

MEDICAL LABORATORY ACCREDITATION PROGRAM

Scope of Accreditation

Legal Name of Accredited Laboratory: LILIUM DIAGNOSTICS INC.

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Program Specialty Area:	Medical
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Accreditation Valid to:	2029-01-12

*Remarque : La présente portée d'accréditation existe également en français, celle-ci est publiée séparément.
 Note: This scope of accreditation is also available in French as a separately issued document.*

SCOPE OF ACCREDITATION

01.0 BIOCHEMISTRY

- 01.1 BIOCHEMISTRY – CLINICAL
- 01.2 BIOCHEMISTRY – HORMONAL
- 01.3 BIOCHEMISTRY – IMMUNOLOGY

02.0 MOLECULAR BIOLOGY

- 02.3 MOLECULAR DIAGNOSIS – INFECTIOUS DISEASES

05.0 HEMATOLOGY

- 05.1 HEMATOLOGY – CYTOCHEMISTRY
- 05.2 HEMATOLOGY – CYTOLOGY
- 05.3 HEMATOLOGY – ERYTHROCYTIC

DETAILS OF SCOPE OF ACCREDITATION

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Albumin	Colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Total protein	Colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Lactate	Colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Bilirubin total	Colorimetric Diazo, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Bilirubin direct	Colorimetric Diazo, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Creatinine eGFR (calc.)	Kinetic colorimetric Assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Urea (BUN)	Enzymatic colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Uric acid	Enzymatic colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
Electrolyte Panel and Minerals				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Electrolytes (Na, K, Cl)	Ion selective Electrode, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Carbon dioxide (CO ₂)	Enzymatic colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Calcium (Ca)	Photometric Assay, Roche Cobas	Blood and derived products (serum, plasma)

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Magnesium (Mg)	Colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Lithium	Colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Phosphate (PO4)	Molybdate UV Assay, Roche Cobas	Blood and derived products (serum, plasma)
Lipid panel				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Cholesterol	Enzymatic and colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Triglycerides	Enzymatic and colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	High-density lipoproteins (HDL)	Enzymatic and colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Low-density lipoproteins (LDL)	Enzymatic and colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
Lipoproteins				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Apolipoprotein A1 (APOA1)	mmunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Apolipoprotein B (APOB)	mmunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Lipoprotein A (LP (a))	mmunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
Anemic Profile				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Iron	Colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Transferrin	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Ferritin	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Unsaturated iron-binding capacity (UIBC)	FerroZine, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Total iron-binding capacity (TIBC)	Calculated	Blood and derived products (serum, plasma)

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
Enzymes				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Alkaline phosphatase (ALP)	Enzymatic colorimetric assay, Roche Cobas	Sang et produits dérivés (sérum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Alanine aminotransferase (ALT)	Enzymatic colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Aspartate aminotransferase (AST)	Enzymatic colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Gamma-glutamyl transferase (GGT)	Enzymatic colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Lactate dehydrogenase (LDH)	Enzymatic colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Amylase (pancreatic)	Enzymatic colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Creatine kinase (CK)	CK-UV test, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Lipase	Kinetic colorimetric Assay, Roche Cobas	Blood and derived products (serum, plasma)
Sample Index				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Lipemia	Absorbance measurements at different bichromatic wavelength pairs, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Hemolysis	Absorbance measurements at different bichromatic wavelength pairs, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Icterus	Absorbance measurements at different bichromatic wavelength pairs, Roche Cobas	Blood and derived products (serum, plasma)
Vitamins				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Folate / RBC Folate	Competition Electro-chemiluminescence Binding Assay (ECLBA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Vitamin D	Competition Electro-chemiluminescence Binding Assay (ECLBA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Vitamin B12 / Vitamin B12 active	Sandwich Electro-chemiluminescence Immuno Assay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
Immunology				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	C-Reactive Protein (CRP)	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	C-Reactive Protein, high sensitivity (CRP-HS)	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Complement C3	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Complement C4	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Immunoglobulin A (IgA)	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Immunoglobulin G (IgG)	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Immunoglobulin M (IgM)	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Rheumatoid Factor (RF)	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Antistreptolysin O (ASO)	Immunoturbidimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Immunoglobulin E (IgE)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
Other				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Homocysteine	Enzymatic Assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Calprotectin (FCAL)	Particle enhanced turbidimetric immunoassay (PETIA), Roche Cobas	Stool (fecal)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Cystatin C	Particle enhanced turbidimetric immunoassay (PETIA), Roche Cobas	Blood and derived products (serum, plasma)
Serum Protein Electrophoresis				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Serum Protein Electrophoresis	Capillary Electrophoresis, Sebia	Blood and derived products (serum, plasma)
Blood sugar				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Glucose	Hexokinase UV-test, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Fructosamine	Colorimetric assay, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Glycated haemoglobin (HbA1c)	Turbidimetric inhibition immunoassay (TINIA), Roche Cobas	Whole blood
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Glycated haemoglobin (HbA1c)	HPLC, Tosoh G11	Whole blood
Urinalysis				
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Microalbumin	Immunoturbidimetric assay, Roche Cobas	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Creatinine	Kinetic colorimetric Assay, Roche Cobas	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Total protein	Colorimetric assay, Roche Cobas	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Amylase (pancreatic)	Enzymatic colorimetric assay, Roche Cobas	Urine

