

# Schedule


Issue date: 24 January 2025  
Valid Until: -



## NO: SAMM 1109

(Issue 2, 24 January 2025 replacement  
of SAMM 1109 dated 24 January 2025)

Page: 1 of 10

<b>LABORATORY LOCATION:</b> (PERMANENT LABORATORY) 	JABATAN PATOLOGI, HOSPITAL TENGGU PERMAISURI NORASHIKIN (HTPN) JALAN SEMENYIH , 43000, SELANGOR MALAYSIA
<b>ACCREDITED SINCE :</b>	15 JUNE 2023
<b>FIELD(S) OF MEDICAL TESTING :</b>	CHEMICAL PATHOLOGY HAEMATOLOGY MEDICAL MICROBIOLOGY MEDICAL MICROBIOLOGY (BACTERIOLOGY) TRANSFUSION MEDICINE

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)

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# Schedule

Issue date: 24 January 2025  
Valid Until: -



## NO: SAMM 1109

(Issue 2, 24 January 2025 replacement of SAMM 1109 dated 24 January 2025)

Page: 2 of 10

<b>CENTRAL LOCATION</b>	JABATAN PATOLOGI, HOSPITAL TENGGU PERMAISURI NORASHIKIN (HTPN) JALAN SEMENYIH , 43000, Selangor
<b>FIELD(S) OF MEDICAL TESTING :</b>	CHEMICAL PATHOLOGY, HAEMATOLOGY MEDICAL MICROBIOLOGY (BACTERIOLOGY) TRANSFUSION MEDICINE

### SCOPE OF MEDICAL TESTING : CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Plasma/serum	Alanine aminotransferase (INOPERATIVE)	Catalytic activity of ALT: oxo-acid conversion (IFCC) with/without P5P /Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-01 HKJG/JP/CP/AK-01 (INOPERATIVE)
	Albumin (INOPERATIVE)	Bromocresol Green (BCG)/Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-02 HKJG/JP/CP/AK-01 (INOPERATIVE)
	Alkaline Phosphatase (INOPERATIVE)	Catalytic activity of ALP: pNPP conversion (IFCC)/Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-03 HKJG/JP/CP/AK-01 (INOPERATIVE)
	Amylase (Total) (INOPERATIVE)	Enzymatic method: ethylidene-G7PNP at 37? (IFCC)/Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-04 HKJG/JP/CP/AK-01 (INOPERATIVE)
	Ammonia (INOPERATIVE)	Enzymatic method : glutamate dehydrogenase/Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-05 HKJG/JP/CP/AK-01 (INOPERATIVE)
	Aspartate aminotransferase (INOPERATIVE)	Catalytic activity of AST : MDH (IFCC) with/without 700 /Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-06 HKJG/JP/CP/AK-01 (INOPERATIVE)

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-mm/120937> for the current scope of accreditation

# Schedule

Issue date: 24 January 2025  
Valid Until: -



## NO: SAMM 1109

(Issue 2, 24 January 2025 replacement of SAMM 1109 dated 24 January 2025)

Page: 3 of 10

Bilirubin direct (INOPERATIVE)	Diazo method (DPD)/DXG 700 /Beckman Coulter DXG 700 as documented in HKJG/JP/CP/CHEM-07 HKJG/JP/CP/AK-01 (INOPERATIVE)
Bilirubin total (INOPERATIVE)	Diazo method (DPD)/DXG 700 /Beckman Coulter DXG 700 as documented in HKJG/JP/CP/AK-01 (INOPERATIVE)
Calcium (INOPERATIVE)	Compleximetric methods : O-Cresolphthalein complexone (oCPC)/Beckman Coulter DXG 700 as documented in HKJG/JP/CP/CHEM-09 HKJG/JP/CP/AK-01 (INOPERATIVE)
Chloride (INOPERATIVE)	Ion Selective Electrode, indirect/Beckman Coulter DXG 700 as documented in HKJG/JP/CP/CHEM-10 HKJG/JP/CP/AK-01 (INOPERATIVE)
Creatine Kinase (INOPERATIVE)	Catalytic activity of CK : CK/G6PDH (IFCC)-CK(NAC)/Beckman Coulter DXG 700 as documented in HKJG/JP/CP/CHEM-11 HKJG/JP/CP/AK-01 (INOPERATIVE)
Glucose (INOPERATIVE)	Enzymatic method : Hexokinase (IFCC)/ Beckman Coulter DXG 700 as documented in HKJG/JP/CP/CHEM-13 HKJG/JP/CP/AK-01 (INOPERATIVE)
Lactate Dehydrogenase (INOPERATIVE)	Enzymatic method : Lactate →Pyruvate (IFCC)/ Beckman Coulter DXG 700 as documented in HKJG/JP/CP/CHEM-14 HKJG/JP/CP/AK-01 (INOPERATIVE)
Magnesium (INOPERATIVE)	Photometric : Xylidyl Blue / Beckman Coulter DXG 700 as documented in HKJG/JP/CP/CHEM-15 HKJG/JP/CP/AK-01 (INOPERATIVE)
Phosphorus, Inorganic (INOPERATIVE)	Phosphomolybdate complex formation/ Beckman Coulter DXG 700 as documented in HKJG/JP/CP/CHEM-16 HKJG/JP/CP/AK-01 (INOPERATIVE)

