Issue date: 06 April 2025
Valid Until: -

NO: SAMM 1082
(Issue 1, 06 April 2025 replacement
of SAMM 1082 dated 06 April 2025)

LABORATORY LOCATION: (PERMANENT LABORATORY)	Department of Pathology, Hospital Sultanah Aminah Jalan Persiaran Abu Bakar Sultan, Johor Bahru , 80000, JOHOR MALAYSIA
ACCREDITED SINCE :	06 APRIL 2025
FIELD(S) OF MEDICAL TESTING :	HISTOPATHOLOGY CYTOPATHOLOGY MEDICAL MICROBIOLOGY HAEMATOLOGY CHEMICAL PATHOLOGY

The standard used for assessment of this laboratory is MS ISO 15189:2022 (ISO 15189:2022, IDT).

A medical laboratory's fulfilment of the requirements of ISO 15189 means the laboratory meets both the technical competence requirements and the management system requirements necessary for it to consistently deliver technically valid test results. The management system requirements in ISO 15189 are written in language relevant to a medical laboratory's operations. Medical laboratories that implement ISO 15189 operate generally in accordance with the principles of ISO 9001. (See Joint IAF-ILAC-ISO Communiquè, November 2021)

CENTRAL LOCATION	Department of Pathology, Hospital Sultanah Aminah Jalan Persiaran Abu Bakar Sultan, Johor Bahru , 80000, Johor
FIELD(S) OF MEDICAL TESTING :	HISTOPATHOLOGY, CYTOPATHOLOGYMEDICAL MICROBIOLOGYHAEMATOLOGYCHEMICAL PATHOLOGY

SCOPE OF MEDICAL TESTING : HISTOPATHOLOGY

Specimen Tested	**Type of Test/ Properties Measured/**	**Test Methods,Specifications/ Equipment/Techniques Used**
Tissue Fixed In 10% Neutral Buffered Formalin	Histopathology Examination	Using Rotary microtome LEICA RM 2245: HSA/JP/AP/HISTO/TPM-034 Rotary microtome THERMO SCIENTIFIC HM 340 E & HM 355 S: HSA/JP/AP/HISTO/TPM-035 Semi Motorised Rotary Microtome PFM Medical: HSA/JP/AP/HISTO/TPM-047 Semi Motorised Rotary Microtome Leica Histocore Multicut: HSA/JP/AP/HISTO/TPM-048 Flotation bath: AP/JP/AP/HISTO/TPM-036 Hematoxylin & Eosin Stain as documented in: AP/JP/AP/HISTO/WI-007 Using Tissue-Tek Prisma Plus Autostainer : HSA/JP/AP/HISTO/TPM-045 Tissue-Tek Film Coverslipper: HSA/JP/AP/HISTO/TPM-046

	Immunohistochemistry and in situ hybridisation	Work instruction on imunohistochemical stain and in situ hybridisation as documented in: HSA/JP/AP/HISTO/WI-009 Immunohistochemical staining using Leica Autostainer BONDMAX: HSA/JP/AP/HISTO/TPM-031 Immunohistochemical staining using Dako Omnis: HSA/JP/AP/HISTO/TPM-032
Tissue Fixed In 10% Neutral Buffered Formalin/fresh Tissue	Histochemistry	Work instruction on histochemical stain as documented in: HSA/JP/AP/HISTO/WI-008
Fresh Tissue	Frozen Sections	Quality procedure of handling of frozen section as documented in: HSA/JP/AP/HISTO/QP-002 Leica CM1950 Cryostat : HSA/JP/AP/HISTO/TPM-029
	Immunofluorescence Examination	Work instruction of immunofluorescence stain as documented in: HSA/JP/AP/HISTO/WI-010

SCOPE OF MEDICAL TESTING : CYTOPATHOLOGY

Specimen Tested	**Type of Test/ Properties Measured/**	**Test Methods,Specifications/ Equipment/Techniques Used**