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Color	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Clarity	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Specific Gravity	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	pH	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Blood	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Glucose	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Bilirubin	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Ketone	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Protein	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Urobilinogen	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Nitrite	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Leucocytes	Test Strips, Siemens	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Red Blood Cells (and Morphology)	Fluorescence Flow Cytometry, Sysmex	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	White Blood Cells	Fluorescence Flow Cytometry, Sysmex	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Epithelial cells	Fluorescence Flow Cytometry, Sysmex	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Crystals	Fluorescence Flow Cytometry, Sysmex	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Casts (hyaline or pathologic)	Fluorescence Flow Cytometry, Sysmex	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Yeast	Fluorescence Flow Cytometry, Sysmex	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Bacteria (and type of bacteria)	Fluorescence Flow Cytometry, Sysmex	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Urine culture with antibiogram	Microbial culture and antibiogram	Urine
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Human chorionic gonadotropin (hCG)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Anti-Müllerian Hormone (AMH)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	C-Peptide	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Follicle Stimulating Hormone (FSH)	Sandwich Electrochemiluminescence	Blood and derived products (serum, plasma)

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
			Immunoassay (ECLIA), Roche Cobas	
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Human Growth Hormone (hGH)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Insulin Growth Factor 1 (IGF-1)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Luteinizing Hormone (LH)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	NT-proBNP	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Parathyroid Hormone (PTH)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Prolactin	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Sex Hormone-Binding Globulin (SHBG)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Insulin	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Thyroid Stimulating Hormone (TSH)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Thyroglobulin (Tg)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Free beta human chorionic gonadotrophin (Free beta-hCG)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Pregnancy associated plasma protein A (PAPP-A)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Adrenocorticotrophic Hormone (ACTH)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	17 α hydroxy Progesterone (17-OHP)	Immunological Competition Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Aldosterone	Immunological Competition Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Cortisol	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Dehydroepiandrosterone sulfate (DHEAS)	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Testosterone	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Progesterone	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Androstenedione	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Aldosterone	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Estradiol	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Triiodothyronine (T3)	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Thyroxine (T4)	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Free Thyroxine (FT4)	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Free Triiodothyronine (FT3)	Competitive Electrochemiluminescence	Blood and derived products (serum, plasma)

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
			Immunoassay (ECLIA), Roche Cobas	
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Anti-TSH receptor antibodies (Anti-TSHR)	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Anti-Thyroid Peroxidase Antibodies (Anti-TPO)	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Anti-Thyroglobulin antibodies (Anti-Tg)	Competitive Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	C-Telopeptide (Beta CrossLaps)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Anti-cyclic citrullinated peptide (ACCP)	IgG-capture test principle, Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Zonulin	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Anti-Transglutaminase / Tissue Transglutaminase	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Anti-double stranded DNA (Anti-dsDNA)	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Anti-Nuclear Antibodies (ANA)	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Anti-Neutrophil Cytoplasmic Antibodies (ANCA)	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Cardiolipin	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	ENA (Extractable Nuclear Antigens: Anti-Jo-1, Anti-Sm, Anti-RNP, Anti-SSA (Ro), Anti-SSB (La), Anti-Scl-70)	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
Tumor Markers				
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Cancer antigen 125 (CA 125)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Cancer Antigen 15-3 (CA 15-3)	Sandwich Electrochemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Cancer Antigen 19-9 (CA 19-9)	Sandwich Electrochemiluminescence	Blood and derived products (serum, plasma)

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
			Immunoassay (ECLIA), Roche Cobas	
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Carcinoembryonic antigen (CEA)	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Alpha-Fetoprotein (AFP)	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Free prostate-specific antigen (FPSA)	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Prostate-specific antigen (PSA)	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
Viral Antibody Tests (Serology)				
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Hepatitis A antibodies (Anti-HAV), total (IgM + IgG)	Competitive Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Hepatitis B core antigen antibodies (Anti-HBc), total (IgM + IgG)	Competitive Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Hepatitis B surface antigen antibodies (Anti-HBs)	Competitive Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Hepatitis A antibodies (Anti-HAV), IgM	µ Capture Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Hepatitis B core antigen antibodies (Anti-HBc), IgM	µ Capture Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Hepatitis B e antigen antibodies (Anti-HBe)	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Hepatitis B surface antigen (HBsAg)	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Hepatitis B e antigen (HBeAg)	Sandwich Electro-chemiluminescence	Blood and derived products (serum, plasma)

