

Schedule

Issue date: 23 June 2025


Valid Until: -



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of SAMM 920 dated 07 January 2025)

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LABORATORY LOCATION: (PERMANENT LABORATORY) 	Jabatan Patologi, Hospital Seberang Jaya Jalan Tun Hussein Onn, 13700 Seberang Jaya, Pulau Pinang. , 13700, PULAU PINANG MALAYSIA
ACCREDITED SINCE :	23 JUNE 2025
FIELD(S) OF MEDICAL TESTING :	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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CENTRAL LOCATION	Jabatan Patologi, Hospital Seberang Jaya Jalan Tun Hussein Onn, 13700 Seberang Jaya, Pulau Pinang. , 13700, Pulau Pinang
FIELD(S) OF MEDICAL TESTING :	CYTOPATHOLOGY, CHEMICAL PATHOLOGYHAEMATOLOGYTRANSFUSION MEDICINEMEDICAL MICROBIOLOGYHISTOPATHOLOGY

SCOPE OF MEDICAL TESTING : CYTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods,Specifications/ Equipment/Techniques Used
Gynaecological Specimens	Gynaecological Cytology Examination (INOPERATIVE)	Management of cytology, specimens, slides, reports method as documented in HSJ/PAT/ HC/CY/QP/01 (INOPERATIVE)
	Gynaecological Cytology Examination (INOPERATIVE)	Papanicolaou Staining (Manual Method) as documented in HSJ/PAT/ HC/CY/WI/08 (INOPERATIVE)
	Gynaecological Cytology Examination (INOPERATIVE)	Processing of Conventional PAP Smear Slides as documented in: i. HSJ/PAT/HC/CY/WI/06 ii. HSJ/PAT/HC/CY/WI/07 (PAP Stain automated) (INOPERATIVE)
Non-gynaecological Specimens	Non-gynaecological Cytology Specimens (INOPERATIVE)	Specimen Preparation and Routine Staining (Manual Method) Method as documented in: i. HSJ/PAT/HC/CY/QP/01 ii. HSJ/PAT/HC/CY/WI/02 iii. HSJ/PAT/HC/CY/WI/03 iv. HSJ/PAT/ HC/CY/WI/04 (INOPERATIVE)
	Non-gynaecological Cytology Specimens (INOPERATIVE)	Diff Quik as documented in HSJ/PAT/ HC/CY/WI/18 (INOPERATIVE)
	Non-gynaecological Cytology Specimens (INOPERATIVE)	Papanicolaou Stain as documented in HSJ/PAT/ HC/CY/WI/07 (INOPERATIVE)

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	Non-gynaecological Cytology Specimens (INOPERATIVE)	May Grunwald-giemsa Stain as documented in HSJ/PAT/ HC/CY/WI/09 (INOPERATIVE)
Fine Needle Aspirates	FNA Cytology Examination (INOPERATIVE)	Specimen Preparation and Routine Staining (Manual Method) Method as documented in: i. HSJ/PAT/HC/CY/QP/01 ii. HSJ/PAT/HC/CY/WI/05—FNA Preparation (INOPERATIVE)
	FNA Cytology Examination (INOPERATIVE)	Diff Quick as documented in HSJ/PAT/ HC/CY/WI/18 (INOPERATIVE)
	FNA Cytology Examination (INOPERATIVE)	May Grunwald-Giemsa Stain as documented in HSJ/PAT/ HC/CY/WI/09 (INOPERATIVE)
	FNA Cytology Examination (INOPERATIVE)	Papanicolaou Staining (Automated) as documented in HSJ/PAT/ HC/CY/WI/07 (INOPERATIVE)
	FNA Cytology Examination (INOPERATIVE)	Papanicolaou Staining (Manual) as documented in HSJ/PAT/ HC/CY/WI/08 (INOPERATIVE)

SCOPE OF MEDICAL TESTING : CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
General Chemistry Plasma	Alanine Transaminase (INOPERATIVE)	IFCC (with Pyridoxal Phosphate Activation) / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A04 (INOPERATIVE)
	Albumin (INOPERATIVE)	Bromocresol Purple (BCP) / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A01 (INOPERATIVE)
	Alkaline Phosphatase (INOPERATIVE)	IFCC p-Nitrophenylphosphate / Cobas Pro c503 as documented in as documented in HSJ/JP/CP/TM-A03 (INOPERATIVE)