Scan this QR Code or visit <https://accreditation.jsm.gov.my/public/listing/cab/samm-m/120937> for the current scope of accreditation

# Schedule

Issue date: 24 January 2025  
Valid Until: -



## NO: SAMM 1109

(Issue 2, 24 January 2025 replacement of SAMM 1109 dated 24 January 2025)

Page: 4 of 10

Potassium (INOPERATIVE)	Ion Selective Electrode, indirect/ Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-10 HKJG/JP/CP/AK-01 (INOPERATIVE)
Sodium (INOPERATIVE)	Ion Selective Electrode, indirect/ Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-10 HKJG/JP/CP/AK-01 (INOPERATIVE)
Total Protein (INOPERATIVE)	Biuret/ Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-19 HKJG/JP/CP/AK-01 (INOPERATIVE)
Urea (SUSPENDED)	Enzymatic method : Urease / GLDH / Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-20 HKJG/JP/CP/AK-01 (SUSPENDED)
C- Reactive Protein (INOPERATIVE)	Latex Particle / Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-23 HKJG/JP/CP/AK-01 (INOPERATIVE)
Cholesterol – Total (INOPERATIVE)	Immunoturbidimetric (PETIA) Enzymatic colorimetric method : Cholesterol Oxidase/ Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-24 HKJG/JP/CP/AK-01 (INOPERATIVE)
Cholesterol – HDL (INOPERATIVE)	Enzymatic Immunoinhibition/Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-25 HKJG/JP/CP/AK-01 (INOPERATIVE)
C3 Complement (INOPERATIVE)	Immuno turbidimetric/ Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-26 HKJG/JP/CP/AK-01 (INOPERATIVE)
C4 Complement (INOPERATIVE)	Immuno turbidimetric/ Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-27 HKJG/JP/CP/AK-01 (INOPERATIVE)
Iron (INOPERATIVE)	Ferene (TPTZ)/ Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-28 HKJG/JP/CP/AK-01 (INOPERATIVE)

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-mm/120937> for the current scope of accreditation

# Schedule

Issue date: 24 January 2025  
Valid Until: -



## NO: SAMM 1109

(Issue 2, 24 January 2025 replacement of SAMM 1109 dated 24 January 2025)

Page: 5 of 10

Total Iron Binding Capacity (TIBC) (INOPERATIVE)	Ferene Calculated (iron + uibe) uibe method : Nitroso-PSAP/ Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-29 HKJG/JP/CP/AK-01 (INOPERATIVE)
Triglycerides (INOPERATIVE)	Enzymatic GPO-POD/ Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-30 HKJG/JP/CP/AK-01 (INOPERATIVE)
Alpha Feto Protein (INOPERATIVE)	Chemiluminescent Immunoassay/ Beckman Coulter DXi 800 as documented in HKJG/JP/CP/IMMUNO-04 HKJG/JP/CP/AK-02 (INOPERATIVE)
Beta human chorionic gonadotrophin (ThCG), Total (INOPERATIVE)	Chemiluminescent Immunoassay/ Beckman Coulter DXi 800 as documented in HKJG/JP/CP/IMMUNO-02 HKJG/JP/CP/AK-02 (INOPERATIVE)
Thyroxine, Free (fT4) (INOPERATIVE)	Chemiluminescent Immunoassay/ Beckman Coulter DXi 800 as documented in HKJG/JP/CP/IMMUNO-04 HKJG/JP/CP/AK-02 (INOPERATIVE)
Tyroid Stimulating Hormone (TSH) (INOPERATIVE)	Chemiluminescent Immunoassay/ Beckman Coulter DXi 800 as documented in HKJG/JP/CP/IMMUNO-05 HKJG/JP/CP/AK-02 (INOPERATIVE)
Folate (INOPERATIVE)	Chemiluminescent Immunoassay/ Beckman Coulter DXi 800 as documented in HKJG/JP/CP/IMMUNO-06 HKJG/JP/CP/AK-02 (INOPERATIVE)
Ferritin (INOPERATIVE)	Chemiluminescent Immunoassay/ Beckman Coulter DXi 800 as documented in HKJG/JP/CP/IMMUNO-07 HKJG/JP/CP/AK-02 (INOPERATIVE)
Vitamin B12 (INOPERATIVE)	Chemiluminescent Immunoassay/ Beckman Coulter DXi 800 as documented in HKJG/JP/CP/IMMUNO-08 HKJG/JP/CP/AK-02 (INOPERATIVE)
Corrected calcium (INOPERATIVE)	Calculated test as documented in HKJG/JP/CP/CHEM-09 (INOPERATIVE)