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
			Immunoassay (ECLIA), Roche Cobas	
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Hepatitis C antibodies (Anti-HCV)	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Herpes Simplex Virus type 1 or type 2 (HSV1 or HSV2) antibodies	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Human Immunodeficiency Virus (HIV) antibodies + p24 antigen	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Treponema pallidum (Syphilis) antibodies	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Human T-lymphotropic viruses type 1 and 2 (HTLV 1/2) antibodies	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Toxoplasma Gondii antibodies, IgG or IgM	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Cytomegalovirus antibodies (CMV), IgG or IgM	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	SARS-COV-2 nucleocapsid or spike RBD antibodies	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Rubella IgG antibodies	Sandwich Electro-chemiluminescence Immunoassay (ECLIA), Roche Cobas	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Epstein-Barr virus early antigen) antibodies (EBV-EA)	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Epstein-Barr nuclear antigen 1 antibodies (EBNA-1)	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Lyme disease (Borrelia) VlsE1-IgG and pepC10-IgM antibodies	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Varicella Zoster Virus antibodies (VZV)	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Parvovirus (B19) antibodies	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Mycoplasma Pneumoniae antibodies	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	QuantiFERON	Immunological Sandwich Assay, Dynex Agility	Blood and derived products (serum, plasma)
Rapid tests				
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	FIT (Fecal Immunochemical Test), RSOsi	Lateral Flow Assay (LFA)	Stool (fecal)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Calprotectin	Lateral Flow Assay (LFA)	Stool (fecal)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Mono test (Infectious Mononucleosis heterophile IgM antibodies)	Lateral Flow Assay (LFA)	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	SARS-CoV-2 (Covid-19)	Lateral Flow Assay (LFA)	Nasopharyngeal
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Streptococcus A	Lateral Flow Assay (LFA)	Oropharyngeal
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Helicobacter pylori (H. pylori)	Lateral Flow Assay (LFA)	Blood and derived products (serum, plasma), stool (fecal)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	RPR (Rapid Plasma Reagin)	Flocculation Test Principle	Blood and derived products (serum, plasma)
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	TPPA (Treponema pallidum particle agglutination)	Particle Agglutination Principle	Blood and derived products (serum, plasma)
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	SARS-CoV-2 (Covid-19)	Real-time (Quantitative) RT-PCR, Fisher Scientific (QuantStudio 7 Pro)	Oropharyngeal, nasopharyngeal, saliva
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	Influenza A, B	Real-time (Quantitative) RT-PCR, Fisher Scientific (QuantStudio 7 Pro)	Oropharyngeal, nasopharyngeal, saliva
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	Respiratory Syncytial Virus (RSV)	Real-time (Quantitative) RT-PCR, Fisher Scientific (QuantStudio 7 Pro)	Oropharyngeal, nasopharyngeal, saliva
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	Streptococcus A, B, C/G	Real-time (Quantitative) RT-PCR, Fisher Scientific (QuantStudio 7 Pro)	Oropharyngeal, genital, urine
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	Human Papilloma Virus (HPV)	Real-time (Quantitative) RT-PCR, Fisher Scientific (QuantStudio 7 Pro)	Genital, urine, throat
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	Herpes Simplex Virus, type 1 and 2	Real-time (Quantitative) RT-PCR, Fisher Scientific (QuantStudio 7 Pro)	Vesicular lesions, oral, genital, urine, rectal, throat
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	Mycoplasma genitalium	Real-time (Quantitative) RT-PCR, Fisher Scientific (QuantStudio 7 Pro)	Body fluids, urine, genital, rectal, throat
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	Chlamydia, Gonorrhea, Trichomonas	Real-time (Quantitative) RT-PCR, Fisher Scientific (QuantStudio 7 Pro)	Urine, genital, rectal, throat
05.0 HEMATOLOGY	05.1 Hematology – cytochemistry	Complete Blood Count (CBC) + differential	Fluorescence / Impedancemetry, Sysmex	Whole blood

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		Reticulocytes Sedimentation rate	Gravity / Sedimentation, Diesse	
05.0 HEMATOLOGY	05.2 Hematology – cytology	Activated Partial Thromboplastin Time (aPTT)	Coagulometry, Werfen	Plasma
05.0 HEMATOLOGY	05.2 Hematology – cytology	Prothrombin Time / INR (PT / INR)	Coagulometry, Werfen	Plasma
05.0 HEMATOLOGY	05.2 Hematology – cytology	Thrombin Time (TT)	Coagulometry, Werfen	Plasma
05.0 HEMATOLOGY	05.2 Hematology – cytology	Antithrombin	Coagulometry, Werfen	Plasma
05.0 HEMATOLOGY	05.2 Hematology – cytology	D-Dimer	Coagulometry, Werfen	Plasma
05.0 HEMATOLOGY	05.2 Hematology – cytology	Protein C	Coagulometry, Werfen	Plasma
05.0 HEMATOLOGY	05.2 Hematology – cytology	Protein S	Coagulometry, Werfen	Plasma
05.0 HEMATOLOGY	05.2 Hematology – cytology	Fibrinogen	Coagulometry, Werfen	Plasma
05.0 HEMATOLOGY	05.3 Hematology – erythrocytic	Haemoglobin Electrophoresis	Capillary Electrophoresis, Sebia	Whole blood

Notes

ISO 15189:2012: Medical laboratories — Requirements for quality and competence

POV-ASB: Accreditation Program Overview



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