

# Schedule


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## NO: SAMM 920

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of SAMM 920 dated 07 January 2025)

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

### SCOPE OF MEDICAL TESTING : CYTOPATHOLOGY

| Specimen Tested              | Type of Test/<br>Properties Measured/                  | Test Methods, Specifications/<br>Equipment/Techniques Used   |
|------------------------------|--|--|
| Gynaecological Specimens     | Gynaecological<br>Cytology Examination (INOPERATIVE)   | Management of cytology,<br>specimens, slides, reports<br>method as documented in<br>HSJ/PAT<br>/HC/CY/QP/01 (INOPERATIVE)  |
|                              | Gynaecological<br>Cytology Examination (INOPERATIVE)   | Papanicolaou Staining (Manual<br>Method) as documented in<br>HSJ/PAT/<br>HC/CY/WI/08 (INOPERATIVE)   |
|                              | Gynaecological<br>Cytology Examination (INOPERATIVE)   | Processing of Conventional PAP<br>Smear Slides as documented in:<br>i. HSJ/PAT/HC/CY/WI/06<br>ii. HSJ/PAT/HC/CY/WI/07 (PAP<br>Stain automated) (INOPERATIVE)   |
| Non-gynaecological Specimens | Non-gynaecological<br>Cytology Specimens (INOPERATIVE) | Specimen Preparation and<br>Routine Staining (Manual<br>Method) Method as documented<br>in:<br>i. HSJ/PAT/HC/CY/QP/01<br>ii. HSJ/PAT/HC/CY/WI/02<br>iii. HSJ/PAT/HC/CY/WI/03<br>iv.<br>HSJ/PAT/<br>HC/CY/WI/04 (INOPERATIVE) |
|                              | Non-gynaecological<br>Cytology Specimens (INOPERATIVE) | Diff-Quik as documented in<br>HSJ/PAT/<br>HC/CY/WI/18 (INOPERATIVE)  |
|                              | Non-gynaecological<br>Cytology Specimens (INOPERATIVE) | Papanicolaou Stain as<br>documented in<br>HSJ/PAT/<br>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:<br>i. HSJ/PAT/HC/CY/QP/01<br>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<br>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 ethyldene (G7) Pnitrophenyl(G1)-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/TMA19 (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)   |
| <b>General Chemistry</b><br>Urine                        | Urine Creatinine (random and 24 hrs) (INOPERATIVE)<br>Kinetic-Colorimetric-Jaffe / Cobas Pro c503 as documented in HSJ/JP/CP/TM-A12 (INOPERATIVE) |

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|   | Urine Albumin/<br>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,<br>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)   |
| <b>General Chemistry</b><br>Heparinized Blood | Blood Gases<br>(pH, PO <sub>2</sub> , PCO <sub>2</sub> ) (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<br>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/<br>Properties Measured/                 | Test Methods, Specifications/<br>Equipment/Techniques Used  |
|------------------------------------|---|---|
| Routine Haematology<br>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 SC120 as documented in HSJ/PAT/HEM/WI05 (INOPERATIVE)   |
|                                    | 3. Full Blood Picture (INOPERATIVE)                   | Automated blood film preparation and staining / Automated Mindray SC120 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 <b>(INOPERATIVE)</b> | PT/APTT: Coagulometric measurement (changed in optical density); Fibrinogen: Chromogenic measurement, D-dimer: Immunologic measurement/ Automated AGL Top 550 Coagulation analyzer as documented in HSJ/PAT/HEM/WI03 <b>(INOPERATIVE)</b> |
| <b>Special Haematology</b><br>Plasma | Mixing test for PT and APTT <b>(INOPERATIVE)</b>  | Coagulometric measurement (changed in optical density)/ Automated AGL Top 550 Coagulation Analyser as documented in HSJ/PAT/HEM/WI11 <b>(INOPERATIVE)</b>   |
| Bone Marrow                          | Bone Marrow Aspirate <b>(INOPERATIVE)</b>   | Manual slide making and staining as documented in HSJ/PAT/HEM/WI08 <b>(INOPERATIVE)</b>   |

