Issue date: 15 December 2025
Valid until: 30 December 2030

NO: SAMM 626

LABORATORY LOCATION:
(PERMANENT LABORATORY)

PREMIER INTEGRATED LABS SDN. BHD.
(GLENEAGLES HOSPITAL KUALA LUMPUR BRANCH)
2ND FLOOR, HOSPITAL BLOCK
286, JALAN AMPANG
50450 KUALA LUMPUR
MALAYSIA

FIELDS OF MEDICAL TESTING: **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).

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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 by using CM 1860 UV Cryostat and Histo Tek PINO as documented in Histhopathology Procedure Manual Chapter PP082 and PP083
	Routine H & E Staining	Manual and Automated method using Dakewe DP360 as documented in Histhopathology Procedure Manual Chapter PP005
	Reporting and Clinical Interpretation	As documented in HIsthopathology Policy Mnual Chapter PX021
Surgical Tissue	Routine Preparation of Tissue 1. Grossing	Manual Procedure as documented in Histhopathology Procedure Manual Chapter PP001
	2. Tissue Processing	Automated method using Leica ASP300 and Leica ASP6025 as documented in Procedure Manual Chapter PP002
	3. Embedding	Semi-automated Leica EG1150C, Thermoscientific Histostar Embedder and Cold Modand HistoCore Arcadia H Paraffin Embedding Section as documented in Histhopathology Procedure Manual Chapter PP003

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SCOPE OF MEDICAL TESTING: HISTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Surgical Tissue	4. Sectioning	Manual Procedure by using Microtome Leica RM2235 and Dakewe Rotary Microtome as documented in Histhopathology Procedure Manual Chapter PP004
	5. Mounting of Sections of Slide	Manual Procedure as documented in Histhopathology Procedure Manual Chapter PP006
Surgical Tissue	Special Stain 1. Haematoxylin & Eosin Staining	Manual and Automated by using Dakewe DP360 as documented in PP005
	2. Ziehl-Neelsen Stain	Manual method as documented in Histhopathology Procedure Manual Chapter PP009 and Histhopathology Work Instruction Manual Chapter PW006
	3. Periodic Acid Schiff (PAS) & Diatase Digestion Stain	Manual method as documented in Histhopathology Procedure Manual Chapter PP007 and Histhopathology Work Instruction Manual Chapter PW008
	4. Reticular Fibres Stain	Manual method as documented in Histhopathology Procedure Manual Chapter PP071 and Histhopathology Work Instruction Manual Chapter PW001
	5. Alcian Blue Diastase Periodic Acid Schiff (ABDPAS) Stain	Manual method as documented in Histhopathology Work Instruction Manual Chapter PW016
	6. Grocott-Gomori Methanamine Silver Stain	Manual method as documented in Histhopathology Procedure Manual Chapter PP074 and Histhopathology Work Instruction Manual Chapter PW003

SCOPE OF MEDICAL TESTING: HISTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Surgical Tissue	Special Stain 7. Masson Trichrome Stain	Manual method as documented in Histhopathology Procedure Manual Chapter PP078 and Histhopathology Work Instruction Manual Chapter PW014
	8. MGG Quick Stain	Manual method as documented in Histhopathology Procedure Manual Chapter PP075 and PW004
	9. Immunofluorescent	Manual method as documented in Histhopathology Procedure Manual Chapter PP081

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
General Chemistry Serum/Plasma	Alanine Transaminase (ALT)	Modified Wroblewski and LaDue, modified IFCC without P5P method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP280
	Albumin	Bromocresol Purple (BCP) dye binding method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP358
	Alkaline Phosphatase (ALP)	Bowers and McComb, IFCC Standardization method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP282
	Amylase	Ethylidene Blocked-pNPG7 method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP284
	Aspartate Aminotransferase (AST)	Modified IFCC without P5P method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP285
	Bilirubin (Conjugated)	Vanadate oxidation method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP291
	Bilirubin (Total)	Vanadate oxidation method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP300
	Calcium	Arsenazo III method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP286
	Chloride	Indirect Integrated Multisensor Technology (IMT) method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP283
	Cholesterol (Total)	Enzymatic cholesterol oxidase, esterase, peroxidase Method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP287
	Complement 3 (C3)	Immunoturbidimetric assay method by using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP319

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
General Chemistry Serum/Plasma	Complement 4 (C4)	Immunoturbidimetric assay method by using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP320
	Cortisol	Competitive immunoassays (direct chemiluminescent) method by using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP710
	Creatine Kinase MB Isoenzyme (CKMB)	Chemiluminescence method by using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP711
	Creatine Kinase (CK)	Modified IFCC reference method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP288
	Creatinine	Enzymatic method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP324
	Gamma-Glutamyltranspeptidase (GGT)	L-ɣ-glutamyl-3-carboxy-4-nitroanilide substrate reaction/IFCC method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP380
	Glucose	Hexokinase method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP293
	Glycated Haemoglobin (HbA1c)	Ion-Exchange High Performance Liquid Chromatography (HPLC) method by using Biorad D-10 hemoglobin Testing System as documented in Biochemistry Procedure Manual chapter CP209
	HDL Cholesterol	Elimination / catalase action method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP290.
	Lactate Dehyrodgenase	Lactate to pyruvate, nicotinamide adenine dinucleotide/ (NAD) using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP297.