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Ammonia (INOPERATIVE)	Enzymatic using Glutamate Dehydrogenase) / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A20 (INOPERATIVE)
Amylase (INOPERATIVE)	Enzymatic Colorimetric 4,6-ethylidene-(G7) Pnitrophenyl(G4)-D Maltoheptaoside / Cobas Pro c503 as documented in HSJ/JP/CP/TMA05 (INOPERATIVE)
Aspartate Transaminase (INOPERATIVE)	IFCC (with Pyridoxal Phosphate Activation) / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A06 (INOPERATIVE)
Bilirubin, Direct (INOPERATIVE)	Colorimetric Diazo / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A07 (INOPERATIVE)
Bilirubin, Total	Colorimetric Diazo / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A08
Bilirubin, Total (INOPERATIVE)	Colorimetric Diazo / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A08 (INOPERATIVE)
Calcium (INOPERATIVE)	NM-BAPTA / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A09 (INOPERATIVE)
Chloride (INOPERATIVE)	Ion-Selective Electrode, indirect potentiometry / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A16 (INOPERATIVE)
Cholesterol (INOPERATIVE)	Enzymatic Colorimetric (Cholesterol-oxidase (CHOD-PAP) as documented in HSJ/JP/CP/TM-A10 (INOPERATIVE)
Creatine Kinase (INOPERATIVE)	UV-Imidazole-Buffer — IFCC / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A11 (INOPERATIVE)
Creatinine (INOPERATIVE)	Colorimetric-Jaffe / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A12 (INOPERATIVE)
Glucose (INOPERATIVE)	Enzymatic-UV, Hexokinase / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A14 (INOPERATIVE)

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	High-Density Lipoprotein (HDL- Cholesterol) (INOPERATIVE)	Enzymatic-Colorimetric Direct HDL: PEG mod. / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A15 (INOPERATIVE)
	Lactate (INOPERATIVE)	Enzymatic (Lactate to Pyruvate) / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A17 (INOPERATIVE)
	Lactate Dehydrogenase (INOPERATIVE)	IFCC Lactate to Pyruvate / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A18 (INOPERATIVE)
	Magnesium (INOPERATIVE)	Colorimetric Endpoint (Xylidyl Blue) / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A19 (INOPERATIVE)
	Phosphate / Inorganic (INOPERATIVE)	Molybdate, UV / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A21 (INOPERATIVE)
	Potassium (INOPERATIVE)	Ion-Selective Electrode, indirect potentiometry / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A16 (INOPERATIVE)
	Protein / Total (INOPERATIVE)	Colorimetric / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A22 (INOPERATIVE)
	Sodium (INOPERATIVE)	Ion-Selective Electrode, indirect potentiometry / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A16 (INOPERATIVE)
	Triglycerides / Total (INOPERATIVE)	Lipase/GPO-PAP (without glycerol correction) / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A24 (INOPERATIVE)
	Urea (INOPERATIVE)	Urease / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A26 (INOPERATIVE)
	Uric Acid (INOPERATIVE)	Uricase / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A25 (INOPERATIVE)
	C-Reactive Protein (INOPERATIVE)	Immuno-turbidimetric assay / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A13 (INOPERATIVE)
General Chemistry Urine	Urine Creatinine (random and 24 hrs) (INOPERATIVE)	Kinetic Colorimetric Jaffe / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A12 (INOPERATIVE)