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-mm/120937> for the current scope of accreditation

# Schedule

Issue date: 24 January 2025  
Valid Until: -



## NO: SAMM 1109

(Issue 2, 24 January 2025 replacement of SAMM 1109 dated 24 January 2025)

Page: 6 of 10

	eGFR (INOPERATIVE)	Calculated test as documented in HKJG/JP/CP/CHEM-12 (INOPERATIVE)
	Globulin (INOPERATIVE)	Calculated test as documented in HKJG/JP/CP/CHEM-22 (INOPERATIVE)
	Indirect bilirubin (INOPERATIVE)	Calculated test as documented in HKJG/JP/CP/CHEM-08 (INOPERATIVE)
	A/G ratio (INOPERATIVE)	Calculated test as documented in HKJG/JP/CP/CHEM-02 (INOPERATIVE)
	LDL-Cholesterol (INOPERATIVE)	Calculated test as documented in HKJG/JP/CP/CHEM-24 (INOPERATIVE)
	Uric acid (INOPERATIVE)	Enzymatic method : Uricase/ peroxidase / Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-24 HKJG/JP/CP/AK-01 (INOPERATIVE)
Plasma/serum/urine	Cortisol (INOPERATIVE)	Chemiluminescent Immunoassay/ Beckman Coulter DXi-800 as documented in HKJG/JP/CP/IMMUNO-03 HKJG/JP/CP/AK-02 (INOPERATIVE)
Serum/urine	Osmolality	Freezing point/ 3320 Micro-Osmometer as documented in HKJG/JP/CP/AK-05
Urine/csf	Total protein (INOPERATIVE)	Pyrogallol Red and molybdate/ Beckman Coulter DXC 700 as documented in HKJG/JP/CP/CHEM-22 HKJG/JP/CP/AK-01 (INOPERATIVE)
Urine	Urine chemistry	Semiquantitative Reflectance Photometer Assay/ iChem Velocity as documented in HKJG/JP/CP/AK-04

## SCOPE OF MEDICAL TESTING : HAEMATOLOGY

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

# Schedule

Issue date: 24 January 2025  
Valid Until: -



## NO: SAMM 1109

(Issue 2, 24 January 2025 replacement of SAMM 1109 dated 24 January 2025)

Page: 7 of 10

Bone Marrow	Bone Marrow Aspiration smear	Manual Smearing & Staining and Microscopic Observation as documented in HKJG/JP/HEMA/PK-05 HKJG/JP/HEMA/AK-09 HKJG/JP/HEMA/AK-10
Plasma	Prothrombine Time (PT)	Chronometric (Clotting time)/ Stago STA Compact Max as documented in HKJG/JP/HEMA/AK-03
	Activated Partial Thromboplastin Time (APTT)	Chronometric (Clotting time)/ Stago STA Compact Max as documented in HKJG/JP/HEMA/AK-03
	D-Dimer	Photometry/ Stago STA Compact Max as documented in HKJG/JP/HEMA/AK-03
Whole Blood	Reticulocytes	Flowcytometry Method / XN 3100 as documented in HKJG/JP/HEMA/AK-02
	Full Blood Picture	Automated Smearing and Staining and Microscopic Examination/SP-50 as documented in HKJG/JP/HEMA/PK-07 & HKJG/JP/HEMA/AK-07
	Full Blood Count (FBC)	Flowcytometry Method / Sheath flow direct current detection method / SLS-Hemoglobin Method / XN 3100 as documented in HKJG/JP/HEMA/AK-02

## SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serology Bacte-serology Serum	Ujian Sifilis	1) Rapid Plasma Reagin (RPR) Latex Agglutination 2) Treponema Pallidum Particle Agglutination as documented in HKJG/JP/MI/AK-23
	Leptospira	Latex agglutination as documented in HKJG/JP/MI/AK-27

# Schedule

Issue date: 24 January 2025  
Valid Until: -



## NO: SAMM 1109

(Issue 2, 24 January 2025 replacement of SAMM 1109 dated 24 January 2025)

