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LABORATORY LOCATION (PERMANENT LOCATION)	**PREMIER INTEGRATED LABS SDN BHD** **GLENEAGLES HOSPITAL PENANG (GHP)** **6TH FLOOR, BLOCK B** **GLENEAGLES HOSPITAL PENANG** **NO. 1, JALAN PANGKOR** **10050 GEORGETOWN** **PULAU PINANG** **MALAYSIA**
FIELDS OF MEDICAL TESTING:	**HISTHOPATHOLOGY & CYTOPATHOLOGY**
BRANCH LOCATION:	
1) PREMIER INTGRATED LABS SDN BHD **PANTAI HOSPITAL PENANG (PHP)** **3RD FLOOR, PANTAI HOSPITAL PENANG** **NO. 82, JALAN TENGAH, BAYAN BARU** **11900 BAYAN LEPAS** **PULAU PINANG** **MALAYSIA**	**FIELDS 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 Communiquè dated November 2021).

CENTRAL LABORATORY:	**PREMIER INTEGRATED LABS SDN BHD** **GLENEAGLES HOSPITAL PENANG (GHP)** **6TH FLOOR, BLOCK B** **GLENEAGLES HOSPITAL PENANG** **NO. 1, JALAN PANGKOR** **10050 GEORGETOWN** **PULAU PINANG**
FIELDS OF MEDICAL TESTING:	**HISTHOPATHOLOGY & CYTOPATHOLOGY**

SCOPE OF MEDICAL TESTING: HISTHOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Intra-operative Unfixed Surgical Tissue	Cryostat Sectioning	Manual procedure by using LEICA CM 1860 UV Cryostat as documented in Histopathology Procedure Manual PP083
	Reporting and Clinical Interpretation	As documented in Histhopathology Policy Manual chapter PX021
Surgical Tissue	Routine Preparation of Tissue: Grossing	Manual procedure as documented in Histopathology Procedure manual PP001
	Tissue Processing	Automated with LEICA ASP300S and ASP 6025 documented in Histopathology Procedure Manual PP002
	Embedding	Embedding module SAKURA Tissue-TEC 6 EM J 2 as documented in Histopathology Procedure Manual chapter PP003
	Sectioning	Manual procedure by using LEICA RM2235 Microtome as documented in Histopathology Procedure Manual PP004
	Routine H&E Staining	Manual and automated by using LEICA Autostainer XL as documented in Histopathology Procedure Manual PP005 and Histopathology Work Instruction Manual chapter PW010
	Mounting of Sections of Slide	Manual procedure as documented in Histopathology Procedure Manual PP006

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 EP006 and EP009
	a. Pap Smear Conventional	Manual procedure as documented in Cytopathology Procedure Manual EP002
	b. Liquid-based Cytology	i) Automated procedure using Thin-Prep 2000 Processor as documented in Cytopathology Procedure Manual chapter EP003 ii) Automated procedure using PathTet 2000 Processor as documented in Cytopathology Procedure Manual chapter EP024
	Reporting and clinical interpretation	As documented in Cytopathology Procedure Manual EP012; Cytopathology Policy Manual EX016 and EX019
All Nongynaecological Cytopathology	Specimen preparation, routine staining and mounting	As documented in Cytopathology Procedure Manual EP005, EP006, EP007 and EP009
	Reporting and clinical interpretation	As documented in Cytopathology Policy Manual EX016 and EX019
Fine needle aspiration	Collection preparation of smear, routine staining and mounting	As documented in Cytopathology Procedure Manual EP006, EP007, EP009 and EP011
	Reporting and clinical interpretation	As documented in Cytopathology Policy Manual EX016 and EX019

BRANCH LOCATION	**PREMIER INTGRATED LABS SDN BHD** **PANTAI HOSPITAL PENANG (PHP)** **3RD FLOOR, PANTAI HOSPITAL PENANG** **NO. 82, JALAN TENGAH, BAYAN BARU** **11900 BAYAN LEPAS** **PULAU PINANG** **MALAYSIA**
FIELDS 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	Bromocresol Purple (BCP) dye Binding method using Architect ci8200 as documented in Biochemistry Procedure Manual chapter CP251
	Alkaline Phosphate	Para-nitrophenyl Phosphate (pNPP) method using Architect ci8200 as documented in Biochemistry Procedure Manual chapter CP252
	ALT	NADDH without pyridoxal – 5'phosphate method using Architect ci8200 as documented in Biochemistry Procedures Manual CP250
	Amylase	Ethylidene-4-NP-G7 (EPS) method using Architect ci8200 as documented in Biochemistry Procedures Manual CP253
	Aspartate aminotransferase (AST)	NADH without P-5'-P method using Architect ci8200 as documented in Biochemistry Procedures Manual CP254
	Bilirubin Total	Diazonium Salt method using Architect ci8200 as documented in Biochemistry Procedures Manual CP266
	Cholesterol (Total)	Enzymatic Choleterol Oxidase, esterase, peroxidase method using Architect ci8200 as documented in Biochemistry Procedures Manual CP257
	Calcium	Arsenazo III method using Architect ci8200 as documented in Biochemistry Procedures Manual CP256
	Chloride	Ion-selective electrode diluted (Indirect) method using Architect ci8200 as documented in Biochemistry Procedures Manual CP272

SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum/Plasma	Creatine Kinase MB (CKMB)	CMIA method using Architect ci8200 as documented in Biochemistry Procedure Manual chapter CP273
	Creatine Kinase	N-acetyl-L-cysteine (NAC) method using Architect ci8200 as documented in Biochemistry Procedures Manual CP258
	Creatine	Kinetic Alkaline Picrate method using Architect ci8200 as documented in Biochemistry Procedures Manual CP259
	Gamma-Glutamyl Transferase	L-Gamma-glutamyl-3-carboxy-4-nitroanilide substrate reaction method using Architect ci8200 as documented in Biochemistry Procedures Manual CP262
	Glucose	Hexokinase/ G-6-PDH method using Architect ci8200 as documented in Biochemistry Procedures Manual CP263
	HDL Cholesterol	Accelerator Selective Detergent method using Architect ci8200 as documented in Biochemistry Procedures Manual CP255
	Lactate Dehydrogenase (LDH)	IFCC recommended forward reaction – Lactate to Pyruvate, method using Architect ci8200 as documented in Biochemistry Procedures Manual CP264
	Phosphate (Inorganic)	Phophomolybdate method using Architect ci8200 as documented in Biochemistry Procedures Manual CP265
	Potassium	Ion-selective electrode diluted (Indirect) method using Architect ci8200 as documented in Biochemistry Procedures Manual CP272
	Sodium	Ion-selective electrode diluted (Indirect) method using Architect ci8200 as documented in Biochemistry Procedures Manual CP272
	Total Protein	Biurect reaction method using Architect ci8200 as documented in Biochemistry Procedures Manual CP267
	Triglyceride	Glycerol Phosphate Oxidase reaction method using Architect ci8200 as documented in Biochemistry Procedures Manual CP268

SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum/Plasma	Urea Nitrogen	Urease method using Architect ci8200 as documented in Biochemistry Procedure Manual chapter CP269
	Uric Acid	Uricase method using Architect ci8200 as documented in Biochemistry Procedure Manual chapter CP270

SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum/Plasma	Hepatitis C Antibody	CMIA Method using Architect ci8200 as documented in Immunology Procedures Manual chapter UP091
Bacterial Isolates	Bacterial Identification	Automated method using VITEK 2 Compact ® as documented in Microbiology Procedure manual chapter VP146 – VITEK 2 ® System
	Antimicrobial Sensitivity Test	Automated method using VITEK 2 Compact ® as documented in Microbiology Procedure manual chapter VP146 – VITEK 2 ® System Manual method as documented in Microbiology Procedure manual chapter VP010
Slide Suspension Smear	Graim Stain	Manual Method as documented in Microbiology Procedure manual Chapter VP030
Ear Swab	Culture	Manual Method as documented in Microbiology Procedure manual Chapter VP050
Eye Swab	Culture	Manual Method as documented in Microbiology Procedure manual Chapter VP055
Genital swab	Cuilture	Manual Method as documented in Microbiology Procedure manual Chapter VP060
Respiratory Specimen	Cultyre	Manual Method as documented in Microbiology Procedure manual Chapter VP065 Semi quantitative culture method as documented in Microbiology Procedure manual chapter VP046
Tissue, pus and wound swab	Culture	Manual Method as documented in Microbiology Procedure manual Chapter VP070
Stool	Culture	Manual Method as documented in Microbiology Procedure manual Chapter VP075
Urine	Culture	Semi quantitative culture method as documented in Microbiology Procedure manual chapter VP090
Blood	Culture	Automated blood culture system (Colorimetric method) using BacT/Alert as documented in Microbiology Procedure manual chapter VP026
Central lines Central venous catherer tips (CVC)	Culture	Semi quantitative culture method as documented in Microbiology Procedure manual chapter VP040
Synovial fluid, Pleural fluid, Pericardial, Ascetic fluid, Peritoneal fluid	Culture	Manual culture method as documented in Microbiology Procedure manual chapter VP041

SCOPE OF MEDICAL TESTING: HAEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Whole Blood	Cross-matching	Column Agglutination Technology method as documented in Blood Bank Procedure Manual, BP026
	ABO & Rh (D) Blood Grouping	Manual tube method as documented in Blood Bank Procedure Manual, BP020
		Semi-automated column agglutination (gel card) method using Banjo ID-Reader as documented in Blood Bank Procedure Manual chapter BP124
	Direct Antiglobulin Test	Column Agglutination Technology method as documented in Blood Bank Procedure Manual, BP085
Serum/Plasma	Antibody Screening / Indirect Antibody Test	Column Agglutination Technology method as documented in Blood Bank Procedure Manual, BP005
Whole Blood	Full Blood Count (FBC) with 5-part differential for WBC	Fluorescent flow cytometry. Hydrodynamic focusing and Cyanide-free SLS method using Sysmex XN1000 and Sysmex XN550 analyzers as documented in Haematology Procedures Manual chapter YP037 & YP036