Issue date: 22 December 2025
Valid until: 12 May 2029

NO: SAMM 419
(Issue 02, 22 December 2025 replacement of SAMM 419 dated 26 June 2024)

LABORATORY LOCATION:
(PERMANENT LABORATORY)

PREMIER INTEGRATED LABS SDN. BHD.
(PANTAI HOSPITAL MELAKA)
GROUND FLOOR
PANTAI HOSPITAL MELAKA
NO. 2418-1, KM 8, LEBUH AYER KEROH
75450 MELAKA
MALAYSIA

FIELD(S) OF MEDICAL TESTING: **CYTOPATHOLOGY, HISTOPATHOLOGY, 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 Communiquè dated November 2021).

SCOPE OF MEDICAL TESTING: CYTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Gynaecological Cytopathology	Specimen preparation, routine staining and mounting.	Manual and automated procedure using Autostainer XL as documented in Cytopathology Procedure Manual chapter EP006 and EP009.
	a. Pap Smear Conventional	Manual procedure as documented in Cytopathology Procedure Manual chapter EP002.
	b. Liquid-based Cytology	Automated procedure using Thin-Prep 2000 Processor and Pathtezt Processor as documented in Cytopathology Procedure Manual chapter EP003 and EP024.
	Reporting and clinical interpretation.	As documented in Cytopathology Procedure Manual chapter EP012; Cytopathology Policy Manual chapter EX016 and EX019.
All Non-gynaecological Cytopathology	Specimen preparation, routine staining and mounting.	As documented in Cytopathology Procedure Manual chapter EP005, EP006, EP007 and EP009.
	Reporting and clinical Interpretation	As documented in Cytopathology Policy Manual chapter EX016 and EX019.

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SCOPE OF MEDICAL TESTING: CYTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Fine needle aspiration	Preparation of smear, routine staining and mounting. Reporting and clinical interpretation.	As documented in Cytopathology Procedure Manual chapter EP006, EP007, EP009 and EP011. As documented in Cytopathology Policy Manual chapter EX016 and EX019.

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SCOPE OF MEDICAL TESTING: HISTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Intra-operative Unfixed Surgical Tissue	Cryostat Sectioning	Manual procedure using LEICA CM 1860 UV Cryostat as documented in Histopathology Procedure Manual chapter PP083.
	Reporting and Clinical Interpretation	As documented in Histhopathology Policy Manual Chapter PX021 and PX016.
Surgical Tissue	Routine Preparation of Tissue	
	1. Grossing	Manual procedure as documented in Histopathology Procedure Manual chapter PP001.
	2. Tissue Processing	Automated with Diapath Donatello Series 3 and LEICA TP1020 documented in Histopathology Procedure Manual chapter PP002.
	3. Embedding	Semi-automated with LEICA Histocore arcadia H,Thermo Scientific HistoStar and Diapath Dante Cold Plate Module SDSDF9000 as documented in Histopathology Procedure Manual chapter PP003.
	4. Sectioning	Manual procedure using LEICA RM2235 Microtome as documented in Histopathology Procedure Manual chapter PP004.
	5. Routine H & E Staining	Manual and automated using LEICA Autostainer XL as documented in Histopathology Procedure Manual chapter PP005.
	6. Mounting of Sections of Slide	Manual procedure as documented in Histopathology Procedure Manual chapter PP006.

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Whole Blood	Glycated Haemoglobin (HbA1c)	Ion-Exchange High Performance Liquid Chromatography (HPLC) method using Biorad D-10 Haemaglobin Testing System as documented in Biochemistry Procedure Manual chapter CP209
Urine	Urine FEME	Semi-Automated Reflectance Spectroscopy method using Clinitek Advantus as documented in Microbiology Procedure Manual chapter VP208 Automated reflectance spectroscopy & digital microscopy imaging method using Atellica 1500 as documented in Microbiology Procedures Manual VP237.
Serum/ Plasma	Alanine Aminotransferase (ALT)	Modified Wroblewski and LaDue, Modified IFCC without P5P method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP280.
	Albumin	Bromocresol Purple (BCP) dye binding method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP281.
	Alkaline Phosphatase (ALP)	Bowers and McComb, IFCC Standardization method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP282.
	Amylase	Ethylidene Blocked -pNPG7 method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP284.
	Aspartate Aminotransferase (AST)	Modified IFCC, without P5P method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP285
	Bilirubin (Total)	Vanadate Oxidation method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP300.
	Calcium	Arsenazo III method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP286.
	Chloride	Indirect Integrated Multisensor Technology (IMT) method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP283.

