

Schedule


Issue date: 21 February 2024
Valid Until: 21 September 2025



NO: SAMM 475

(Issue 1, 21 February 2024 replacement
of SAMM 475 dated 21 February 2024)

Page: 1 of 6

LABORATORY LOCATION: (PERMANENT LABORATORY) 	Clinipath (M) Sdn. Bhd. No. 23, Galeri Empire, Jalan Empayar Off Persiaran Sultan Ibrahim / KU 1 41150 Klang, Selangor. , 41150, SELANGOR MALAYSIA
ACCREDITED SINCE :	21 SEPTEMBER 2010
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 Communiqué, November 2021)

NO: SAMM 475(Issue 1, 21 February 2024 replacement
of SAMM 475 dated 21 February 2024)

Page: 2 of 6

CENTRAL LOCATION	Clinipath (M) Sdn. Bhd. No. 23, Galeri Empire, Jalan Empayar Off Persiaran Sultan Ibrahim / KU 1 41150 Klang, Selangor. , 41150, Selangor
FIELD(S) OF MEDICAL TESTING :	CHEMICAL PATHOLOGY, HAEMATOLOGYMEDICAL MICROBIOLOGY

SCOPE OF MEDICAL TESTING : CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods,Specifications/ Equipment/Techniques Used
General Chemistry Serum / Plasma (lithium Heparin / Edta)	Albumin	Bromocresol Green (BCG) / Roche Cobas 6000 as documented in electronically in Roche Cobas Link
	ALT	IFCC with Pyridoxal Phosphate / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	AST	IFCC with Pyridoxal Phosphate / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Cholesterol	Cholesterol Oxidase - IDMS / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Creatinine	Jaffé Rate-Blank Compensated / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	GGT	GGT IFCC / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Inorganic Phosphate	Phosphomolybdate UV / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Total Bilirubin	DPD liquid / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Total Protein	Biuret / Roche Cobas 6000 as documented in electronically in Roche Cobas Link

NO: SAMM 475(Issue 1, 21 February 2024 replacement
of SAMM 475 dated 21 February 2024)

Page: 3 of 6

	Triglycerides	Lipase / GPO-PAP / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Urea	Urease UV / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Uric Acid	Colorimetric Uricase Peroxidase / Roche Cobas 6000 as documented electronically in Roche Cobas Link
General Chemistry Serum / Plasma (lithium Heparin)	ALP	IFCC / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Calcium	NM - BAPTA / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	HDL-C	Direct HDL / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	ISE (Na,K,Cl)	Indirect Potentiometry / Roche Cobas 6000 as documented electronically in Roche Cobas Link
General Chemistry Serum / Plasma (fluoride / Lithium Heparin / Edta)	Glucose	Hexokinase / Roche Cobas 6000 as documented electronically in Roche Cobas Link
General Chemistry Urine	Pregnancy test (UPT)	Rapid Immunochromatographic Assay as documented in GPQD/MIC/SOP-33
	Urine FEME	Semi Quantitative Reflectance Photometer Assay / Roche Cobas u601 as documented electronically in Roche Cobas Link
Drug Of Abuse Testing Urine	Amphetamine / Metamphetamine	Kims/ Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Cannabinoids	Kims/ Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Opiates	Kims/ Roche Cobas 6000 as documented electronically in Roche Cobas Link
Tumor Markers Serum / Plasma (edta / Lithium Heparin)	AFP	ECLIA / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	HCG + ?	ECLIA / Roche Cobas 6000 as documented electronically in Roche Cobas Link

NO: SAMM 475(Issue 1, 21 February 2024 replacement
of SAMM 475 dated 21 February 2024)

