Issue date: 22 December 2025
Valid until: 26 February 2029

NO: SAMM 869
Issue 02, 22 December 2025 replacement
of SAMM 869 dated 30 January 2024)

LABORATORY LOCATION:
(PERMANENT LABORATORY)

PREMIER INTEGRATED LABS SDN BHD
(PRINCE COURT MEDICAL CENTRE)
LEVEL 4A, PATHOLOGY DEPARTMENT
NO.39, JALAN KIA PENG,
50450 W.P. KUALA LUMPUR
MALAYSIA

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

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
General Chemistry Serum	Alanine Aminotransferase (ALT)	NADH without P-5'-P / Architect ci8200 as documented in PCM-CHEM-SOP024
	Albumin	Bromcresol green / Architect ci8200 as documented in PCM-CHEM-SOP022
	Alkaline Phosphatase (ALP)	Para-Nitrophenyl-phosphate (pNPP) / Architect ci8200 as documented in PCM-CHEM-SOP023
	Amylase	Enzymatic/ colorimetric/ Architech ci8200 as documented in PCM-CHEM-SOP025
	Aspartate Aminotransferase (AST)	NADH without P-5'-P / Architect ci8200 as documented in PCM-CHEM-SOP026
	Calcium	Arsenazo III/ Architect ci8200 as documented in PCM-CHEM-SOP028
	Cholesterol (Total)	Enzymatic cholesterol oxidase, esterase, peroxidase / Architect ci8200 as documented in PCM-CHEM-SOP030

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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	Cholesterol LDL	Calculated based on triglyceride and cholesterol as documented in PCM-CHEM-SOP040
	Complement C3	Immunoturbidimetric / Architect ci8200 as documented in PCM-CHEM-SOPI031
	Complement C4	Immunoturbidimetric / Architect ci8200 as documented in PCM-CHEM-SOP032
	Creatine Kinase MB Isoenzyme (CKMB)	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP060
	Creatinine	Enzymatic / Architect ci8200 as documented in PCM-CHEM-SOP034
	Direct Bilirubin	Method: Diazo Reaction / Architect ci8200 as documented in PCM-CHEM-SOP035
	Gamma-Glutamyl Transferase (GGT)	L-gamma-glutamyl-3-Carboxy-4-Nitroanilide substrate/ Architect ci8200 as documented in PCM-CHEM-SOP038
	Glucose	Hexokinase / G-6-PDH / Architect ci8200 as documented in PCM-CHEM-SOP039
	Estimated Glomerular Filtration Rate (eGFR)	Calculated / Architect ci8200 as documented in PCM-CHEM-SOP034
	HDL Cholesterol	Accelerator Selective Detergent / Architect ci8200 as documented in PCM-CHEM-SOP040
	Indirect Bilirubin	Calculated / Architect ci8200 as documented in PCM-CHEM-SOP035
	Iron	Ferene / Architect ci8200 as documented in PCM-CHEM-SOP041
	Lactate Dehydrogenase (LDH)	IFCC recommended forward Reaction, Lactate to Pyruvate / Architect ci8200 as documented in PCM-CHEM-SOP043
	Magnesium	Arsenazo / Architect ci8200 as documented in PCM-CHEM-SOP044
	Phosphorus	Phosphomolybdate / Architect ci8200 as documented in PCM-CHEM-SOP046

SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
General Chemistry		
Serum	Potassium	Ion selective electrodes (indirect)/ Architect ci8200 as documented in PCM-CHEM-SOP036
	Rheumatoid Factor	Immunoturbidimetric / Architect ci8200 as documented in PCM-CHEM-SOP047
	Sodium	Ion selective electrodes (indirect)/ Architect ci8200 as documented in PCM-CHEM-SOP036
	Total Bilirubin	Diazonium Salt/ Architect ci8200 as documented in PCM-CHEM-SOP048
	Total Protein	Architect ci8200 as documented in PCM-CHEM-SOP049
	Transferrin Saturation	Calculated / Architect ci8200 as documented in PCM-CHEM-SOP050
	Triglyceride	Glycerol Phosphate Oxidase / Architect ci8200 as documented in PCM-CHEM-SOP051
	Urea	Urease / Architect ci8200 as documented in PCM-CHEM-SOP052
	Urid Acid	Uricase / Architect ci8200 as documented in PCM-CHEM-SOP053
Urine	Creatinine	Kinetic Alkaline Picrate/ Architect ci8200 as documented in PCM-CHEM-SOP034
	Microalbumin	Turbidimetric / Immunoturbidimetric / Architect ci8200 as documented in PCM-CHEM-SOP045
	Protein	Benzethonium Choride / Architect ci8200 as documented in PCM-CHEM-SOP054
	FEME (Dipstick)	Reflective as documented in PCM-FE-SOP001 UN 2011 Operation Manual
	FEME (Microscopic Exam)	Fluorescence flow cytometry as documented in PCM-FE-SOP001 UN 2011 Operation Manual

