


NO: SAMM 705

Page: 1 of 15

LABORATORY LOCATION: (PERMANENT LABORATORY) 	Jabatan Patologi, Hospital Sultanah Nur Zahirah Jalan Sultan Mahmud, 20100 Kuala Terengganu, Terengganu , 20100, TERENGGANU MALAYSIA
ACCREDITED SINCE :	05 JUNE 2025
FIELD(S) OF MEDICAL TESTING :	
SITE:	
1 . SITE LABORATORY(HQ) :	DEPARTMENT OF PATHOLOGY
FIELD(S) OF MEDICAL TESTING :	CHEMICAL PATHOLOGY,CYTOPATHOLOGY,HAEMATOLOGY,HI STOPATHOLOGY,MEDICAL MICROBIOLOGY,MEDICAL MICROBIOLOGY (BACTERIOLOGY)

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 Communiqué, November 2021)

NO: SAMM 705

Page: 2 of 15

CENTRAL LOCATION	Jabatan Patologi, Hospital Sultanah Nur Zahirah Jalan Sultan Mahmud, 20100 Kuala Terengganu, Terengganu , 20100, Terengganu
FIELD(S) OF MEDICAL TESTING :	

SITE LOCATION (HQ)	1. DEPARTMENT OF PATHOLOGY
FIELD(S) OF MEDICAL TESTING :	CYTOPATHOLOGY,HISTOPATHOLOGY,CHEMICAL PATHOLOGY,HAEMATOLOGY,MEDICAL MICROBIOLOGY,MEDICAL MICROBIOLOGY

FIELD(S) OF MEDICAL TESTING : CYTOPATHOLOGY

Specimen Tested	Type Of Test / Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Gynaecological Cytopathology (gyn Cytopathology)	Gynaecological Cytology Examination	Specimen Preparation and Staining / Conventional Smear + Papanicolaou Staining Method as documented in: WP/SS/001 Pengendalian Spesimen Sitologi WP/SS/004 Pengendalian Kawalan Mutu Dalam dan Luaran WI/SS/001 Penyediaan Slaid Gynae WI/SS/004 Pencelupan Papanicolaou WI/SS/007 Penyimpanan dan Pelupusan di Unit Sitologi
Non-gynaecological Cytopathology (non-gyn Cytopathology)	Non-Gynaecological Cytology Examination	Method as documented in: WP/SS/001 Pengendalian Spesimen Sitologi WI/SS/002 Penyediaan Slaid Non Gynae WI/SS/004 Pencelupan Papanicolaou WI/SS/005 Pencelupan May Grunwald Giemsa WI/SS/007 Penyimpanan dan Pelupusan di Unit Sitologi

Schedule

Issue date: 05 June 2025

Valid Until: -



NO: SAMM 705

Page: 3 of 15

Fine Needle Aspiration Cytology (fnac)	FNA Cytology Examination	Method as documented in: WP/SS/001 Pengendalian Spesimen Sitologi WP/SS/003 Penyediaan Spesimen FNA (Fine Needle Aspiration) WI/SS/004 Pencelupan Papanicolaou WI/SS/005 Pencelupan May Grunwald Giemsa WI/SS/007 Penyimpanan dan Pelupusan di Unit Sitologi
--	--------------------------	---

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-mt/3005148> for the current scope of accreditation

