

# Schedule

Issue date: 30 June 2023  
Valid until: 08 February 2025



## NO: SAMM 357

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of SAMM 357 dated 06 April 2022

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### LABORATORY LOCATION: (PERMANENT LABORATORY)



**PREMIER INTEGRATED LABS SHD. BHD.  
REFERENCE CORE LABORATORY  
c/o PANTAI HOSPITAL AMPANG  
LOWER GROUND FLOOR, BANGUNAN MOB  
JALAN PERUBATAN 3  
55100 PANDAN INDAH  
WP KUALA LUMPUR  
MALAYSIA**

### FIELDS OF MEDICAL TESTING: **CHEMICAL PATHOLOGY, HAEMATOLOGY, & MEDICAL MICROBIOLOGY**

The standard used for assessment of this laboratory is MS ISO 15189:2014 (ISO 15189:2012 IDT).

A medical laboratory's fulfillment of the requirements of ISO 15189:2012 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 (Section 4) are written in a language relevant to a medical laboratory's operations and meet the principles of ISO 9001:2008 Quality management systems - Requirement and are aligned with its pertinent requirements (Joint IAF-ILAC-ISO Communiqué issued in 2015)

### 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 Atlas as documented in Fomema Procedure Manual chapter FLP036
		Automated Reflectance spectroscopy & digital microscopy imaging method using Atellica 1500 as documented in Microbiology Procedures Manual chapter VP237
	Urine Pregnancy Test	Test Strip Method using rapid chromatographic immunoassay as documented in FLP042 of FLP01
	Microalbumin	PEG enhance immunoturbidimetric method using Atellica Chemistry as documented in Biochemistry Procedures Manual (V2 of 2) CP298

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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 Procedures 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 Procedures Manual (V2 of 2) CP284
	Aspartate aminotransferase (AST)	Modified IFCC, without P5P method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP285
	Bilirubin (Direct)	Vanadate Oxidation method using Atellica Chemistry as documented in Biochemistry Procedures 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 Procedures Manual (V2 of 2) CP283
	Cholesterol (Total)	Enzymatic cholesterol oxidase, esterase, peroxidase method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP287
	Creatine Kinase MB Isoenzyme (CKMB)	2-site sandwich immunoassay (direct chemiluminescent) 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 Procedures Manual (V1 of 2) CP288

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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 Procedures Manual chapter CP289
	Gamma-Glutamyltranspeptidase (GGT)	L-γ-glutamyl-3-carboxy-4-nitroanilide substrate reaction/IFCC Method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP292
	Glucose	Hexokinase method using Atellica Chemistry as documented in Biochemistry Procedures Manual (V2 of 2) CP293
	HDL Cholesterol	Elimination/catalase method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP290
	Lactate Dehydrogenase	Lactate to pyruvate, nicotinamide adenine dinucleotide (NAD) method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP297
	Iron	Ferrozine method using Atellica Chemistry as documented in Biochemistry Procedures Manual (V2 of 2) CP296
	Phosphate (Inorganic)	Phosphomolybdate method using Atellica Chemistry as documented in Biochemistry Procedures Manual (V2 of 2) CP295
Serum	Total Iron Binding Capacity (TIBC)	Sequential release and uptake of iron method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP301
Serum / Plasma	Transferrin	Polyethylene glycol (PEG) enhanced immunoturbidimetric method using Atellica Chemistry as documented in Biochemistry Procedures Manual (V2 of 2) CP304
	Potassium	Indirect Integrated Multisensor Technology (IMT) method using Atellica Chemistry as documented in Biochemistry Procedures Manual (V2 of 2) CP283
	Sodium	Indirect Integrated Multisensor Technology (IMT) method using Atellica Chemistry as documented in Biochemistry Procedures Manual (V2 of 2) CP283

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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 Procedures Manual chapter CP302
	Triglyceride	Glycerol Phosphate Oxidase reaction method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP305
	Urea Nitrogen	Urease / glutamate dehydrogenase method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP306
	Uric acid	Uricase method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP307
	C-Reactive Protein (CRP)	Latex-enhanced immunoturbidimetric method using Atellica Chemistry as documented in Biochemistry Procedures Manual chapter CP294
Whole Blood	Rheumatoid Factor	Latex-enhanced immunoturbidimetric method using Atellica Chemistry as documented in Biochemistry Procedures Manual (V2 of 2) CP299
	Glycated Haemoglobin (HbA1c)	Boronate Affinity and High-Performance Liquid Chromatography (HPLC) using Premier Hb9210 as documented in Biochemistry Procedures Manual (V2 of 2) CP217
	Troponin T	Two Monoclonal Antibodies Lateral Flow test method using Cobas h232 as documented in Biochemistry Procedures Manual chapter CP148

