



ACCREDITATION UNIT

GUIDELINES FOR THE FORMULATION OF THE SCOPES FOR MEDICAL LABORATORIES

Purpose

This document is established to provide guidelines for the formulation of the scopes for medical laboratories to ensure the consistency in the accreditation scopes of medical laboratories.

Scope

This document is applied for applied and accredited medical laboratories.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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Further information

It is available at JAS-AU website where you can check updates directly.

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1 Classification of Parameters/Analytes

Parameters/Analytes were classified based on state of the art (Members of JAS-AU Medical Working Group), nevertheless the laboratories shall specify the test methods and techniques/equipment used.

Main Profile	Sub-Profile	Parameter / Analyte
Clinical Chemistry	Routine	Acetone (ketone bodies) Acid phosphatase (total/prostatic) Aldolase Albumin Albumin /Creatinine Ratio (Spot urine) * Alkaline Phosphatase (ALP) ALP Isoenzymes Ammonia Amylase (Serum/Urine) (Amy s/u) Bicarbonate Bilirubin Direct (BD) Bilirubin Total (BT or T-bill) Calcium (Ca) (Serum/Urine) (Cas/u) Calcium Ionized Calcium Corrected* Chloride (Cl) (Serum/Urine) (Cls/u) Cholesterol Total (CHT) Copper (Serum) (Cus) Copper (Urine) (Cu24H) Creatinine (Serum/Urine) (Crs/u) Creatinine Clearance* Creatine Kinase (CK or CPK) Creatine Kinase-Myocardial Band (CK-MB) Ethanol Gamma-Glutamyl Transferase (GGT) Glucose Glutamic Oxalate Transaminase (GOT/AST) Glutamic Pyruvate Transaminase (GPT/ALT) Glycosylated Hemoglobin (HbA1C) Globulin* HDL-Cholesterol (High-Density Lipoprotein) Cholesterol Iron (Fe) Lactate Dehydrogenase (LDH) LDL-Cholesterol (Low-Density Lipoprotein) Cholesterol Lipase Lactose Tolerance Test (LTT) Lithium Magnesium (Serum/Urine) (Mgs/u) Microalbuminuria Osmolality (Serum/Urine) Measured Phosphorous (Serum/Urine) (Ps/u) Potassium (K) (Serum/Urine) (Ks/u) Sodium (Na) (Serum/Urine) (Nas/u) Spot Urine (Creatinine, Protein, etc.)

Main Profile	Sub-Profile	Parameter / Analyte
		Total Iron Binding Capacity (TIBC) Total Protein (Serum/Urine) (TPs/u) Triglycerides (TG) Unsaturated Iron Binding Capacity (UIBC) Urea Breath test (UBT) Urea / BUN (Serum/Urine) (URs/u) Uric Acid (Serum/Urine) (UAs/u) 24 hr. Urine Collection (Microalbuminuria, etc.) Zinc (Zn)
	Special Chemistry	Acylcarnitines (Serum/urine) Alpha-1 Antitrypsin Alpha-2 Antiplasmin Alpha-2 Macroglobulin Alpha Fetoprotein (Amniotic Fluid/Serum) Amikacin Amino Acids Angiotensin Converting Enzyme (ACE) Apolipoproteins (A1 & B) Arylsulphatase A (Urine/Blood) Beta-glucuronidase Bile Acids Blood gases (PO ₂ , PCO ₂ , pH, HCO ₃ , etc.) C-peptide CA125 CA15-3 CA19-9 CA 50 CA 72-4 Cadmium Carbohydrate Deficient Transferrin (CDT) Carnitine Free Carnitine Total Carotene Ceruloplasmin Carbamazepine (Tegretol) Carcinoembryonic Antigen (CEA) Cyclosporine Cystatin C Delta Aminolaevulinic Acid (DALA) (Urine) Digoxin Ferritin Fluoride (Serum and Urine) Folate Folate (erythrocytes) Fructosamine Fructose (semen) Galactokinase Galactose (Urine, Blood and Dried Spots) Gastrin 17 Gentamicin Guanidinoacetic Acid (urine) Haptoglobin Hemosiderin Heparin