Page: 4 of 6

Others Whole Blood (edta)	HbA1c	TINIA/Roche Cobas 6000 as documented electronically in Roche Cobas Link
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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 (edta)	Erythrocyte Sedimentation Rate (ESR)	Westergren's Method / Sedimentation of Red Cells as documented in GPQD/CP- HAE/SOP-4
	Erythrocyte Sedimentation Rate (ESR) Automated	Automated Method/IR Detector as documented in GPQD/CP- HAE/SOP-4
	Microscopy Reporting	Manual as documented in GPQD/HAE/SOP-16, 17
	Red Blood Cell Count (RBC)	Sheath Flow DC Detection / Sysmex XN 1000 as documented GPQD/HAE/SOP-26
	Haemoglobin (Hb)	Selective Laser Sintering (SLS) / Sysmex XN 1000 as documented in GPQD/HAE/SOP-26
	Packed Cell Volume (PCV)	Sheath Flow DC Detection / Sysmex XN 1000 as documented in GPQD/HAE/SOP-26
	Mean Corpuscular Volume (MCV)	Calculated from RBC & HCT / Sysmex XN 1000 as documented in GPQD/HAE/SOP-26
	Mean Corpuscular Hemoglobin (MCH)	Calculated from Hb & RBC / Sysmex XN 1000 as documented in GPQD/HAE/SOP-26
	Mean Corpuscular Hemoglobin Concentration (MCHC)	Calculated from HGB and HCT / Sysmex XN 1000 as documented in GPQD/HAE/SOP-26
	Red Distribution Width (RDW)	Analysis from Size Distribution of RBC / Sysmex XN 1000 as documented in GPQD/HAE/SOP-26
	Platelet count (PLTC)	Sheath Flow DC Detection / Sysmex XN 1000 as documented in GPQD/HAE/SOP-26

NO: SAMM 475(Issue 1, 21 February 2024 replacement
of SAMM 475 dated 21 February 2024)

Page: 5 of 6

	Total White and Differential Count (TWCC) • Neutrophils • Lymphocytes • Monocytes • Eosinophils • Basophils	Fluorescent Flow Cytometry / Sysmex XN 1000 as documented in GPQD/HAE/SOP-26
	Total White and Differential Count (TWCC) • Neutrophils • Lymphocytes • Monocytes • Eosinophils • Basophils	Manual Slide Preparation / Microscopic Examination as documented in GPQD/HAE/SOP-14, 16,17
Immunohaematology Serum / Plasma / Whole Blood (edta / Plain Tube)	ABO / Rh D Blood Grouping	Microplate Technique / Galileo Neo as documented in GPQD/CP-HAE/SOP-7
	ABO /Rh D (Tube Method)	Manual method as documented in GPQD/HAE/SOP-47

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Whole Blood (edta / Lithium Heparin)	Malaria Parasite (MP)	Microscopic examination of thin & thick film / Giemsa stain as documented in GPQD/HAE/SOP-22,28
	Malaria Parasite (MP)	ELISA GPQD/CP-BI/SOP-8
Serology Serum / Whole Blood / Plasma (edta / Lithium Heparin)	Dengue Ig G Dengue Ig M	Fluorescence Immunoassay as documented in GPQD/HAE/SOP-30
	Dengue NS1	Fluorescence Immunoassay as documented in GPQD/HAE/SOP-29
Serology Serum / Plasma (edta / Lithium Heparin)	RPR	Carbon Particle Antigen as documented in GPQD/SER/SOP-15
	RPR	Immunoturbidimetry / Roche Cobas 6000 as documented in Roche Cobas Link and GPQD/BI/SOP-32
	<i>Treponema Pallidum</i> Particle Agglutination Assay (TPPA)	Passive Particle Agglutination as documented in GPQD/SER/SOP-12
Viral Serology Serum / Plasma (lithium Heparin / Edta / Sodium Citrate)	Anti HBe	ECLIA / Roche Cobas 6000 as documented electronically in Roche Cobas Link

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Page: 6 of 6

	Anti HBc	ECLIA / Roche Cobas 6000 as documented electronically in Roche Cobas Link
Viral Serology Serum / Plasma (edta)	Anti HBs	ECLIA / Roche Cobas 6000 as documented electronically in Roche Cobas Link
Viral Serology Serum / Plasma (sodium Citrate / Edta)	HBe Ag	ECLIA / Roche Cobas 6000as documented electronically in Roche Cobas Link
Viral Serology Serum / Plasma (lithium Heparin / Edta / Sodium Citrate)	HBs Ag	ECLIA / Roche Cobas 6000 as documented electronically in Roche Cobas Link
Viral Serology Serum / Plasma (lithium Heparin / Edta)	HIV Combi PT	ECLIA / Roche Cobas 6000 as documented electronically in Roche Cobas Link
	Hepatitis C Ab	ECLIA / Roche Cobas 6000 as documented electronically in Roche Cobas Link

NOTE :