NO: SAMM 705

Page: 4 of 15

FIELD(S) OF MEDICAL TESTING : HISTOPATHOLOGY

Specimen Tested	Type Of Test / Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Diagnostic Histopathology Formalin-fixed Tissue	Specimen Preparation and Examination of Tissue: <ul style="list-style-type: none"> — Grossing — Tissue Processing — Tissue Embedding — Tissue Sectioning — Decalcification — Mounting of Slide 	Manual Method as documented in WI/HS/001 and WI/HS/002 Automated Method by using tissue processor Eprelia Excelsior US as documented in WI/HS/002
	Staining of Slides <ul style="list-style-type: none"> • Routine Haematoxylin and Eosin 	Manual and Semi Automated Method by using Sakura Autostainer as documented in WI/HS/003
	Special staining <ul style="list-style-type: none"> • Histochemistry 	Manual Method as documented in WI/HS/007/1 - WI/HS/007/20
	<ul style="list-style-type: none"> • Immunohistochemistry 	Manual Method and Semi Automated Metho by using Dako Autostainer as documented in WI/HS/008
	Clinical Interpretation and Reporting	As documented in: WP/HS/002 (LIS) WP/HS/003 (Reporting)
Intraoperative Frozen Sections For Fresh Tissue Specimens And Biopsies	Specimen Preparation and Staining (manual)	Hirisan Beku as documented in WI/HS/005

NO: SAMM 705

Page: 5 of 15

FIELD(S) OF MEDICAL TESTING : CHEMICAL PATHOLOGY

Specimen Tested	Type Of Test / Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Routine Chemistry Serum/ Plasma	ALT	UV without P5P method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Albumin	Bromocresol Green by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Alkaline Phosphatase (ALP)	IFCC Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Amylase	IFCC Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Aspartate Aminotransferase (AST)	IFCC Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Bilirubin, Direct	Dichlorophenyl Diazonium Tetrafluoroborate (DPD) by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Bilirubin, Total	Dichlorophenyl Diazonium Tetrafluoroborate (DPD) Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Calcium	Arsenazo II by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Chloride	ISE Method, Indirect by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Cholesterol, Total	CHOD-PAP Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia

NO: SAMM 705

Page: 6 of 15

Creatinine	Alkaline Picrate No Proteinization by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Gamma Glutamyl Transferase (GGT)	IFCC Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
HDL-Cholesterol	Direct Immuno-Inhibition Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Iron	TPTZ Chromogen Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Lactate Dehydrogenase (LD)	IFCC Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Magnesium	Xylidyl Blue Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Phosphate	Phosphomolybdate UV Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Glucose	Hexokinase Method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Protein, Total	Biuret, reagent blank, end point method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Sodium	ISE Method, Indirect by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Creatine Kinase	NAC activated method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia

NO: SAMM 705

Page: 7 of 15

	Triglycerides	Enzymatic, end point method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Urea Nitrogen	Urease, UV method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	Uric Acid	Uricase, colorimetric method by using analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
	UIBC	Nitroso PSAP method by using - analyzer AU5800 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Routine Chemistry Serum / Urine	Osmolality	Freezing point Method by using analyzer Advanced Microosmometer 3320 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Urine	<ul style="list-style-type: none"> — SG — pH — Leukocytes — Nitrite — Protein — Glucose — Ketone — Urobilinogen — Bilirubin — Blood (RBC) 	Tests Strips (Chemical and enzymatic reaction) method by using analyzer Uriscan Super Plus & Beckman Coulter IRIS Chem Velocity as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia.
Special Chemistry Whole Blood	HbA1c	HPLC method by using analyzer Biorad D10 as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
Special Chemistry Serum	<ul style="list-style-type: none"> • Acetaminophen • Salicylate • Digoxin • Vancomycin • Amikacin • Carbamazepine • Gentamicin • Phenobarbital • Phenytoin • Theophylline • Valproic acid 	Homogeneous enzyme immunoassay technique by using EMIT/ Beckman Coulter AU 5800 as documented in WP/CP/002 Pengendalian Chemistry Analyser-BC AU5800