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	Urine Albumin/ Microalbumin (INOPERATIVE)	Immunoturbidimetric / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A02 (INOPERATIVE)
	Urine Magnesium (INOPERATIVE)	Colorimetric Endpoint (Xylidyl Blue) / Cobas Pro c503 as documented in HSJ/JP/CP/TMA19 (INOPERATIVE)
	Urine Phosphate, Inorganic (INOPERATIVE)	Molybdate, UV / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A21 (INOPERATIVE)
	Urine Potassium (INOPERATIVE)	Ion Selective Electrode, Indirect Potentiometry / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A16 (INOPERATIVE)
	Urine Protein, Total (INOPERATIVE)	Benzathonium Chloride / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A24 (INOPERATIVE)
	Urine Sodium (INOPERATIVE)	Ion Selective Electrode, Indirect Potentiometry / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A16 (INOPERATIVE)
	Urine Urea (INOPERATIVE)	Urease / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A26 (INOPERATIVE)
	Urine Uric Acid (INOPERATIVE)	Uricase / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A25 (INOPERATIVE)
General Chemistry Heparinized Blood	Blood Gases (pH, PO ₂ , PCO ₂) (INOPERATIVE)	Selective Electrode Technology / ABL 90 Flex Plus as documented in HSJ/JP/CP/TM-C01 (INOPERATIVE)
Csf	Csf Glucose (INOPERATIVE)	Enzymatic UV, Hexokinase (G-6-PDH) / Cobas Pro c503 as documented in HSJ/JP/CP/TMA14 (INOPERATIVE)
	Csf Protein (INOPERATIVE)	Benzathonium Chloride / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A24 (INOPERATIVE)
	Csf Lactate (INOPERATIVE)	Enzymatic (Lactate to Pyruvate) / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A17 (INOPERATIVE)
Urine	Urine Calcium (INOPERATIVE)	NM-BAPTA / Cobas Pro c503 as documented in HSJ/JP/CP/TM- A09 (INOPERATIVE)

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	Urine Chloride (INOPERATIVE)	Ion Selective Electrode, Indirect Potentiometry / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A16 (INOPERATIVE)
Special Chemistry Plasma	Thyroid Stimulating Hormone (TSH) (INOPERATIVE)	Electrochemiluminescence / Cobas Pro e801 as documented in HSJ/JP/CP/TM-A30 (INOPERATIVE)
	Thyroxine / Free (FT4) (INOPERATIVE)	Electrochemiluminescence / Cobas Pro e801 as documented in HSJ/JP/CP/TM-A29 (INOPERATIVE)
	? HCG (INOPERATIVE)	Electrochemiluminescence / Cobas Pro e801 as documented in HSJ/JP/CP/TM-A28 (INOPERATIVE)

SCOPE OF MEDICAL TESTING : HAEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Routine Haematology Whole Blood	1. Full Blood Count (INOPERATIVE)	Haemoglobin: Colorimetric method Cell differentiation and counting: Impedance method, laser scatter and SF Cube cell analysis technology / Automated Mindray BC 6200 Haematology Analyzer as documented in HSJ/PAT/HEM/WI04 (INOPERATIVE)
	2. Slide Review (INOPERATIVE)	Automated blood film preparation and staining / Automated Mindray SG120 as documented in HSJ/PAT/HEM/WI05 (INOPERATIVE)
	3. Full Blood Picture (INOPERATIVE)	Automated blood film preparation and staining / Automated Mindray SG120 as documented in HSJ/PAT/HEM/WI04 (INOPERATIVE)
	4. Erythrocyte sedimentation rate (ESR) (INOPERATIVE)	Westergreen method / Automated Jokoh Smart Rate as documented in HSJ/PAT/HEM/WI07 (INOPERATIVE)

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Plasma	Prothrombin Time (PT), Activated Partial Thrombin Time (APTT), Fibrinogen and D-Dimer Quantitative (INOPERATIVE)	PT/APTT: Coagulometric measurement (changed in optical density); Fibrinogen: Chromogenic measurement, D-dimer: Immunologic measurement/ Automated ACL Top 550 Coagulation analyzer as documented in HSJ/PAT/HEM/WI03 (INOPERATIVE)
Special Haematology Plasma	Mixing test for PT and APTT (INOPERATIVE)	Coagulometric measurement (changed in optical density)/ Automated ACL Top 550 Coagulation Analyser as documented in HSJ/PAT/HEM/WI11 (INOPERATIVE)
Bone Marrow	Bone Marrow Aspirate (INOPERATIVE)	Manual slide making and staining as documented in HSJ/PAT/HEM/WI08 (INOPERATIVE)