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum/ Plasma	Cholesterol (Total)	Enzymatic cholesterol oxidase, esterase, peroxidase method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP287.
	Creatine Kinase MB Isoenzyme (CKMB)	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP711.
	Creatine Kinase (CK)	Modified IFCC method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP288.
	Creatinine	Enzymatic method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP324.
	Gamma Glutamyltranspeptidase (GGT)	L-γ-glutamyl-3-carboxy-4-nitroanilide substrate reaction/ IFCC method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP292.
	Glucose	Hexokinase method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP293.
	HDL Cholesterol	Elimination/catalase method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP290.
	Lactate Dehydrogenase	Lactate to pyruvate, nicotinamide adenine dinucleotide (NAD) method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP297.
	Phosphate (Inorganic)	Phosphomolybdate method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP295.
	Potassium	Indirect Integrated Multisensor Technology (IMT) method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP283
	Sodium	Indirect Integrated Multisensor Technology (IMT) method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP283.
	Total Protein	Biuret reaction method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP302

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum/ Plasma	Triglyceride	Glycerol Phosphate Oxidase reaction method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP305
	Urea Nitrogen	Urease/ glutamate dehydrogenase method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP306.
	Uric Acid	Uricase method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP307
Special Chemistry Serum/ Plasma	Alpha Feto Protein (AFP)	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP700.
	CA 125	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP706.
	CA 153	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP707.
	CA 19-9	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP708.
	CEA	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP709.
	Free T3	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP718.
	Free T4	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP717.
	Prostate Specific Antigen, Total	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP734.
	Thyroid Stimulating Hormone (TSH)	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP741.
	Total HCG	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP742.

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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 (FBC)	Fluorescent flow cytometry, hydrodynamic focusing and Cyanide-free SLS method using Sysmex XN1000 analyser as documented in Haematology Procedures Manual, chapter YP037.
Plasma	APTT	Clotting method using STA-Compact as documented in Haematology Procedure Manual chapter YP142.
	PT	Clotting method using STA-compact as documented in in Haematology Procedure Manual chapter YP144.
Immunohaematology		
Whole Blood	ABO & Rh D Blood Grouping	Manual tube method as documented in Blood Bank Procedure Manual, chapter BP020. Automated column agglutination (gel card) method using Bio-Rad IH1000 as documented in Blood Bank Procedure Manual Chapter BP021.
	Cross-matching	Column Agglutination (gel card) method as documented in Blood Bank Procedure Manual, chapter BP026.
	Direct Antiglobulin test	Column Agglutination (gel card) method as documented in Blood Bank Procedure Manual, chapter BP085.
Serum / Plasma	Antibody screening/ Indirect Antiglobulin Test	Column Agglutination (gel card) method as documented in Blood Bank Procedure Manual, chapter BP005.

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SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
AFB Smear	Acid Fast Bacilli (AFB) Stain	Manual Method using Acid Fast Bacili Stain (Kinyoun Stain) as Documented in Microbiology Procedure Manual chapter VP032.
Slide suspension smear	Gram stain	Manual method as documented in Microbiology Procedure manual chapter VP030.
Bacterial Isolates	Antimicrobial sensitivity test	Manual method as documented in Microbiology Procedure manual chapter VP010. Automated method using VITEK 2 Compact 60® as documented in Microbiology Procedure manual chapter VP146.
CSF	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP045.
Ear swab	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP050.
Eye swab	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP055.
Genital swab	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP060.
Respiratory swab	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP065.
Pus, wound and tissue (Aerobe)	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP070.
Stool	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP075.
Urine	Culture	Semi quantitative culture method as documented in Microbiology Procedure manual chapter VP090

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SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Blood	Culture	Automated Blood culture system (Colorimetric method) using BacT/Alert as documented in Microbiology Procedure Manual chapter VP026.
Central lines/catheter tips	Culture	Semi quantitative Culture method as documented in Microbiology Procedure manual chapter VP040.
Serum/ Plasma	Hepatitis A Total Antibody	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP721.
	Hepatitis B (s) Antigen	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP723.
	Hepatitis B (s) Antibody	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP703.
	Hepatitis C Antibody	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP719.
	HIV Combo	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP726.
	Syphilis (Antibodies to Treponema pallidum)	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP738.

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