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
General Chemistry Serum/Plasma	Magnesium	Modified xylidyl blue reaction method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP316
	Phosphate (Inorganic)	Phosphomolybdate by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP295.
	Potassium	Indirect Integrated Multisensor Technology (IMT) method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP283.
	Sodium	Indirect Integrated Multisensor Technology (IMT) method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP283.
	Total Protein	Biuret reaction method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP302.
	Triglyceride	Glycerol Phosphate Oxidase reaction Method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP305
	Urea Nitrogen	Urease/ glutamate dehydrogenase method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP306
	Uric Acid	Uricase method by using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP307.
Whole Blood	Troponin T	Two Monoclonal Antibodies Lateral Flow Test method by using Roche Cobas h232 as documented in Biochemistry Procedure Manual chapter CP148
Urine	Urine FEME	Automated Reflectance Spectrophotometry method by using Clinitek Novus as documented in Microbiology Procedures Manual chapter VP208
Immunology Serum/Plasma	Alpha Feto Protein (AFP)	Chemiluminescence method by using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP700
	Total HCG	Chemiluminescence method by using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP742

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Immunology Serum/Plasma	CA 125	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP706
	CA 153	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP707
	CA 19.9	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP708
	CEA	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP709
	C-Reactive Protein	Latex enhanced immunoturbidimetric method using Atellica CH Analyzer as documented in Biochemistry Procedure Manual chapter CP294
	Ferritin	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP714
	Free T3	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP718
	Free T4	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP717
	Prolactin	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP733
	Prostate Specific Antigen, Total	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP734
	Testosterone	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP739
	Thyroid Stimulating Hormone (TSH)	Chemiluminescence method using Atellica IM Analyzer as documented in Immunology Procedure Manual chapter UP741

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SCOPE OF MEDICAL TESTING: HAEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
General Haematology		
Whole Blood	Full Blood Count (FBC)	Fluorescent flow cytometry, hydrodynamic focusing and Cyanide-free SLS method by using Sysmex XN 1000 Analyzer as documented in Haematology Procedure Manual chapter YP037
	PBF	Manual Microscopy by using Leishman Stain as documented in Haematology Procedure Manual chapter YP040, YP055 & YP080 Automated Leishman staining method by using Aerospray Hematology PRO Model 7152 as documented in Haematology Procedure Manual chapter YP161
	ESR	Photometrical Rheology to method by using Alcor iSED as in Haematology Procedure Manual chapter YP031
Plasma	APTT PT Fibrinogen	Clotting Scattered Light detection method by using Sysmex CA620 Analyser as documented in Haematology Procedure Manual chapter YP162
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 by using Bio-Rad IH500 as documented in Blood Bank Procedure Manual chapter BP127
	Cross-matching	Column Agglutination (gel card) method as documented in Blood Bank Procedure Manual chapter BP026 Automated column agglutination (gel card) method by using Bio-Rad IH500 as documented in Blood Bank Procedure Manual chapter BP127
	G6PD Screen	Fluorescence Spot Test method as documented in Haematology Procedure Manual chapter YP045
	Direct Antiglobulin Test	Column Agglutination (gel card) as documented in Blood Bank Procedure Manual chapter BP085. Automated column agglutination (gel card)

		method using Bio-Rad IH500 as documented in Blood Bank Procedure Manual chapter BP127

SCOPE OF MEDICAL TESTING: HAEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
General Haematology Serum/Plasma	Indirect Antiglobulin Test	Column Agglutination (gel card) method as documented in Blood Bank Procedure Manual chapter BP005. Automated column agglutination (gel card) method using Bio-Rad IH500 as documented in Blood Bank Procedure Manual chapter BP127

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SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Bacteriology		
Bacterial Isolates	Sensitivity Testing	Automated method using VITEK 2 XL as documented in Microbiology Procedure manual chapter VP146
Blood	Culture	Automated blood culture system (Colorimetric method) using BacT/Alert as documented in Microbiology Procedure manual chapter VP026
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
Nasal Swab	MRSA Screen	Manual culture method as documented in Microbiology Procedure manual chapter VP037
Pus (Aerobes)	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP070
Sputum	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP065
Pus, Aspirate, Fluid, Excretion, Smear, Swab	Direct Microscopy - Gram Stain	Manual method as documented in Microbiology Procedure Manual chapter VP030
	Direct Microscopy – AFB Stain	Acid Fast Bacilli Stain (Kinyoun Stain) method as documented in VP032
Stool	Culture	Manual culture method for Salmonella, Shigella, Yersinia, Enteropathogenic E. coli and Vibrio as documented in Microbiology Procedure manual chapter VP075
Throat Swab	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP065
Urine	Culture	Semi quantitative culture method as documented in Microbiology Procedure manual chapter VP090
Cervical / Vaginal Swab	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP060
Whole Blood	Malaria Parasite	Manual thick and thin film method as documented in Haematology Procedure Manual chapter YP015
Immunology		
Serum/Plasma	Syphilis (Antibodies to Treponema pallidum)	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP738

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SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (VIROLOGY)

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum/Plasma	Hepatitis A Total Antibody	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP721.
	Hepatitis B (e) Antigen	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP722
	Hepatitis B (s) Antigen	Chemiluminescence method 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 Ag/Ab Combo Assay	Chemiluminescence method as documented in Immunology Procedure Manual chapter UP726
	Hepatitis B Antibody	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP702

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