

Schedule

Issue date: 28 April 2025
Valid until: 29 April 2030



NO: SAMM 591

(Issue 03, 28 April 2025 replacement
of SAMM 591 dated 21 October 2024)

LABORATORY LOCATION: (PERMANENT LABORATORY)



1) MEDICAL LABORATORIES
PUSAT DARAH NEGARA
JALAN TUN RAZAK
50400 WILAYAH PERSEKUTUAN
KUALA LUMPUR
MALAYSIA

2) CLINICAL TRANSFUSION LABORATORY
HOSPITAL TUNKU AZIZAH
LOT 25, JALAN RAJA MUDA ABDUL AZIZ
KAMPUNG BARU
50300 KUALA LUMPUR
MALAYSIA

FIELD(S) OF MEDICAL TESTING: HEMATOLOGY & VIROLOGY

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)

SCOPE OF MEDICAL TESTING: HEMATOLOGY (HEMATOLOGY LABORATORY)

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Whole Blood	Full Blood Count (FBC) • Red Blood Cell • White Blood Cell • Haemoglobin • Haematocrit • MCV • MCH • MCHC • Platelet	FBC Using 5-Part Analyser: Combined Flow Cytometry with semiconductor laser and DC detection with hydro dynamic focusing method by Sysmex XN 1000 Hematology Analyzer as documented in PDN/HA/WI-05
Plasma	Fibrinogen	Clauss Method on Sysmex CS2500 as documented in PDN/HA/WI-35
Specialised Hematology Plasma	FVIII:C	One Stage Method on Sysmex CS2500 Sysmex CS2500 as documented in PDN/HA/WI-35

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Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Blood Transfusion Plasma / Serum Whole Blood Serum	Antibody Screening	Manual Testing by Tube and Gel Card Technique as Documented in PDN/IH/PTM-25
	Antibody Identification	Manual Testing by Tube and Gel Card Technique as Documented in PDN/IH/PTM-25
	Crossmatching	Manual Testing by Tube and Gel Card Technique as Documented in PDN/IH/PTM-25
	Red Cell Phenotyping	Manual Testing by Tube and Gel Card Technique as Documented in PDN/IH/PTM-21
	Direct Coombs' Test	Manual Testing by Tube and Gel Card Technique as Documented in PDN/IH/PTM-23
	Elution Techniques	Manual Testing by Tube and Gel Card Technique as Documented in PDN/IH/PTM-24
	ABO/RhD Grouping	Manual Testing by Tube, Microtiter Plate and Gel Card Technique as Documented in PDN/IH/PTM-18
	Platelet antibody testing	Rapid-Monoclonal Antibody Immobilization of Platelet Antigen (MAIPA) as in document PDN/IH/PTM-33

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Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Whole Blood	HLA Typing	NGS HLA Typing as documented in PDN/HI/WI-15 Management of Donor Registry Testing in Histocompatibility as documented in PDN/HI/QP-01 Manual DNA Extraction and Quantitation as Documented in PDN/HI/WI-01 Automated DNA Extraction and Quantitation as Documented in PDN/HI/WI-19

SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (VIROLOGY)**(MAKMAL RUJUKAN KEBANGSAAN)**

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Virology (Alternative Assay/ Counseling/Confirmatory /Supplementary testing) Plasma / Serum	HIV Ag/-Ab Anti-HCV HBsAg Anti HBs Anti HBc Confirmatory Test Confirmatory Test	Abbott Alinity System: An Automated System for Chemiluminescent Microparticle Immunoassay (CMIA) - PDN/ TM/WI-61 HCV Line Immunoassay (LIA) – PDN/TM/WI-50 Geenius™ HIV 1/2 Confirmatory Assay PDN/ TM/WI-60

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CLINICAL TRANSFUSION LABORATORY
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LOT 25, JALAN RAJA MUDA ABDUL AZIZ
KAMPUNG BARU
50300 KUALA LUMPUR
MALAYSIA**

FIELD(S) OF MEDICAL TESTING: HEMATOLOGY & VIROLOGY

SCOPE OF MEDICAL TESTING: HEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Blood Transfusion Whole Blood	ABO/RhD Grouping	Automated testing by Gel Card Technique as Documented in PDN/TL/WI/02
Serum/Plasma	Red Cell Antibody Screening	Automated testing by Gel Card Technique as Documented in PDN/TL/WI/02
	Crossmatching	Manual testing by Gel Card Technique as Documented in PDN/TL/WI/15
		Manual Testing by Tube Method as documented in PDN/TL/WI-16

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