ORTHO VISION, Ortho Clinical Diagnostics)	Haemagglutination and diffusion by centrifugation on glass bead columns
General domain: MED	3 - Immunology		
Technical domain: ME	ED3.2 - Autoimmune diag	gnostics	
	Anti-thyroglobulin antibodies, Anti-TPO antibodies	ELISA and related immunoassays (automated system, Abbott Architect-I)	СМІА
	Anti-acetylcholine receptor antibodies Anti-Musk antibodies Anti-insulin antibodies Anti-IA2 antibodies Anti-calcium channel antibody (VGCC) Anti-GAD2 antibodies	Radioimmunoassay (automated system, Gamma Counter C-12 Siemens)	RIA Manual sample preparation and gamma emission measurement of the tracer radioisotope
	Anti-phospholipid antibodies	ELISA and related immunoassays	Search for a mixture of anti-phospholipid Ac (ELISA)
Serum	Anti-mitochondria, anti- actin, anti-LKM, anti-LC1 antibodies	Fluorescence microscopy	Triple substrate (kidney- liver-stomach) IF detection (Adaptation of commercial technique)
	Anti-neuron antibodies	Fluorescence microscopy	Detection of Ac in neural tissue sections by IF (Adaptation of commercial technique)
	Anti-pancreas antibodies	Fluorescence microscopy	Detection of Ac in pancreatic tissue by IF
	Anti-nuclear factor	Automated fluorescence microscopy Europattern ELISA and related	Antibody detection on Hep-2 cells by fluorescence microscopy and confirmation of specificity by
		immunoassays Immunoassay	IF EIA DOT



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Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	ANCA	Fluorescence microscopy	Neutrophil Antibody Detection by IF (Adaptation of commercial technique)
	Anti-myelin antibodies	Fluorescence microscopy	Antibody detection on sciatic nerve section by IF
	Anti-endomysium antibodies	Fluorescence microscopy	Antibody detection in oesophageal sections by IF
	Anti-mitochondria antibodies, Anti-intrinsic factor antibodies, Anti-liver antibodies, Anti-gliadine/anti-tTG antibodies, Anti-MPO/anti-PR3 antibodies, Anti-MPO/anti-PR3/anti- MBG antibodies	Immunoassay	DOT
	Anti-gangliosides antibodies	Immunoassay	DOT (Adaptation of commercial technique)
	Anti-synapse antibodies Anti-MOG antibodies Anti-aquaporine 4 antibodies Anti-Iglon5 antibodies	Fluorescence microscopy	Indirect detection in transfected cells by IF
	CIBD: - Indirect detection on transfected cells (pancreatic antigen) - Detection of ASCA - Indirect detection on colonic cells - Antibody detection on neutrophils	Fluorescence microscopy	IF
	Anti-skin antibodies	Fluorescence microscopy	Detection of antibodies on skin sections by IF
	Anti-DSG1 antibodies		Detection of anti-DSG1 antibodies (ELISA)
	Anti-DSG3 antibodies		Detection of anti-DSG3 antibodies (ELISA)
	Anti-BP180 antibodies	ELISA and related	Detection of anti-BP180 antibodies (ELISA)
	Anti-BP230 antibodies	immunoassays	Detection of anti-BP230 antibodies (ELISA)
	Anti-ZnT8 antibodies		Detection of anti-ZnT8 antibodies (ELISA) (Adaptation of commercial technique)



Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	Anti-TSH receptor antibodies (TRAK)	ELISA and related immunoassays (automated system, Abbott Architect-I)	СМІА
Technical domain: ME	ED3.1 – Allergology		
Serum	IgE, specific IgE	ELISA and related immunoassays (automated system, Thermofischer Scientific Phadia 1000)	FEIA
General domain: MED	5 – Serology		
Technical domain: ME	ED5.1 – Infectious serolo	ал	
	Anti HBcore IgM antibodies, Total anti HBcore antibodies, Anti Hbe antibodies, Anti HBs antibodies, Anti HCV antibodies, Anti HCV antibodies, Anti HIV 1,2 antibodies + Ag P24, HBe antigen, HBs antigen, CMV IgM antibodies, E.B.N.A. IgG antibodies, E.B.N.A. IgG antibodies, Hépatitis A IgG, IgM antibodies, Rubella IgM antibodies, Syphilis screening, Toxoplasmosis IgM antibodies V.C.A. IgG, IgM antibodies	ELISA and related immunoassays (automated system, Abbott Architect-I)	СМІА
Serum	CMV IgG, Rubella IgG, Toxoplasmosis IgG	ELISA and related immunoassays (automated system, Abbott Architect-I, Rochen Cobas e801 et Biomérieux Vidas)	CMIA ECLIA ELFA
	Borrelia IgG, IgM, Mumps IgG, IgM MeaslesIgG, IgM	ELISA and related immunoassays (automated system, Diasorin Liaison)	CLIA
	Coronavirus SARS-CoV- 2 Ig	ELISA and related immunoassays (automated system, Abbott Architect-I)	СМІА
	Syphilis : - antivbody detection - RPR antigen	Agglutination (manual measurement)	TPPA agglutination test RPR agglutination test
	Borrelia IgG, IgM confirmation, Syphilis IgG, IgM confirmation	Immunoassays (Euroimmun, Euroblotone)	DOT



Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods	
General domain: MED	4 – Medical microbiolog	у		
Technical domains: I MED4.4 – Medical myo		iology / MED4.3 – Medical par	asitology /	
Macro- and microscop	bic examinations			
URINARY TRACT INFEC	TION / CYTOBACTERIOLO	GICAL EXAMINATION OF URINE		
	Red blood cells, leukocytes, epithelial cells, yeast, crystals, spermatozoa.	Flow cytometry Light microscopy Automated measurement (Sysmex UF-5000 and UD-10)	Enumeration of red and white blood cells, epithelial cells and yeast. Detection of crystals and spermatozoa.	
Urine	Microorganisms	Light microscopy (manual method)	Fresh state: Search for bacteria and yeast on the slide	
	Bacteria and yeast	Semi-automatic method (KIESTRA robotic chain)	Culture on OXOID and BIOMERIEUX agar media by semi-automatic method Semi-quantitative enumeration of colonies on culture	
DIGESTIVE INFECTION /	STOOL CULTURE			
	Bacteria and yeast	Light microscopy (manual method)	Direct examination: Search for bacteria and yeast on a GRAM stained slide	
	Parasites	Light microscopy (manual method)	Direct examination with or without concentration	
Stool	Bacteria and yeast	Semi-automatic method (KIESTRA robotic chain)	Culture on OXOID and BIOMERIEUX agar media by semi-automatic method Semi-quantitative enumeration of colonies on culture	
UROGENITAL AND SEXUALLY TRANSMITTED INFECTIONS				
	Bacteria and yeast	Light microscopy (manual method)	Direct examination: Search for bacteria and yeast on a GRAM stained slide	
Genital swabs	Bacteria and yeast	Semi-automatic method (KIESTRA robotic chain)	Culture on OXOID and BIOMERIEUX agar media by semi-automatic method Semi-quantitative enumeration of colonies on culture	



Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
OTHER TYPES OF INFE	CTIONS		
ENT area (throat, pharynx, tonsil, tongue, sinuses, nostrils, ears) Sputum Wounds Pus from closed collection Joint fluid Eye, conjunctiva and adnexa	Bacteria and yeast	Light microscopy (manual method)	Direct examination: Search for bacteria and yeast on a GRAM stained slide
Phanera and skin	Filamentous fungi and dermatophytes	Light microscopy (manual method)	Culture in solid medium Macroscopic and microscopic examination in the fresh state and after culture
Whole blood	Parasites	Light microscopy (manual method)	Light microscopic slide reading after staining with MGG
Antibiograms and add	litional tests		
<b>Culture from matrices:</b> Urine Stool Genital swabs ENT area (throat, pharynx, tonsil, tongue, sinuses, nostrils, ears)	Antibiotic susceptibility for Campylobacter MRSA ESBL	Diameter measurement (manual method, BIORAD disks)	ANTIMICROBIAL SUSCEPTIBILITY TESTING MIC and complementary tests in solid media: diffusion in agar media
Sputum Wounds Pus from closed collection Joint fluid Eye, conjunctiva and adnexa	Sensibilité aux antibiotiques pour les entérobactéries, Enterococcus sp, Staphylococcus sp, Streptococcus, Pseudomonas et autres bactéries à Gram négatif non-fermentants	Colorimetry (automated method, BIOMERIEUX VITEK)	ANTIMICROBIAL SUSCEPTIBILITY TESTING MIC and complementary tests: Measurement of growth inhibition in liquid medium in the presence of antibiotics
Identification			
Culture from matrices : Urine Stool Genital swabs ENT area (throat, pharynx, tonsil, tongue, sinuses, nostrils, ears) Sputum Wounds Pus from closed collection Joint fluid Eye, conjunctiva and adnexa	Identification of bacteria	Automated method Mass spectrometry Maldi-Tof (Biotyper BRUKER)	Automated identification by mass spectrometry



Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Technical domain: ME	D4.6 – Infectious molec	ular biology	
Stool	Search for pathogenic bacteria: Salmonella sp, Shigella sp, Yersinia enterocolitica, Campylobacter spr, Aeromonas sp, Clostridium difficile Vibrio sp	Nucleic acid amplification - real-time fluorescence detection (automated system, CFX Biorad machine and Seegene kits)	Multiplex PCR, qualitative method
	Search for protozoa: Entamoeba histolytica, Giardia intestinalis, Cryptosporidium sp, Dientamoeba fragilis, Blastocystis hominis Cyclospora	Nucleic acid amplification - real-time fluorescence detection (automated system, CFX Biorad machine and Seegene kits)	Multiplex PCR, qualitative method
Whole blood	Search for Plasmodium sp.	Isothermal nucleic acid amplification (automated system, Illumipro- 10, Illumigène – Meridian)	Simplex PCR, qualitative method
Genital (vaginal) swab	Detection of Candida albicans, Candida non albicans, semi- quantification of Lactobacillus, Gardnerella vaginalis, Atopobium vaginae and Mobiluncus sp (Hay Ison score)	Nucleic acid amplification - real time fluorescence detection (automated system, CFX Biorad et kits Seegene)	Multiplex PCR, qualitative method
Genital swab, ENT sample, rectal swab, urine, sperm	Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma genitalium	Nucleic acid amplification - real time fluorescence detection (automated system, CFX Biorad et kits Seegene)	Multiplex PCR, qualitative method
Genital swab, urine	Trichomonas vaginalis	Nucleic acid amplification - real time fluorescence detection (automated system, CFX Biorad et kits Seegene)	Multiplex PCR, qualitative method
Genital swab, urine, sperm	Urogenital mycoplasma : Ureaplasma urealyticum, Mycoplasma hominis, Ureaplasma parvum	Nucleic acid amplification - real time fluorescence detection (automated system, CFX Biorad et kits Seegene)	Multiplex PCR, semi- quantitative method
Nasopharyngeal or oropharyngeal swab	Coronavirus SARS-Cov2	Nucleic acid amplification - real time fluorescence detection (automated system, CFX Biorad et kits Seegene)	Multiplex PCR, qualitative method



Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods	
Nasopharyngeal or oropharyngeal swab	Influenza A - Influenza B - RSV - Coronavirus SARS-Cov2	Nucleic acid amplification - real time fluorescence detection (automated system, CFX Biorad and Seegene kits)	Multiplex PCR, qualitative method	
ENT sample (nose, throat or nasopharynx swabs, sputum)	Chlamydia pneumoniae, Mycoplasma pneumoniae, Legionella pneumophila	Nucleic acid amplification - real time fluorescence detection (automated system, CFX Biorad and Seegene kits)	Multiplex PCR, qualitative method	
General domain: MED	7 – Reproductive biolog	у		
Technical domain: ME	D7.1 – Spermiology			
Sperm	Spermogram: Determination of volume, pH, viscosity, agglutination, motility, vitality, count, concentration and differentiation of sperm, round cells and leukocytes	Manual method Direct macro- and microscopic examination, with or without treatment (centrifugation, gradient,) on fresh sample	WHO Standard 2021	
Sperm	Spermocytogram Morphological study of spermatozoa	Manual method Staining and microscopic examination	WHO Standard 2021	
Sperm	Capacitation and survival test	Manual method Direct microscopic examination, with or without treatment (centrifugation, gradient,) on fresh sample	WHO Standard 2021	
General domain: MED	9 – Collection of biologi	cal samples		
	Technical domain: MED9.1 – Collection of biological samples, carried out by the laboratory or under its responsibility			
Blood	1	Venipuncture	MO_PREL_37 MO_PREL_38	
Other samples and collections : - genital swab - ENT specimen - sampling of the eye, conjunctiva and adnexa - sampling of wounds - sampling of skin and skin appendages	/	Other samples and collections	MO_PREL_40	