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Whole Blood	Glycated Haemoglobin (HbA1c)	Ion-exchange High performance liquid chromatography (HPLC) / Biorad D10 as documented in PCM-CHEM-SOPI003
Immunology/ Special Chemistry		
Serum	Ferritin	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP063
	Folate	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP064
	Vitamin B12	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP077
Tumor Markers	Alpha Feto Protein (AFP)	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP055
	Ca-125	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP057
	Ca-15-3	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP058
	Ca-19-9	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP056
	CEA	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP059
	Prostate Specific Antigen (PSA), Total	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP076

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SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Hormones Serum	BHCG Total	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP075
	Cortisol	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP061
	Estradiol	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP062
	Folicle Stimulating Hormone (FSH)	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP065
	Free T3	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP066
	Free T4	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP066
	Luteinizing Hormone (LH)	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP069
	Prolactin	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP070
	Testosterone	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP073
	TSH	CMIA / Architect ci8200 as documented in PCM-CHEM-SOP074

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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	Fluorescent flow cytometry, hydrodynamic focusing Cyanide free SLS / Sysmex XN-1000 as documented in Sysmex XN Operation, PCM-HAEM-SOP002, Full Blood Count, PCM-HAEM-SOP005, Correcting of Blood Cell Count Results Affected by Interfering Substances, PCM-HAEM-SOP016
	Erythrocyte Sedimentation Rate	Photometrical Rheology / Alcor iSED as documented in iSED ErythrocyteSedimentation Rate Automated Analyzer, PCM-HAEM-SOP004
	Differential count	Slide (Manual Method) as documented in Manual Differential White Cell Count, PCM-HAEM-SOP021 & Peripheral Blood Film Preparation, PCM-HAEM-SOP019
	Peripheral blood film examination	Manual microscopy as documented in Wright's Eosin Methylene Blue Staining, PCM-HAEM-SOP018, Full blood count, PCM-HAEM-SOP005 & Peripheral Blood Film Examination, PCM-HAEM-SOP020, Hematek 3000 Slide Autostainer, PCM-HAEM-SOP017
	PBF (Morphology)	Manual microscopy as documented in Reporting of Peripheral Blood Film, PCM-HAEM-SOP002
Haemostasis Citrate Plasma	APTT	Clotting Time Measurements / Stago STA Satellite as documented in STAGO Sta Satellite Operation, PCM-HAEM-SOP007, Stago STA Satellite Operational Manual, PCM-HAEM-SOP003, PT APTT and Fibrinogen test semi automated using Stago start analyzer, PCM-HAEM-SOP012, Prothrombin Time & Activated Partial Thromboplastin Time mixing studies, PCM-HAEM-SOP013, Calculation of mean normal prothrombin time (MNOT), PCM-HAEH-SOP014, Calculation of Mean Normal Activated Partial Thromboplastin Time (MNAPTT), PCM-HAEM-SOP015

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SCOPE OF MEDICAL TESTING: HAEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Haemostasis Citrate Plasma	PT INR	Clotting Time Measurements / Stago STA Satellite as documented in STAGO Sta Satellite Operation, PCM-HAEM-SOP009, Stago STA Satellite Operational Manual, PCM-HAEM-SOP003, PT APTT and Fibrinogen test semi automated using Stago start analyzer, PCM-HAEM-SOP012, Prothrombin Time & Activated Partial Thromboplastin Time mixing studies, PCM-HAEM-SOP013, Calculation of mean normal prothrombin time (MNOT), PCM-HAEH-SOP014, Calculation of Mean Normal Activated Partial Thromboplastin Time (MNAPTT), PCM-HAEM-SOP015
	Fibrinogen	Clotting Time Measurements / Stago STA Satellite as documented in STAGO Sta Satellite Operation, PCM-HAEM-SOP011, Stago STA Satellite Operational Manual, PCM-HAEM-SOP003, PT APTT and Fibrinogen test semi automated using Stago start analyzer, PCM-HAEM-SOP012, Prothrombin Time & Activated Partial Thromboplastin Time mixing studies, PCM-HAEM-SOP013, Calculation of mean normal prothrombin time (MNOT), PCM-HAEH-SOP014, Calculation of Mean Normal Activated Partial Thromboplastin Time (MNAPTT), PCM-HAEM-SOP015
Immunohaematology Whole Blood	ABO R(h) Grouping	Tube Method as documented in PCM-IHAEM-SOP004, Daily Quality Control for Anti-A, Anti-B, Anti-AB, Anti-D, PCM-IHAEM-SOP001, Daily Quality Control for Antibody Screen, PCM-IHAEM-SOP002, Quality Control Testing on the new batch of Immunohematology reagents, PCM-IHAEM-SOP003
	Compatibility Testing	Column Agglutination (gel card) as documented in PCM-IHAEM-WI007 & PCM-IHAEM-SOP008
	Direct Coombs Test	Column Agglutination (gel card) as documented in PCM-IHAEM-SOP010
Serum/ Plasma	Antibody Screening	Column Agglutination (gel card) as documented in PCM-IHAEM-SOP006