Non-gynaecological Specimens	Non-Gynaecological Cytology Examination	Specimen preparation: Handling And Processing Of Specimens In The Cytology Laboratory as documented in HSA/JP/AP/CYTO/QP-001 Preparation Of Smears For Non-Gynae Specimen HSA/JP/AP/CYTO/WI-001 Cell Block as documented in HSA/JP/AP/CYTO/WI-003 Staining: Procedure Papanicolaou Staining as documented in HSA/JP/AP/CYTO/TPM-001 Procedure May Grunwald Giemsa Staining as documented in HSA/JP/AP/CYTO/TPM-002 Automated autostainer : Procedure Operating Autostainer Sakura Tissue-Tek Prisma Plus HSA/JP/AP/CYTO/TPM-007 Procedure Operating Autostainer Gemini AS HSA/JP/AP/CYTO/TPM-008
Fine Needle Aspirates (fna)	FNA Cytology Examination	Specimen preparation (routine sample): Handling And Processing Of Specimens In The Cytology Laboratory as documented in HSA/JP/AP/CYTO/QP-001 Process Of Aspiration Material From FNAC As Documented in HSA/JP/AP/CYTO/WI- 002 Cell Block as documented in HSA/JP/AP/CYTO/WI-003

	FNA Cytology Examination	Specimen preparation (FNAC clinic sample): Handling of FNAC From The Patient To Cytology Laboratory as documented in HSA/JP/AP/CYTO/QP-003 Staining: Procedure Papanicolaou Staining as documented in HSA/JP/AP/CYTO/TPM-001 Procedure May Grunwald Giemsa Staining as documented in HSA/JP/AP/CYTO/TPM-002 Procedure Diff Quick Staining as documented in HSA/JP/AP/CYTO/TPM-003 Automated Autostainer: Automated autostainer : Procedure Operating Autostainer Tissue-Tek Prisma Plus HAS/JP/AP/CYTO/TPM-007 Procedure Operating Autostainer Gemini AS HAS/JP/AP/CYTO/TPM-008

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY

Specimen Tested	**Type of Test/ Properties Measured/**	**Test Methods,Specifications/ Equipment/Techniques Used**
Blood	Culture & Sensitivity	Bactec Fluorescent technology as documented in HSA/JP/MIC/BAK/WI-001
Sterile Body Fluid/ Capd/ Peritoneal	Culture & Sensitivity	Manual method as documented in HSA/JP/MIC/BAK/WI-002
Ear	Culture & Sensitivity	Manual method as documented in HSA/JP/MIC/BAK/WI-014
Specimen	Culture & Sensitivity	Manual method as documented in HSA/JP/MIC/BAK/WI-013

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Eye Swab Throat Swab Sputum/ Bba / Bal	Culture & Sensitivity Culture & Sensitivity	Manual method as documented in HSA/JP/MIC/BAK/WI-019 Manual method as documented in HSA/JP/MIC/BAK/WI-010
Csf	Culture & Sensitivity	Manual method as documented in HSA/JP/MIC/BAK/WI-008
Urine	Culture & Sensitivity	Manual method as documented in HSA/JP/MIC/BAK/WI-007
	Legionella Urinary Antigen Test	Immunochromatographic assay as documented in HSA/JP/MIC/SERO/WI-010
Nasal	Culture & Sensitivity	Manual method as documented in HSA/JP/MIC/BAK/WI-016
Swab	Culture & Sensitivity Culture for MRSA screening	Manual method as documented in HSA/JP/MIC/BAK/WI-015 Manual method as documented in HSA/JP/MIC/BAK/WI-026
Csf/serum	Cryptococcus antigen test	New method: Lateral flow method HSA/JP/MIC/BAK/WI-008
Culture	Antibiotic susceptibility testing (AST)	Manual method as documented in Semi- automated (New : HSA_JP_MIC_BAK_TPM005) HSA/JP/MIC/BAK/WI-021
Respiratory Specimen, Urine, Pus, Gastric Aspirate/lavage, Tissue, Csf, Other Body Fluids	AFB Direct Smear	Auramine staining method as documented in HSA/JP/MIC/TIBI/WI-001
Sputum, Bronchiol Washing, Blind Bronchiol Aspirate, Bronchoalveolar Lavage, Tracheal Aspirate, Urine, Pus, Body Fluids, Tissue, Csf, Blood, Laryngeal Swab	TB Culture	BD MGIT Fluorescent technology and manual method as documented in HSA/JP/MIC/TIBI/WI- 002