Schedule

Issue date: 05 June 2025
Valid Until: -



NO: SAMM 705

Page: 8 of 15

Serum	<ul style="list-style-type: none"> —• Alpha Fetoprotein (AFP) —• Cancer Antigen 125 (CA 125) —• Carcinoembryonic Antigen (CEA) —• Cortisol —• Estradiol —• Ferritine —• Follicular Stimulating Hormone (FSH) —• HCG —• Luteinizing Hormone (LH) —• Progesterone —• Prolactin —• Prostatic Specific Antigen, Total (TPSA) —• Free T3 (FT3) —• Free T4 (FT4) —• TSH —• Testosterone 	Chemiluminescence method by using DXi800 analyser as documented in WP/CP/001 Pengendalian Spesimen Patologi Kimia
(drug Laboratory) Special Chemistry Urine	<ul style="list-style-type: none"> —• Opiates Screening —• Cannabinoids Screening —• Amphetamine Type Stimulant (ATS) Screening 	EIA method by using analyser Cobas C501 as documented in WI/DD/005 Ujian saringan dadah dalam urin menggunakan kaedah immunoassay
	Morphine Confirmation Test	Thin Layer Chromatography Method as documented in WI/DD/002 Ujian Pengesahan Morphine didalam urin menggunakan TLC
	Cannabinoids Confirmation Test	Thin Layer Chromatography Method as documented in WI/DD/003 Ujian Pengesahan Cannabinoid didalam urin menggunakan TLC
	Amphetamine Confirmation Test	GCMS method by using analyser GCMS Shimadzu QP2010 and GCMS Agilent G7077B-5977B as documented in WI/DD/004 Ujian Pengesahan Amphetamine Type Stimulant didalam Urin menggunakan GCMS

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-mt/3005148> for the current scope of accreditation

NO: SAMM 705

Page: 9 of 15

FIELD(S) OF MEDICAL TESTING : HAEMATOLOGY

Specimen Tested	Type Of Test / Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Routine Haematology Whole Blood	Full Blood Count / Full Blood Picture	WBC / RBC / Platelet Laser Light Scatter / Hemoglobin / Cyanide Free Hb method by using analyser Sysmex XN 1000 as documented in WI/HM/032.
	Slides	Manual Method as documented in WI/HM/002
	Slides	Automated Slide Preparation by using analyser Sysmex SP-50 as documented in WI/HM/009.
	Reticulocyte Count	Flowcytometry with semi-conductor laser method by using analyser Sysmex XN1000 as documented in WI/HM/032
Plasma	<ul style="list-style-type: none"> Prothrombin Time / INR Activated Partial Thromboplastin Time Mixing Study 	Nephelometric method by using ACL TOP 350 CTS as documented in WI/HM/008, WI/HM/009, WI/HM/010.
	Fibrinogen	Chromogenic method by using ACL TOP 350 CTS as documented in WI/HM/008.
	Erythrocyte Sedimentation Rate	Photometry Red Cell Aggregation method by using Alifax Roller 20PN as documented in WI/HM/016
	G6PD fluorescence spot test	Manual / Visual Fluorescence Method as documented in WI/HM/017
	D-Dimer Semi quantitative	Latex Agglutination Method as documented in WI/HM/012
	D-Dimer Quantitative	Automated Latex Enhanced Immunoassay method by using ACL TOP 350 CTS as documented in WI/HM/008
Specialised Haematology Whole Blood	Hemoglobin Analysis	Capillary Electrophoresis method by using Sebia II Flex Piercing as documented in WI/HM/031
	Hemoglobin Analysis	High performance liquid chromatography method by using Biorad Variant II as documented in WI/HM/004
Plasma	Factor VIII, Factor IX Assay	Nephelometric method by using ACL TOP 350 CTS Method as documented in WI/HM/013

Schedule

Issue date: 05 June 2025
Valid Until: -



NO: SAMM 705

Page: 10 of 15

Lupus Anticoagulant	Nephelometric method by using ACL TOP 350 CTS as documented in WI/HM/014
CD4 and CD8 Enumeration	Flowcytometry method by using Beckman Coulter AQUIOS CL as documented in WI/HM/015
Bone Marrow Aspiration	Leishman stain, manual method as documented in WI/HM/018