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SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Bacteriology		
Urine	Culture	As documented in PCM-MICRO-SOP009
Blood	Culture	As documented in PCM-MICRO-SOP002
Body fluid	Culture	As documented in PCM-MICRO-SOP003
Tissue & Biopsy	Culture	As documented in PCM-MICRO-SOP004
Ear & Eye	Culture	As documented in PCM-MICRO-SOP005
Respiratory	Culture	As documented in PCM-MICRO-SOP006
Superficicial Wound & Non-surgical wound	Culture	As documented in PCM-MICRO-SOP007
Slide Suspension Smear	Gram Stain	As documented in PCM-MICRO-SOP012
Mycobacteriology		
AFB Smear	Acid Fast Bacili (AFB) Stain	Kinyoun method As documented in PCM-MICRO-SOP013
Serology		
erum	Hepatitis B Surface Antigen	Chemiluminescence / Architect ci8200 as documented in PCM-CHEM-SOP019
	Antibody to Hepatitis B surface antigen	Chemiluminescence / Architect ci8200 as documented in PCM-CHEM-SOP020
	Anti HCV	Chemiluminescence / Architect ci8200 as documented in PCM-CHEM-SOP018
	Hepatitis A IgG	Chemiluminescence / Architect ci8200 as documented in PCM-CHEM-SOP021
	HIV Screening	Chemiluminescence / Architect ci8200 as documented in PCM-CHEM-SOP017

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SCOPE OF MEDICAL TESTING: HISTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Diagnostic Histopathology	Routine HPE (Histopathology Examination)	Specimen preparation and routine staining as documented in: PCM-HISTO-SOP002 PCM-HISTO-SOP003 PCM-HISTO-SOP004 PCM-HISTO-SOP005 PCM-HISTO-SOP006
	Special stain (SS) staining	Special Staining as documented in: PCM-HISTO-SOP011 PCM-HISTO-SOP012 PCM-HISTO-SOP013 PCM-HISTO-SOP014 PCM-HISTO-SOP015 PCM-HISTO-SOP016 PCM-HISTO-SOP017
	Immunohistochemistry (IHC) and Immunofluorescence (IF) staining	Immunohistochemistry and Immunofluorescence stain as documented in: PCM-HISTO-SOP008 PCM-HISTO-SOP018
Intraoperative Frozen Section	Frozen section	Specimen preparation and routine staining as documented in: PCM-HISTO-SOP009

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SCOPE OF MEDICAL TESTING: CYTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured	Test Methods, Specifications/ Equipment/Techniques Used
Gynaecological Specimens	Evaluation of cervical cells from Conventional Pap smear	Staining of cervical specimen smears on slides as documented in PCM-CYTOL-SOP001 PCM-CYTOL-SOP003 PCM-CYTOL-SOP004 PCM-CYTOL-SOP008 PCM-CYTOL-SOP009 PCM-CYTOL-SOP0010 PCM-CYTOL-SOP011 PCM-CYTOL-SOP017
	Evaluation of cervical cells collected in BD SurePath	Preparation and processing of cervical specimen / Liquid-based Cytology as documented in PCM-CYTOL-SOP001 PCM-CYTOL-SOP004 PCM-CYTOL-SOP005 PCM-CYTOL-SOP008 PCM-CYTOL-SOP019 PCM-CYTOL-SOP0010 PCM-CYTOL-SOP0012 PCM-CYTOL-SOP017
Non-gynaecological Cytopathology	Abnormal non-gynaecological cells	Processing of non-gynaecological specimens as documented in PCM-CYTOL-SOP001 PCM-CYTOL-SOP004 PCM-CYTOL-SOP007 PCM-CYTOL-SOP008 PCM-CYTOL-SOP009 PCM-CYTOL-SOP0010 PCM-CYTOL-SOP0011 PCM-CYTOL-SOP0013 PCM-CYTOL-SOP0014 PCM-CYTOL-SOP0015 PCM-CYTOL-SOP016
Fine Needle Aspiration Cytology	Abnormal cells from FNAC	Processing of smears made from FNA as documented in PCM-CYTOL-SOP001 PCM-CYTOL-SOP002 PCM-CYTOL-SOP004 PCM-CYTOL-SOP006 PCM-CYTOL-SOP008 PCM-CYTOL-SOP009 PCM-CYTOL-SOP0010 PCM-CYTOL-SOP0011 PCM-CYTOL-SOP0014 PCM-CYTOL-SOP016

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