Page: 8 of 10

Parasitology Blood Smear	Malaria parasite	Microscopy thick and thin blood smear Giemsa stained as documented in HKJG/JP/MI/AK-16
Serology Immunology Serum	Anti-nuclear antibody(ANA)	Indirect Fluorescent Antibody Test/ UV Microscope as documented in HKJG/JP/MI/AK-20
	Rheumatoid Factor	Latex Agglutination as documented in HKJG/JP/MI/AK-25
Mycology Serum & Csf	Cryptococcal Antigen	Manual method as documented in HKJG/JP/MI/TPM-MIKO.04
Tuberculosis Sputum / Urine / Csf / Pus / Body Fluid / Pleural Fluid	Direct Smear AFB	Manual method as documented in HKJG/JP/MI/AK-17
Mycology Sterile & Non-sterile	Culture & Sensitivity	Manual method as documented in HKJG-JP-MI-AK-18
Serology Virology Serum	NS1 Ag Rapid to Dengue Virus	Immunochromatography as documented in HKJG/JP/MI/AK-28
	IgG & IgM Antibodies for Dengue Virus	Immunochromatography as documented in HKJG/JP/MI/AK-28
	Hepatitis B Ab Screening (INOPERATIVE)	Electrochemiluminescence immunoassay (ECLIA) Test/ Cobas E411 as documented in HKJG/JP/MI/PK-03 (INOPERATIVE)
	COMBO HIV antigen and antibodies (HIV-1 and HIV-2) Screening & Supplementary Test (HIV Particles agglutination, PA) (INOPERATIVE)	Electrochemiluminescence immunoassay (ECLIA) Test/ Cobas E411 as documented in HKJG/JP/MI/PK-03 (INOPERATIVE)
	HCV Antibody Screening (INOPERATIVE)	Electrochemiluminescence immunoassay (ECLIA) Test/ Cobas E411 as documented in HKJG/JP/MI/PK-03 (INOPERATIVE)
	Hepatitis B Surface Ag Screening (INOPERATIVE)	Electrochemiluminescence immunoassay (ECLIA) Test/ Cobas E411 as documented in HKJG/JP/MI/PK-03 (INOPERATIVE)

### SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY (BACTERIOLOGY)

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

# Schedule

Issue date: 24 January 2025  
Valid Until: -



## NO: SAMM 1109

(Issue 2, 24 January 2025 replacement of SAMM 1109 dated 24 January 2025)

Page: 9 of 10

Blood	Culture & Sensitivity Testing	Semi-automated method as documented in HKJG- JP-MI-AK-05 HKJG-JP-MI-AK-14
Body Fluid	Culture & Sensitivity Testing & Microscopy	Manual method as documented in HKJG-JP-MI-AK-06 HKJG-JP-MI-AK-14
Csf	Culture & Sensitivity Testing & Microscopy	Manual method as documented in HKJG-JP-MI-AK-07
Genital	Culture & Sensitivity Testing	Manual method as documented in HKJG-JP-MI-AK-11
Pus Aspirate & Pus Swab	Culture & Sensitivity Testing	Manual method as documented in HKJG-JP-MI-AK-13 HKJG-JP-MI-AK-14
Sterility And Monitoring (surveillance) Respiratory	Culture & Sensitivity Testing	Manual method as documented in HKJG-JP-MI-AK-31
	Culture & Sensitivity Testing	Manual method as documented in HKJG-JP-MI-AK-09
Stool	Culture & Sensitivity Testing	Manual method as documented in HKJG-JP-MI-AK-12
Tissue & Bone	Culture & Sensitivity Testing	Manual method as documented in HKJG-JP-MI-AK-08 HKJG-JP-MI-AK-14
Urine	Culture & Sensitivity Testing	Manual method as documented in HKJG-JP-MI-AK-10

## SCOPE OF MEDICAL TESTING : TRANSFUSION MEDICINE

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Whole Blood	ABO Grouping	Tube method/Tube method/Gel card as documented in HKJG/JP/TRANS/AK-02 HKJG/JP/TRANS/AK-03
	Crossmatching (GXM)	Tube method/Gel card as documented in HKJG/JP/TRANS/PK-11 HKJG/JP/TRANS/PK-12 HKJG/JP/TRANS/PK-17 HKJG/JP/TRANS/AK-02 HKJG/JP/TRANS/AK-03 HKJG/JP/TRANS/AK-04 HKJG/JP/TRANS/AK-10
	Direct & Indirect Coombs Test	Gel card as documented in HKJG/JP/TRANS/AK-07

# Schedule

Issue date: 24 January 2025  
Valid Until: -



## NO: SAMM 1109

(Issue 2, 24 January 2025 replacement of SAMM 1109 dated 24 January 2025)

Page: 10 of 10

	Group Screen & Hold (GSH)	Tube method/Gel card as documented in HKJG/JP/TRANS/PK-10 HKJG/JP/TRANS/AK-02 HKJG/JP/TRANS/AK-03 HKJG/JP/TRANS/AK-04
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