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-mt/3005148> for the current scope of accreditation

NO: SAMM 705

Page: 11 of 15

FIELD(S) OF MEDICAL TESTING : MEDICAL MICROBIOLOGY (BACTERIOLOGY)

Specimen Tested	Type Of Test / Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Bacteriology —• Feces Or Stool —• Urine —• Throat, Nasal, Nasopharyngeal —• Pus, Wound, Tissue, Bone, Slough —• Ear —• Body Fluids Or Effusions (tracheal Aspirates, Peritoneal, Pleural Fluids Etc.) —• Eye, Corneal Scrapping —• Urogenital (urethral, Cervical, Vaginal, Etc) —• Sputum, Bronchial Alveolar Lavage (bal) —• Skin Scrapping	Stain	Gram Stain method as documented in WI/MK/STAINS/001-002
	Culture	Manual method as documented in WI/MK/001-011 & 014
	Bacterial Identification	Maldi-tof method as documented in WI/MK/022
	Antibiotic Susceptibility Testing	Kirby-Bauer Disc Diffusion method as documented in WI/MK/SENSI/001-005
Blood	Stain	Gram Stain method as documented in WI/MK/STAINS/001-002
	Culture (Aerobic, Anaerobic and Fungi)	Culture (Aerobic, Anaerobic and Fungi)
	Bacterial Identification	Maldi-tof method by using Bruker MALDI Biotyper as documented in WI/MK/022
	Antibiotic Susceptibility Testing	Kirby-Bauer Disc Diffusion method as documented in WI/MK/SENSI/001-005

NO: SAMM 705

Page: 12 of 15

FIELD(S) OF MEDICAL TESTING : MEDICAL MICROBIOLOGY

Specimen Tested	Type Of Test / Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Bacteriology Faeces Or Stool	Rotavirus and Adenovirus Detection	Immunochromatographic (ICT) method as documented in WI/MK/016
	Clostridium difficile Toxin A & B Detection	Immunochromatographic (ICT) method as documented in WI/MK/019
Mycobacteriology Blood	TB Culture	Semi-Automated method as documented in WI/MK/018
<ul style="list-style-type: none"> —• Urine —• Ear —• Body Fluids Or Effusions (tracheal Aspirates, Peritoneal, Pleural Fluids Etc.) —• Eye, Corneal Scrapping —• Sputum, Bronchial Alveolar Lavage (bal) —• Skin Scraping —• Nail, Hair —• Blood —• Csf 	Isolation and Identification of Fungi:	KOH and Lactophenol Cotton Blue method as documented in WI/MK/STAINS/005 - 006
	<ul style="list-style-type: none"> i. Stain ii. Culture 	Manual method as documented in WI/MK/001-012, 018
Faeces Or Stool	IDirect Examination and Identification of Parasites:	Direct Microscopic method as documented in WI/MK/021
	<ul style="list-style-type: none"> i. Cryptosporidium ii. Cyclosporidium Microsporidium Isospora belli 	Direct Microscopic method as documented in WI/MK/021
Blood	Malaria Parasite (BFMP)	Giemsa Stain method as documented in WI/MK/PARASITE/001
(tb Laboratory) Mycobacteria <ul style="list-style-type: none"> —• Urine —• Body Fluids Or Effusions (tracheal Aspirates, Peritoneal, Pleural Fluids Etc.) —• Sputum, Bronchial Alveolar Lavage (bal) —• Gastric Lavage —• Pus, Wound, Tissue, Bone, Slough 	Isolation of Mycobacteria	Manual method of Acid Fast Bacilli (AFB) Stain and Culture as documented in WI/TB/001 - 002
Serology Cerebrospinal Fluids	Stain	Gram Stain method as documented in WI/MK/STAINS/001-002

