


Schedule

Issue date: 15 May 2025
Valid Until: -



NO: SAMM 1173

Page: 1 of 5

LABORATORY LOCATION: (PERMANENT LABORATORY) 	Unit Patologi, Hospital Batu Gajah Jalan Changkat Batu Gajah, Jalan Hospital , 31000, PERAK MALAYSIA
ACCREDITED SINCE :	15 MAY 2025
FIELD(S) OF MEDICAL TESTING :	CHEMICAL PATHOLOGY HAEMATOLOGY MEDICAL MICROBIOLOGY

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: 15 May 2025
Valid Until: -



NO: SAMM 1173

Page: 2 of 5

CENTRAL LOCATION	Unit Patologi, Hospital Batu Gajah Jalan Changkat Batu Gajah, Jalan Hospital , 31000, Perak
FIELD(S) OF MEDICAL TESTING :	CHEMICAL PATHOLOGY, HAEMATOLOGY MEDICAL MICROBIOLOGY

SCOPE OF MEDICAL TESTING : CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum / Plasma	Albumin	Method: Bromcresol Purple (BCP) Machine: Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
	Alkaline Phosphatase (ALP)	Method: PNPP, AMP Buffer Machine: Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
	Alanine aminotransferase (ALT)	Method: UV without P5P Machine: Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
	Amylase	Method: CNP?triose/CNPG3 Machine: Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
	Aspartate aminotransferase (AST)	Method: UV without P5P Machine: Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
	Bilirubin Total	Method: Diazotization Machine: Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
	Bilirubin Direct	Method: Diazonium Ion Machine: Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
	Chloride	Method: ISE indirect Machine: Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01

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Schedule

Issue date: 15 May 2025
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NO: SAMM 1173

Page: 3 of 5

Cholesterol-Total	Method: Cholesterol oxidase, esterase, peroxidase Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
Creatine Kinase	Method: NAC activated Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
Creatinine	Method: Alkaline picrate method, IFCC?IDMS Standardized Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
Glucose	Method: Hexokinase Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
Iron	Method: Ferene Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
Potassium	Method: ISE indirect Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
Protein (Total)	Method: Biuret method Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
Sodium	Method: ISE indirect Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
Triglyceride	Method: Enzymatic, end point Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
UIBC	Method: Ferene Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
Urea	Method: Urease, UV Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01
Uric Acid	Method: Uricase, colorimetric Machine:Architect Plus C4000 Procedures are as documented in HBG-PATSTM-CP-01

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NO: SAMM 1173

Page: 4 of 5

Urine	SG, pH, Leucocytes, Nitrite, Protein, Glucose, Ketone, Urobilinogen, Bilirubin, Blood RBC), Haemoglobin	Method: Urine Dip Stick Method Machine: ERBA LAURA Procedures are as documented in HBG-PATSTM-CP-02
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SCOPE OF MEDICAL TESTING : HAEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Whole Blood	Full Blood Count	Method: Flowcytometry Method using electrical resistant Machine: Sysmex XN-1000 Procedures are as documented in HBG-PATSTM-HEM-02
	ABO/RhD Grouping	Forward and reverse grouping using Tube Method Procedures are as documented in HBG-PATSTM-BB-02
	Direct Coombs Test	Gel Card (Antibody-Antigen Reaction) Procedures are as documented in HBG-PATSTM-BB-04
Plasma	Prothrombin Time / INR	Method: Mechanical Clot Detection Machine: STA Compact Max2 Procedures are as documented in HBG-PATSTM-HEM-03 and HBG-PAT-STM-HEM-04
	Activated Partial Thromboplastin Time	Method: Mechanical Clot Detection Machine: STA Compact Max2 Procedures are as documented in HBG-PATSTM-HEM-03 and HBG-PAT-STM-HEM-05
Plasma / Serum	Indirect Coombs Test	Gel Card (Antibody-Antigen Reaction) Procedures are as documented in HBG-PATSTM-BB-04
	Crossmatching	Manual Testing by Tube and Gel Card Procedures are as documented in HBG-PATSTM-BB-05

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY

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NO: SAMM 1173

Page: 5 of 5

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Sputum	AFB Smear	Examination of AFB-Stained Smear Procedures are as documented in HBG-PATSTM-MM-01
Blood/blood Smear	Malarial parasite	Microscopy as documented in HBG-PATSTM-MM-02

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