Main Profile	Sub-Profile	Parameter / Analyte
		Hexokinase Hexosaminidase A Hippuric Acid Homocysteine Homogentistic Acid Lactate Lead (Blood/Urine/Serum), Pb Lipoprotein A Mercury (Urine/Serum) Metanephhrines (24 hrs.) Methotrexate Mucopolysaccharides Myoglobin (Urine/Serum) Methylmalonic Acid Neonatal Screening (TSH, 17OHP, TGAL, G6PD, GALT and Biotinidase) Phenytoin (Epanutin) Procalcitonin Prostatic Specific Antigen Free (PSA-Free/ FP SA) Prostatic Specific Antigen Total (PSA-Total/ TP SA) Salicylate Selenium Serum Protein Electrophoresis Sirolimus Soluble transferrin receptor (sTfR) Stone Analysis Tacrolimus (Prograf) Theophylline Thyroglobulin Transferrin Troponin I Troponin I High Sensitive (HS) Troponin T Troponin T High Sensitive (HS) Valproic Acid (Depakine) Vanilmandelic Acid (VMA) Vancomycin Vitamin D (1, 25 DHVD & 25-VD) Vitamin D (3) Vitamin A (retinol) Vitamin B1 (thiamine) Vitamin B12 Vitamin B2 (riboflavin) Vitamin B6 (pyridoxin) Vitamin E (tocopherol) Vitamin H (biotin)

Main Profile	Sub-Profile	Parameter / Analyte
	Endocrinology	17-Hydroxy Progesterone Adrenocorticotrophic Hormone (ACTH) Aldosterone Androstenedione Androsterone Anti Muellerian Hormone (AMH) Beta Human Chorionic gonadotropin (Beta-HCG) B-Type Natriuretic Peptide (BNP) Calcitonin Catecholamines Fractionation Catecholamines Free Catecholamines Total Cortisol Free Cortisol Total Dehydroepiandrosterone (Sulfate) (DHEA-S) Dihydrotestosterone (DHT) Erythropoietin Estradiol (E2) Esteriol Free Esteriol Total Follicular Stimulating Hormone (FSH) Gastrin Glucagon Growth Hormone HCG in urine Homeostatic Model Assessment for Insulin Resistance (HOMA-IR)* Inhibin A Inhibin B Insulin Insulin-Like Growth Factor1 (IGF-1) Insulin-Like Growth Factor Binding Protein 3 (IGFBP-3) Leptin Luteinizing Hormone (LH) Melatonin Parathyroid Hormone (PTH) Pregnancy Associated Plasma Protein-A (PAPP-A) Pro-B-Type Natriuretic Peptide (Pro-BNP) Prolactin Progesterone Proinsulin PTH Related Protein Renin Activity Serotonin Sex Hormone Binding globulin Testosterone (Total, Free) (T.TESTO./F.TESTO.) Thyroid Stimulating Hormone (TSH) Thyroxine free FT4 Triiodothyronine, free FT3 Vasoactive Intestinal Peptide (VIP) Vasopressin (ADH) Antidiuretic Hormone

Main Profile	Sub-Profile	Parameter / Analyte
Haematology	Routine	• ESR • HCT/ PCV • Hemoglobin (Hb) • MCH • MCHC • MCV • Red Cell Distribution Width (RDW) • Platelets (PLT) • Mean Platelet Volume (MPV) • RBC • Reticulocytes • WBC • WBC Diff/ Differential Leukocyte Count (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils)
	Special Haematology	Blood Film Flow Cytometry (CD4, CD8) Haptoglobin HbA2\Hemoglobin Variant Hemoglobin Electrophoresis Glucose-6-Phosphate Dehydrogenase (G6PD)
	Bone Marrow Aspirate	Bone Marrow Aspirate
Coagulation	Routine	Bleeding time Clotting time D-Dimer Fibrinogen Partial thromboplastin time (PTT) Prothrombin time (PT)
	Special Coagulation	Activated Protein C Resistance (Factor V Leiden) Anti-Thrombin III Factor Assay Lupus anti-coagulant Protein S free Protein C functional Thrombophilia Screening
Clinical Microbiology	Bacteriology	C. difficile detection (stool) Culture and sensitivity (Urine, Blood, Stool, etc.) Gram stain H. pylori antigen (stool)
	Mycobacteriology	T.B culture (sputum, Sterile body fluids, Urine, etc.) Ziehl-Neelsen stain
	Virology	Adenovirus antigen (stool) Rotavirus antigen (stool)