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Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
<b>Immunology / Special Chemistry</b> Serum / Plasma	Alpha Feto Protein (AFP)	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP700
	Total HCG	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP742
	CA125	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP0706
	CA 153	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V1 of 4) UP707
	CA 19.9	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V1 of 4) UP708
	CEA	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP709
	sHBG	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) 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	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP715
	Vitamin B12	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP743
Enhanced Estradiol	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP713	

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<b>Immunology / Special Chemistry</b> Serum / Plasma	Ferritin	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP714
	Follicle Stimulating Hormone (FSH)	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP716
	Free T3	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP718
	Free T4	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP717
	Luteinizing Hormone (LH)	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP730
	Progesterone	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP732
	Prolactin	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP733
	Prostate Specific Antigen (PSA)	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP734
	Testosterone	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP739
	Insulin	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP728
	Cortisol	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) UP710
Thyroid Stimulating Hormone (TSH)	CMIA method using Atellica Immunology as documented in Immunology Procedure Manual (V2 of 4) 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
<b>Immunohaematology</b>		
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 FLP011 of FLP01
Whole blood / Serum	Cross-matching	Column Agglutination (gel card) method as documented in Blood Bank Procedure Manual BP026
Whole blood	G6PD screening	Fluorescence spot test as documented in Haematology Procedure Manual YP045
Serum / Plasma	Antibody screening	Column Agglutination (gel card) method as documented in Blood Bank Procedure Manual BP005

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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 FLP017 of FLP01
Whole Blood	Malarial Parasite	ELISA Method as documented in FLP021 of FLP01  Thick & Thin Film Using Microscopy Method as Documented in FLP020 of FLP01
Pus, aspirate, fluid, excretion, smear, swab	Gram stain	Manual method as documented in Microbiology Procedure Manual (V1 of 2) VP030
	AFB Stain	Acid Fast Bacilli Stain (Kinyoun Stain) method as documented in Microbiology Procedure Manual chapter VP025

**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	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP720
	Hepatitis A Total Antibody	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP721
	Hepatitis B Core Total Antibody	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP701
	Hepatitis B (e) Antigen	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP722
	Hepatitis B (e) Antibody	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP702



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Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum / Plasma	Hepatitis B (s) Antigen	CMIA method using Architect System as documented in Immunology Procedures Manual (V2 of 4) UP345  CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP723
	Hepatitis B (s) Antibody	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP703
	Hepatitis C Antibody	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP719
	Anti HIV 1/O/2	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP725
	HIV Combo	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP726
	HIV antigen / antibody	CMIA method using Architect System as documented in (V1 of 4) UP031
	Rubella IgG	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP735
	Rubella IgM	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP736
	Syphilis	CMIA method using Atellica Immunology as documented in Immunology Procedures Manual (V2 of 4) UP738
	H. Pylori IgG	CMIA method using IMMULITE as documented in Immunology Procedures Manual (V2 of 4) UP435

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### 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)
5.	Noorzaniza bt Omar	Deputy Quality Manager / Technical Manager (Chemical Pathology / Medical Microbiology / Hematology)
6.	Nur Hafidza bt Kamaron	Deputy Technical Manager (Chemical Pathology)
7.	Ambika a/p Subramaniam	Deputy Technical Manager (Hematology)
8.	Crystal Kho Wen Wen	Deputy Technical Manager (Medical Microbiology)
9.	Erzawati bt Abd Sani	Deputy Technical Manager (Medical Microbiology (Immunology))
10.	Shari Ann A/P Santhana Dass	Deputy Technical Manager (Medical Microbiology (Immunology))
11.	Noor Idayana bt Muhammad Daud	Deputy Technical Manager (Immunochemistry)
12.	Mohamed Riyazudeen bin Mohamed Iqbal	Deputy Technical Manager (Medical Microbiology / Hematology)

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