SCOPE OF MEDICAL TESTING : TRANSFUSION MEDICINE

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Immunohaematology Plasma And Red Blood Cell	Blood Grouping including ABO, Rh (D)	Tube method (Manual) as documented in: i. HSJ/PAT/TM/WI/017 ii. HSJ/PAT/TM/WI/021
	Blood Grouping including ABO, Rh (D)	Gel Card Method (Automated) / Automated Analyser IH-500 as documented in HSJ/PAT/TM/WI/063
Plasma	Antibody Screening	Gel Card Method (Manual) as documented in HSJ/PAT/TM/WI/024
	Antibody Screening	Gel Card Method (Automated) / Automated Analyser IH-500 as documented in HSJ/PAT/TM/WI/066
Plasma, Donor Red Cells	Compatibility Test (Crossmatch)	Gel Card Method (Manual) as documented in HSJ/PAT/TM/WI/027

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY

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Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Bacteriology Urine Blood csf/body Fluids Sputum/respiratory Specimen Pus/swab/tissue Stool/rectal Swab High Vaginal Swab Antibiotic sensitivity Testing	Culture and Sensitivity	Routine culture as documented in: i. HSJ/PAT/MM/BC/WI 13 ii. HSJ/PAT/MM/BC/WI 14 iii. HSJ/PAT/MM/BC/WI 20 iv. HSJ/PAT/MM/BC/WI 22 v. HSJ/PAT/MM/BC/WI 15 vi. HSJ/PAT/MM/BC/WI 16 vii. HSJ/PAT/MM/BC/WI 17 viii. HSJ/PAT/MM/BC/WI 27
Sputum	AFB Microscopy	Immunofluorescence stain/ AFB stain as documented in HSJ/PAT/MM/BC/WI 30 and HSJ/PAT/MM/BC/WI 08
Serology Serum	Enzyme Immunoassay: 1. HIV test (INOPERATIVE)	Electrochemiluminescence Immunoassay (ECLIA) method/ Cobas e402 as documented in HSJ/PAT/MM/SRAWI 11 (INOPERATIVE)
	2. Hepatitis B Surface Antigen Test (INOPERATIVE)	Electrochemiluminescence Immunoassay (ECLIA) method/ Cobas e402 as documented in HSJ/PAT/MM/SRAWI 12 (INOPERATIVE)
	3. Hepatitis B Surface Antibody Test (INOPERATIVE)	Electrochemiluminescence Immunoassay (ECLIA) method/ Cobas e402 as documented in HSJ/PAT/MM/SRAWI 14 (INOPERATIVE)
	4. Hepatitis C Antibody Test (INOPERATIVE)	Electrochemiluminescence Immunoassay (ECLIA) method/ Cobas e402 as documented in HSJ/PAT/MM/SRAWI 13 (INOPERATIVE)
	<u>Manual Test:</u> HIV Particle Agglutination 1 and 2 Mix (INOPERATIVE)	Particle Agglutination method as documented in HSJ/PAT/MM/SRAWI 16 (INOPERATIVE)
	Rapid Plasma Reagin (RPR) (INOPERATIVE)	Flocculation method as documented in HSJ/PAT/MM/SRAWI 19 (INOPERATIVE)
	Treponemal Pallidum Particle Agglutination (TPPA) (INOPERATIVE)	Particle Agglutination method as documented in HSJ/PAT/MM/SRAWI 09 (INOPERATIVE)

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SCOPE OF MEDICAL TESTING : HISTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Surgical Pathology Specimens	Specimen Preparation (INOPERATIVE)	Manual Method as documented in HSJ/PAT/HC/QP/01 (INOPERATIVE)
	Specimen Preparation (INOPERATIVE)	Validation of Histology Database as documented in HSJ/PAT/HC/WI05 (INOPERATIVE)
	Specimen Preparation (INOPERATIVE)	Barcode Reader/ Scanner Verification Procedure as documented in HSJ/PAT/HC/WI06 (INOPERATIVE)
Intra-operative Frozen Section For Fresh Tissue Specimens And Biopsies	Histology Examination (INOPERATIVE)	Specimen preparation and Routine Staining (Manual Method) Method as documented in HSJ/PAT/HC/QP/01 and HSJ/PAT/HC/WI/03 (INOPERATIVE)

NOTE :