Main Profile	Sub-Profile	Parameter / Analyte
	Parasitology	Fecal Fat (Sudan III) Fecal Immunochemical Testing (FIT) Reducing Substances (Stool) Occult blood Stool Analysis (concentration) Stool Analysis (direct)
	Mycology	Culture (Sputum, Sterile body fluids, etc.) KOH preparation (skin, hair, nail, etc.) India ink preparation Sensitivity (Yeast)
Immunology and Serology		Anticardiolipin/ IgG, IgM Anti DNA,AB,Double Stranded Anti Neutrophil Cytoplasmic Antibodies (ANCA) Anti-Nuclear Abs (ANA) Anti Smooth Muscle Antibodies (ASMA) Anti Streptolysin O (ASO) / Anti Streptolysin O Titer (ASOT) Anti thyroglobulin Anti thyroid peroxidase Brucella IgG Brucella IgM Complement 3 Complement 4 C1q C2 CH50 COVID antibody IgG COVID antibody IgM Cryoglobulin C-Reactive Protein (CRP-Titer) Cyclic Citrullinated Peptide antibodies (Anti CCP) Cytomegalovirus IgG (CMV IgG) Cytomegalovirus IgM (CMV IgM) Endomysial AB IgA Endomysial AB IgG Endomysial AB IgM Epstein Barr Virus Capsid Ag (VAC) Abs IgG Epstein Barr Virus Capsid Ag (VAC)Abs IgM Extractable Nuclear Antigen Abs (ENA) Fecal Calprotectin Glutamic Acid Decarboxylase Abs (Anti GAD) HAV, IgM HBcAb IgG/IgM HBe Abs HBeAg HBsAg HCV Abs Helicobacter Pylori Abs IgA (H. PYLORI IgA) Helicobacter Pylori Abs IgG (H.PYLORI IgG) Hepatitis A total

Main Profile	Sub-Profile	Parameter / Analyte
		Hepatitis B surface Ab Herpes Simplex 1 IgG Herpes Simplex 1 IgM Herpes Simplex 2 IgG Herpes Simplex 2 IgM HIV 1 & 2 Ab HIV 1 & 2 (Ag/Ab) Immunoglobulin A (IgA) Immunoglobulin D (IgD) Immunoglobulin E (IgE) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Insulin Antibodies Measles Virus IgG Measles Virus IgM Mumps Virus IgG Mumps Virus IgM Mycoplasma Pneumonia IgG Mycoplasma Pneumonia IgM Phospholipid Abs IgG Phospholipid Abs IgM Rheumatoid Factor (RF) Rubella IgG Rubella IgM Syphilis Abs Thyroid Stimulating Hormone Receptor Abs Tissue Transglutaminase IgA Tissue Transglutaminase IgG Toxoplasma, Gondii IgG Toxoplasma, Gondii IgM Varicella Zoster Virus IgG (VZV IgG) Varicella Zoster Virus IgM (VZV IgM)
Blood Banking	Immunohaematology	ABO Grouping Blood component preparation Cross matching (major and minor) Direct coombs test Indirect coombs testing Panel (Antibody screening) Rh Grouping Rh phenotyping
Molecular Biology and Genetics	Cytogenetics	Chromosomal Study
	Molecular Genetics	Alpha Thalassemia Beta Thalassemia Cardiovascular disease (CVD) Factor II (Prothrombin G 20210A) Factor V (Leiden) Familial Mediterranean Fever (FMF) HBV Quantitative HCV Genotyping HCV Quantitative HLA-B*27 HLA-B*51/52 typing Methylene tetra hydro folate reductase (MTHFR) (C677T, A1298C) SARS CoV-2

Main Profile	Sub-Profile	Parameter / Analyte
Urine and other Body Fluids		- Reducing Substances (URINE) - Urine analysis (leukocytes, Nitrite, Urobilinogen, Protein, pH, Occult blood, Specific gravity, Ketones, Bilirubin, Glucose) (PH, Protein, Glucose). (Microscopic analysis) - All other body fluids analysis
Reproductive Biology		Seminal Fluid Analysis
Cytopathology		Fine needle Aspiration (Fluid – Smear/s) Fluid – Smear/s Pap Smear
Histopathology and Immunohistochemistry		Anti-bcl-2 Oncoprotein Anti-CD3 (T-Cell) Anti-CD5 Anti-CD20 (B-Cell) Anti-CD30 (Ki-1 antigen) Anti CD45 LCA Leukocyte common antigen Anti-CD68 (Macrophage) Anti-CD99 (MIC2 antigen) Anti-CD117 (c-kit protein) Anti-Chromogranin A Anti-Cytokeratin Cocktail, Broad Spectrum Anti-Desmin Anti-GFAP Glial Fibrillary Acidic Protein Anti-Melanoma Anti-NSE Neuron Specific Enolase Anti-Vimentin CK5/6 Estrogen HER-2 neu c-erbB-2 Protein Histopathological Examination Ki67 P63 Progesterone Receptor S-100 Protein

* Calculated Test: This test depends on calculation and it is not considered as a new test.

General Notes

- Terms "Automated/Manual" shall not be used in the scope of accreditation of medical laboratories. The laboratory shall specify the used method/equipment.

Example:

SOP	Parameter/ Analyte	Main Profile / Sub-Profile	Sample Type	Test Method	Instrument
SOP#1	Glucose	Clinical Chemistry (Routine)	Serum	Automated (Wrong expression) The correct expression (for example Hexokinase- colorimetric)	Cobas pro

3 References

- [1] NATA Specific Accreditation Guidance "Scope of accreditation - service descriptors for human pathology", March, 2022