Serum	HIV 1/2 Ag/Ab Combo assay	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	HIV 1/2 antibodies (Particle Agglutination)	Particle Agglutination method as documented in HSA/JP/MIC/SERO/WI-003
	Hep B Surface Antigen	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Hep B Surface Antibody	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Hep B Core Total Antibody	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Hep B Core IgM Antibody	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Hep B Envelope Antigen	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Hep B Envelope Antibody	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Hep C Antibody	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Hep C Antigen	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Hep A IgM Antibody	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Toxoplasma IgM	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Toxoplasma IgG	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Rubella IgM	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Rubella IgG	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005
	Cytomegalovirus IgM	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005

	Cytomegalovirus IgG Epstein Barr Virus IgM Epstein Barr Virus IgG Herpes Simplex Virus IgM Herpes Simplex Virus IgG Dengue IgM Dengue IgG Dengue Rapid Test (Dengue NS1 Protein, Dengue IgM, Dengue IgG) Anti-Streptolysin –O Titre (ASOT) Rapid Plasma Reagin (RPR) Treponema Pallidum Particle Agglutination Test (TPPA) Leptospira IgM	Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005 Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005 Architect CMIA technology as documented in HSA/JP/MIC/SERO/WI-005 ELISA technology as documented in HSA/JP/MIC/SERO/WI-007 ELISA technology as documented in HSA/JP/MIC/SERO/WI-007 ELISA technology as documented in HSA/JP/MIC/SERO/WI-008 ELISA technology as documented in HSA/JP/MIC/SERO/WI-008 Immunochromatographic assay as documented in HSA/JP/MIC/SERO/WI-020 Latex Agglutination assay as documentation in HSA/JP/MICSERO/TPM-001 Latex Agglutination assay as documentation in HSA/JP/MICSERO/TPM-001 Particle Agglutination method as documented in HSA/JP/MIC/SERO/WI-011 Latex Agglutination assay as documentation in HSA/JP/MIC/SERO/WI-009

SCOPE OF MEDICAL TESTING : HAEMATOLOGY

Specimen Tested	**Type of Test/ Properties Measured/**	**Test Methods,Specifications/ Equipment/Techniques Used**

Whole Blood	Full Blood Count (FBC)	Automation method based on flowcytometry / Sysmex XN Series as documented in Full Blood Count Using Sysmex XN Analyser: HSA/JP/HM/TPM-001
	ESR	Automation method based on photometry method / Alifax ESR analyzer as documented in ESR: HSA/JP/HM/TPM-026
	Full Blood Picture (FBP)	Slide preparation: Automation method based on smear slide and Leishman staining on peripheral Blood Film / Sysmex SP 10 as documented in Handling of Automated Haematology Slide Preparation SP-10: HSA/JP/HM/WI-015.
	Excluded from the recent scope because receive new analyzer replacement	
	CD4/CD8	Automation method based on AQUIOS CL Flow Cytometer as documented in CD4 & CD8 Enumeration: HSA/JP/HM/TPM-038
	Full Blood Count	Automation Method based on Flow Cytometry method, Hydro Dynamic Focusing, SLS hemoglobin detection/ Sysmex XN1000 as documented HSA/JP/LABK/TPM-002
	ESR	Automation method based on photometry method / Alifax ESR analyzer as documented HSA/JP/LABK/TPM-006
	PT/INR APTT	Automation method:Mechanical viscosity-based detection system/ STAGO Analyser as documented in PROTHROMBIN TIME (PT) AND ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) USING STAGO ANALYSER : HSA/JP/HM/TPM-005