Schedule

Issue date: 05 June 2025
Valid Until: -



NO: SAMM 705

Page: 13 of 15

	Stain	Indian Ink method as documented in WI/MK/STAINS/003
	Cryptococcus Antigen Detection	Latex Agglutination method as documented in WI/MK/ID/019
	Culture	Manual method as documented in WI/MK/012
	Bacterial Identification	Maldi-tof method by using Bruker MALDI Biotyper as documented in WI/MK/022
	Antibiotic Susceptibility Testing	Kirby-Bauer Disc Diffusion method as documented in WI/MK/SENSI/001-005
Virology Serum	Human Immunodeficiency Virus Antigen/Antibody (HIV Ag/Ab)	Electrochemiluminescence Immunoassay (ECLIA) method by using COBAS e801 as documented in WI/MS/042
	Serodia 1/2 Mix Particle Agglutination	Particle Agglutination method as documented in WI/MS/032
	Hepatitis B Surface Antigen (HBsAg)	Electrochemiluminescence Immunoassay (ECLIA) method by using COBAS e801 as documented in WI/MS/042
	Hepatitis B Surface Antibody (Anti-HBs)	Electrochemiluminescence Immunoassay (ECLIA) method by using COBAS e801 as documented in WI/MS/042
	Hepatitis C Virus Antibody (Anti-HCV)	Electrochemiluminescence Immunoassay (ECLIA) method by using COBAS e801 as documented in WI/MS/042
	RPR (Rapid Plasma Reagin)	Latex Agglutination method as documented in WI/MS/035
	Syphilis TP	Manual method by using analyser Architect i2000 SR as documented in WI/MS/007
	Cytomegalovirus IgM	Electrochemiluminescence Immunoassay (ECLIA) method by using COBAS e801 as documented in WI/MS/042
	Toxoplasma IgG / IgM	Electrochemiluminescence Immunoassay (ECLIA) method by using COBAS e801 as documented in WI/MS/042
	Anti-Nuclear Antibody (ANA)	CMIA method by using Inova Bioflash as documented in WI/MS/039

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-mt/3005148> for the current scope of accreditation

Schedule

Issue date: 05 June 2025
Valid Until: -



NO: SAMM 705

Page: 14 of 15

Mycoplasma	Particle agglutination method as documented in WI/MS/030
Extractable Nuclear Antigen (ENA)	CMIA method by using Inova Bioflash as documented in WI/MS/03
DsDNA	CMIA method by using Inova Bioflash as documented in WI/MS/039

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-mt/3005148> for the current scope of accreditation

NO: SAMM 705

Page: 15 of 15

SITE LOCATION (HQ)	2. DEPARTMENT OF TRANSFUSION MEDICINE
FIELD(S) OF MEDICAL TESTING :	HAEMATOLOGY

FIELD(S) OF MEDICAL TESTING : HAEMATOLOGY

Specimen Tested	Type Of Test / Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Transfusion / Blood Bank Blood	Blood Grouping	Manual Method by using Tube Techniques as documented in WI/BB/002
	Blood Grouping	Manual System Method by using Gel Card Techniques as documented in WI/BB/002
	Blood Grouping	Gel Card Techniques by using automated analyser Biorad IH 500 as documented in WI/BB/002
	Antibody Screening	Manual System Method by using Gel Card Techniques as documented in WI/BB/004
	Antibody Screening	Gel Card Techniques by using automated analyser Biorad IH 500 as documented in WI/BB/004
	Coombs Test (direct / indirect)	Manual System Method /by using Gel Card Techniques as documented in WI/BB/010
	Antibody Identification	Manual System Method by using Gel Card Techniques as documented in WI/BB/006
	Red Cell Phenotyping	Manual System Method by using Tube Techniques as documented in WI/BB/007
	Blood Compatibility Test	Manual System Method by using Gel Card Techniques as documented in WI/BB/013
	Blood Compatibility Test	Saline Phase Manual Method by using Tube Techniques as documented in WI/BB/012 (Emergency Crossmatched)

NOTE :