### SCOPE OF MEDICAL TESTING : TRANSFUSION MEDICINE

| Specimen Tested                                | Type of Test/<br>Properties Measured/ | Test Methods, Specifications/<br>Equipment/Techniques Used                                 |
|--|---------------------------------------|--|
| Immunohaematology<br>Plasma And Red Blood Cell | Blood Grouping including ABO, Rh (D)  | Tube method (Manual) as documented in:<br>i. HSJ/PAT/TM/WI/017<br>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/<br>Properties Measured/   | Test Methods, Specifications/<br>Equipment/Techniques Used   |
|---|---|--|
| <b>Bacteriology</b><br>Urine Blood<br>csf/body Fluids<br>Sputum/respiratory Specimen<br>Pus/swab/tissue<br>Stool/rectal Swab<br>High<br>Vaginal Swab<br>Antibiotic<br>sensitivity Testing | Culture and Sensitivity   | Routine culture as documented<br>in:<br>i. HSJ/PAT/MM/BC/WI 13<br>ii. HSJ/PAT/MM/BC/WI 14<br>iii. HSJ/PAT/MM/BC/WI 20<br>iv. HSJ/PAT/MM/BC/WI 22<br>v. HSJ/PAT/MM/BC/WI 15<br>vi. HSJ/PAT/MM/BC/WI 16<br>vii. HSJ/PAT/MM/BC/WI 17<br>viii. HSJ/PAT/MM/BC/WI 27 |
| Sputum  | AFB Microscopy  | Immunofluorescence stain/ AFB<br>stain as documented in<br>HSJ/PAT/MM/BC/WI 30 and<br>HSJ/PAT/MM/BC/WI 08  |
| <b>Serology</b><br>Serum  | Enzyme Immunoassay:<br>1. HIV test (INOPERATIVE)                                  | Electrochemiluminescence<br>Immunoassay (ECLIA) method/<br>Cobas e402 as documented in<br>HSJ/PAT/MM/SRAWI<br>11 (INOPERATIVE)   |
|   | 2. Hepatitis B Surface Antigen<br>Test (INOPERATIVE)                              | Electrochemiluminescence<br>Immunoassay (ECLIA) method/<br>Cobas e402 as documented in<br>HSJ/PAT/MM/SRAWI<br>12 (INOPERATIVE)   |
|   | 3. Hepatitis B Surface Antibody<br>Test (INOPERATIVE)                             | Electrochemiluminescence<br>Immunoassay (ECLIA) method/<br>Cobas e402 as documented in<br>HSJ/PAT/MM/SRAWI<br>14 (INOPERATIVE)   |
|   | 4. Hepatitis C Antibody<br>Test (INOPERATIVE)                                     | Electrochemiluminescence<br>Immunoassay (ECLIA) method/<br>Cobas e402 as documented in<br>HSJ/PAT/MM/SRAWI<br>13 (INOPERATIVE)   |
|   | <b>Manual Test:</b><br>HIV Particle<br>Agglutination 1 and 2<br>Mix (INOPERATIVE) | Particle Agglutination method as<br>documented in<br>HSJ/PAT/MM/SRAWI<br>16 (INOPERATIVE)  |
|   | Rapid Plasma Reagin<br>(RPR) (INOPERATIVE)  | Flocculation method as<br>documented in<br>HSJ/PAT/MM/SRAWI<br>19 (INOPERATIVE)  |
|   | Treponemal Pallidum Particle<br>Agglutination (TPPA) (INOPERATIVE)                | Particle Agglutination method as<br>documented in<br>HSJ/PAT/MM/SRAWI<br>09 (INOPERATIVE)  |

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**SCOPE OF MEDICAL TESTING : HISTOPATHOLOGY**

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

**NOTE :**