Blood Plasma	Routine Coagulation PT/INR APTT Fibrinogen D-Dimer Thrombin Time DIVC	Automation method based on Clotting Method & Immunologic Assay as documented in PT & APTT Using Stago Analyser : HSAJP/HM/TPM-031 Fibrinogen : HSAJP/HM/TPM-032 Thrombin Time : HSAJP/HM/TPM-033 DIVC Screening : HSA/JP/HM/WI-006
	Special Coagulation: Factor Assays (Factor VIII) Factor Assays (Factor IX) Factor Inhibitor (Factor VII) VIII Factor Inhibitor (Factor IX) Lupus Anticoagulant (LA) Mixing Test	Automation method based on Clotting Method/ Stago Analyser as documented in Factor Assays: HSA/JP/HM/TPM-035 Factor Inhibitor: HSA/JP/HM/TPM-036 Lupus Anticoagulant : HSA/JP/HM/TPM-037 Mixing test : HSA/JP/HM/TPM-008
Blood Spot On Filter Paper	G6PD Screening	Qualitative method based on interpretation in the presence of fluorescence blood spot / UV Light Box as in documented in HSA/JP/HM/TPM-012
Whole	Immunophenotyping (IPT)	Automation method based on flowcytometry / Facs Canto as documented in IPT Using facs Canto Analyser: HSA/JP/HM/WI-013
Bone Marrow	Bone Marrow Aspirate (BMA) Trephine Roll/Imprint	Specimen preparation : Smear manual method as documented in Preparation of Thin Blood Smear, Bone Marrow Smear and Trephine Roll HSA/JP/HM/TPM-004 Routine Staining as documented in Perl's staining : HSA/JP/HM/TPM-013 May Grunwald Giemsa : HSA/JP/HM/TPM- 017

SCOPE OF MEDICAL TESTING : CHEMICAL PATHOLOGY

Specimen Tested	**Type of Test/ Properties Measured/**	**Test Methods,Specifications/ Equipment/Techniques Used**
Serum, Plasma	Albumin	Bromocresol Purple Alinity-C as documented in HSA/JP/LABK/TPM-001
	Bromocresol Purple Alinity-C as documented in HSA/JP/LABK/TPM-001	Para-nitrophenyl Phosphate/Alinity-C as documented in HSA/JP/LABK/TPM-001
	Alanine Amino Transferase (ALT)	NADH (without P-5'-P)/Alinity-C as documented in HSA/JP/LABK/TPM-001
	Aspartate Transaminase (AST)	NADH (without P-5'-P)/Alinity-C as documented in HSA/JP/LABK/TPM-001
	Calcium	Arsenazo III Alinity-C as documented in HSA/JP/LABK/TPM-001
	Cholesterol	Enzymatic / Alinity-C as documented in HSA/JP/LABK/TPM-001
	Creatine Kinase, CK	NAC (N-acetyl-L-cysteine) / Alinity-C as documented in HSA/JP/LABK/TPM-001
	Creatinine	Enzymatic / Alinity-C as documented in HSA/JP/LABK/TPM-001
	Bilirubin, Total	Diazonium Salt/ Alinity C as documented in HSA/JP/LABK/TPM-001
	Bilirubin, Direct	Diazo reaction/ AlinityC as documented in HSA/JP/LABK/TPM-001
	High Density Lipoprotein (HDL)	Accelerator Selective Detergent /Alinity-C as documented in HSA/JP/LABK/TPM-001
	Chloride, Cl Potassium, K Sodium, Na	Ion Selective Electrode diluted (Indirect)/ Alinity-C as documented in HSA/JP/LABK/TPM-001

	Lactate Dehydrogenase, LDH	Lactate to Pyruvate/Alinity-C as documented in HSA/JP/LABK/TPM-001
	Magnesium	Enzymatic/Alinity-C as documented in HSA/JP/LABK/TPM-001
	Phosphate	Phosphomolybdate/Alinity-C as documented in HSA/JP/LABK/TPM-001
	Protein	Biuret/Alinity-C System as documented in HSA/JP/LABK/TPM-001
	Urea	Urease/Alinity-C System as documented in HSA/JP/LABK/TPM-001
	Uric Acid	Uricase/Alinity-C as documented in HSA/JP/LABK/TPM-001
Plasma	Glucose	Hexokinase/ Alinity-C as documented in HSA/JP/LABK/TPM-001
Urine	Urinalysis	Automated method/ disptick base onwavelenght reflectance, SG base on reflective index, clarity based on light scattering and microscopy based on flow digital imaging/ Beckman Coulter IRIS iRICELL 3000 as Documented in HSA/JP/LABK/TPM-004

NOTE :