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LABORATORY LOCATION:
(PERMANENT LABORATORY)**PREMIER INTEGRATED LABS SDN BHD
(BANGSAR BRANCH)
LEVEL 2 & 8, BLOCK A, WEST WING
NO 8, JALAN BUKIT PANTAI
59100 KUALA LUMPUR
MALAYSIA****FIELDS 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 Communiqué dated November 2021).

SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
General Chemistry Serum	Alanine Transaminase (ALT)	Modified Wroblewski and LaDue, Modified IFCC without P5P method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP280
	Albumin	Bromocresol Green (BCG) 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 Procedures Manual chapter CP284
	Aspartate Aminotransferase (AST)	Modified IFCC, without P5P method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP285
	Bilirubin (Conjugated)	Vanadate oxidation Reaction method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP291

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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	Bilirubin (Total)	Vanadate Oxidation Reaction 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
	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
	Creatinine 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-y-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
Whole Blood	Glycated Haemoglobin (HbA1c)	Enzymatic method using Atellica chemistry as documented in Biochemistry Procedure Manual chapter CP322
Serum	HDL Cholesterol	Elimination/catalase reaction method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP290

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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	Lactate Dehydrogenase	Lactate to pyruvate, nicotinamide adenine dinucleotide (NAD) method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP297
	Magnesium	Modified xylidyl blue reaction method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP316
	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
	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
	A2-Macroglobulin	Immunonephelometry method using BN ProSpec as documented in Biochemistry Procedure Manual chapter CP021
	C3	Immunonephelometry method using BN ProSpec as documented in Biochemistry Procedure Manual chapter CP067
	C4	Immunonephelometry method using BN ProSpec as documented in Biochemistry Procedure Manual chapter CP067

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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	Immunoglobulin G	Immunonephelometry method using BN ProSpec as documented in Biochemistry Procedure Manual chapter CP091
	Immunoglobulin A	Immunonephelometry method using BN ProSpec as documented in Biochemistry Procedure Manual chapter CP091
	Immunoglobulin M	Immunonephelometry method using BN ProSpec as documented in Biochemistry Procedure Manual chapter CP091
	Urine	Automated Reflectance Spectrophotometry method using Clinitek Novus as documented in Microbiology Procedure Manual chapter VP208
	Urine FEME	Automated Reflectance Spectrophotometry method using Clinitek Novus as documented in Microbiology Procedure Manual chapter VP208
Special Chemistry, Immunology Serum / Plasma	Urine Microalbumin	PEG-enhanced immunoturbidimetric assay method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP298
	Urine Creatinine	Enzymatic method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP324
	Alpha Feto Protein (AFP)	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP700
	Total HCG	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP742
	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

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Special Chemistry, Immunology Serum / Plasma	CEA	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP709
	C-Reactive Protein	Latex-enhanced immunoturbidimetric using Atellica Chemistry as documented in Immunology Procedures Manual chapter CP294
	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
	Rheumatoid Factor	Latex-enhanced immunoturbidimetric method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP299
	Thyroid Stimulating Hormone (TSH)	Chemiluminescence method using Atellica Immunology 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
Whole Blood	Full Blood Count (FBC)	Fluorescent flow cytometry, hydrodynamic focusing and Cyanide-free SLS method using Sysmex XN 1000 analyser as documented in Haematology Procedure Manual chapter YP037
Plasma	APTT	Clotting method by STA-Compact as documented in Haematology Procedure Manual chapter YP142
	PT	Clotting method by STA-Compact as documented 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
	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
Bacterial / Yeast Isolates	Bacterial / Yeast Identification	Automated method using VITEK 2 Compact® as documented in Microbiology Procedure Manual chapter VP146 VITEK ® MS PRIME as documented in Microbiology Procedure Manual chapter VP148
Bacterial / Yeast Isolates	Antimicrobial Sensitivity Test	Automated method using VITEK 2 Compact® as documented in Microbiology Procedure Manual chapter VP146 Manual method as documented in Microbiology Procedure Manual chapter VP010
AFB Smear	AFB Stain	Acid Fast Bacilli (Kinyoun Stain) as documented in Microbiology Procedure Manual chapter VP032
Slide Suspension Smear	Gram Stain	Automated method using PREVI-Color Gram Autostainer as documented in Microbiology Procedure Manual chapter VP042
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 Specimens	Culture	Manual culture method as documented in Microbiology Procedure Manual chapter VP065
Tissue, Pus and Wound Swab	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 Venous Catheter Tips (CVC)	Culture	Semi-quantitative cultures 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
Virology 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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REFERENCE SPECIALISED LABORATORY (RSL)**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
	Pap Smear Conventional	Manual procedure as documented in Cytopathology Procedure Manual chapter EP002
	Liquid-based Cytology	i) Automated procedure using Thin-Prep 2000 Processor as documented in Cytopathology Procedure Manual chapter EP003
		ii) Automated procedure using Thin-Prep 5000 Processor as documented in Cytopathology Procedure Manual chapter EP021
		iii) Automated procedure using PathText PT2000 Processor as documented in Cytopathology Procedure Manual chapter EP024
	Reporting and clinical interpretation	iv) Automated procedure using PathText Infinity Processor as document in Cytopathology Procedure Manual Chapter EP029 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
Fine needle aspiration	Collection, preparation of smear, routine staining and mounting	As documented in Cytopathology Procedure Manual Chapter EP006, EP007, EP009 and EP011
	Reporting and clinical interpretation	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 1950 UV Cryostat and Cryostar Thermo NX70 as documented in Histopathology Procedure Manual Chapter PP084 and PP085
Surgical Tissue	Reporting and Clinical Interpretation	As documented in Histopathology Policy Manual chapter PX020 and PX021
	Routine Preparation of Tissue	
	1. Grossing	Manual Procedure as documented in Histopathology Procedure Manual chapter PP001
	2. Tissue Processing	Automated with Thermo Excelsior AS and Diapath Donatello Series II as documented in Histopathology Procedure Manual chapter PP002
	3. Embedding	Semi-automated with LEICA EG1150 and Diapath Dante as documented in Histopathology Procedure Manual chapter PP003
	4. Sectioning	Manual Procedure using LEICA 2025, LEICA RM2235 and PFM rotary 3004M 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

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SCOPE OF MEDICAL TESTING: HISTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
	6. Mounting of Sections of Slide	Automated using TissueTek Film Coverslipper and Manual Procedure as documented in Histopathology Procedure Manual chapter PP006 and PP080
	7. Histochemical Stains	Manual Procedure as documented in Histopathology Procedure Manual chapter PP007, PP009, PP071-PP075, PP078, PP079 and Histopathology Work Instruction Manual chapter PW001-PW006, PW008, PW013, PW017
	8. Immunohistochemistry Stains	Automated Procedure using Ventana Benchmark Ultra and Dako Omnis as documented in Histopathology Procedure Manual chapter PP076 and Histopathology Work Instruction Manual chapter PW009
	9. Immunofluorescence stain	Manual procedure as documented in Histopathology Procedure Manual chapter PP081