Issue date: 03 March 2025
Valid until: 08 February 2030

NO: SAMM 357
(Issue 02, 03 March 2025 replacement
of SAMM 357 dated 30 June 2023)

LABORATORY LOCATION:
(PERMANENT LABORATORY)

PREMIER INTEGRATED LABS SDN. BHD.
REFERENCE CORE LABORATORY
LOWER GROUND FLOOR, BANGUNAN MOB
JALAN PERUBATAN 3
55100 PANDAN INDAH
WP KUALA LUMPUR
MALAYSIA

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 Communiquè dated November 2021).

SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Urine	Screening for Opiates (OP)	Enzyme Immunoassay (EIA) method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP313
	Screening for Cannabinoids (THC)	Enzyme Immunoassay (EIA) method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP312
	Urine FEME	Urine Protein and Urine Glucose test Strip method using Clinitek Novus as documented in Fomema Procedure Manual chapter FLP036
		Automated Reflectance spectroscopy & digital microscopy imaging method using Atellica 1500 as documented in Microbiology Procedure Manual chapter VP237
	Urine Pregnancy Test	Test Strip Method using rapid chromatographic immunoassay as documented in Microbiology Procedure Manual chapter VP110
	Microalbumin	PEG-enhanced immunoturbidimetric method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP298

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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	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 Green solution (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 Procedure Manual chapter CP284
	Aspartate aminotransferase (AST)	Modified IFCC, without P5P method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP285
	Bilirubin (Direct)	Vanadate Oxidation method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP291
	Bilirubin (Total)	Vanadate Oxidation method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP300
	Calcium	Arsenazo III method using Atellica Chemistry as documented in Biochemistry Procedures 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
Serum / Plasma	Creatine Kinase (CK)	Modified IFCC method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP288

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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	Creatinine	Kinetic alkaline picrate, method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP289
	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
	Iron	Ferrozine method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP296
	Phosphate (Inorganic)	Phosphomolybdate method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP295
Serum	Total Iron Binding Capacity (TIBC)	Sequential release and uptake of iron method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP301
Serum / Plasma	Transferrin	Polyethylene glycol (PEG) enhanced immunoturbidimetric method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP304
	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

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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	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
	C-Reactive Protein (CRP)	Latex-enhanced immunoturbidimetric method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP294
	Rheumatoid Factor	Latex-enhanced immunoturbidimetric method using Atellica Chemistry as documented in Biochemistry Procedure Manual chapter CP299
Whole Blood	Glycated Haemoglobin (HbA1c)	Ion-exchange High-Performance Liquid Chromatography (HPLC) using Biorad D100 as documented in Biochemistry Procedure Manual chapter CP323
	Troponin T	Two Monoclonal Antibodies Lateral Flow test method using Cobas h232 as documented in Biochemistry Procedure Manual chapter CP148

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Immunology / Special Chemistry Serum / Plasma	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
	CA125	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
	sHBG	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP737
	DHEA	Chemiluminescence method using IMMULITE as documented in Immunology Procedure Manual chapter UP712
	Growth Hormone	Chemiluminescence method using IMMULITE as documented in Immunology Procedure Manual chapter UP330
	Folic Acid/ Folate	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP715
	Vitamin B12	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP743
	Enhanced Estradiol	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP713

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Immunology / Special Chemistry Serum / Plasma	Ferritin	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP714
	Follicle Stimulating Hormone (FSH)	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP716
	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
	Luteinizing Hormone (LH)	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP730
	Progesterone	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP732
	Prolactin	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP733
	Prostate Specific Antigen (PSA)	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP734
	Testosterone	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP739
	Insulin	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP728
	Cortisol	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP710
	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 analyzer as documented in Haematology Procedure Manual chapter YP037
	ESR	Photometrical Rheology method using Alcor iSED as documented in Haematology Procedure Manual chapter YP031
Plasma	APTT	Turbodensitometric measuring method using Sysmex CA-104 as documented in Haematology Procedure Manual chapter YP151
	PT	Turbodensitometric Measuring method using Sysmex CA-104 as documented in Haematology Procedure Manual chapter YP152
Immunohaematology		
Whole Blood	ABO and Rh(D) Blood Grouping	Automated column agglutination (Gel Card) method using Bio-Rad IH1000 as documented in Blood Bank Procedure Manual chapter BP021 Manual tube method as documented in Blood Bank Procedure Manual chapter BP020 Microplate method as documented in Fomema Procedure Manual chapter FLP011
Whole blood / Serum	Cross-matching	Column Agglutination (gel card) method as documented in Blood Bank Procedure Manual chapter BP026
Whole blood	G6PD screening	Fluorescence spot test as documented in Haematology Procedure Manual chapter YP045
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
Serum / Plasma	Syphilis Serology: RPR	RPR Antigen-Antibody Method as documented in Fomema Procedure Manual chapter FLP045
	TPHA	Indirect Haemagglutination Method (IHM) as documented in Fomema Procedure Manual Chapter FLP050
Whole Blood	Malarial Parasite	ELISA method as documented in Fomema Procedure Manual chapter FLP046
		Thick & Thin blood film using microscopy method as documented in Hematology Procedure Manual chapter YP015
Pus, aspirate, fluid, excretion, smear, swab	Gram stain	Manual method as documented in Microbiology Procedure Manual chapter VP030
	AFB Stain	Acid Fast Bacilli Stain (Kinyoun Stain) method as documented in Microbiology Procedure Manual chapter VP032

SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (VIROLOGY)

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum / Plasma	Hepatitis A IgM Antibody	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP720
	Hepatitis A Total Antibody	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP721
	Hepatitis B Core Total Antibody	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP701
	Hepatitis B (e) Antigen	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP722
	Hepatitis B (e) Antibody	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP702

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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 B (s) Antigen	ELISA method as documented in Fomema Procedure Manual chapter FLP052 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
	HIV antigen / antibody	ELISA method as documented in Fomema Procedure Manual chapter FLP051
	Rubella lgG	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP735
	Rubella lgM	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP736
	Syphilis (Antibodies to Treponema pallidum)	Chemiluminescence method using Atellica Immunology as documented in Immunology Procedure Manual chapter UP738
	H. Pylori lgG	Chemiluminescence method using IMMULITE as documented in Immunology Procedure Manual chapter UP435

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Laboratory Key Personnel:

	Name	Designation
1.	Dato Dr. Sharifah Noor Akmal	Laboratory Director
2.	Yong Sook Yong	Deputy Laboratory Director
3.	Woo Yee Suet	Quality Manager
4.	K. Sri Sharmila A/P Kumarason	Document Controller & Technical Manager (Medical Microbiology & Hematology - FOMEMA)
5.	Noorzaniza bt Omar	Deputy Quality Manager / Technical Manager (Chemical Pathology / Medical Microbiology / Hematology)
6.	Shari Ann A/P Santhana Dass	Deputy Technical Manager (Chemical Pathology & Medical Microbiology (Immunology))
7.	Ambika a/p Subramaniam	Deputy Technical Manager (Hematology)
8.	Christine Jonny	Deputy Technical Manager (Medical Microbiology)
9.	Rajeetha a/p T. Manogaran	Deputy Technical Manager (Immunohematology)
10.	Mohamed Riyazudeen bin Mohamed Iqbal	Deputy Technical Manager (Medical Microbiology / Hematology - FOMEMA)

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