

Schedule


Issue date: 28 April 2025
Valid Until: -



NO: SAMM 591

(Issue 2, 28 April 2025 replacement of SAMM 591 dated 21 October 2024)

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LABORATORY LOCATION: (PERMANENT LABORATORY) 	Medical Laboratories, Pusat Darah Negara Jalan Tun Razak, 50400 WP Kuala Lumpur. , 50400, WILAYAH PERSEKUTUAN KUALA LUMPUR MALAYSIA
ACCREDITED SINCE :	21 OCTOBER 2024
FIELD(S) OF MEDICAL TESTING :	HEMATOLOGY HEMATOLOGY (HEMATOLOGY LABORATORY) MEDICAL MICROBIOLOGY (VIROLOGY) HEMATOLOGY(HISTOCOMPATIBILITY (HLA) LABORATORY)
SITE:	
1 . SITE LABORATORY(HQ) :	CLINICAL TRANSFUSION LABORATORY, HOSPITAL TUNKU AZIZAH LOT 25, JALAN RAJA MUDA ABDUL AZIZ, KAMPUNG BARU, MALAYSIA
FIELD(S) OF MEDICAL TESTING :	HEMATOLOGY

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)

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-mt/3000882> for the current scope of accreditation

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CENTRAL LOCATION	Medical Laboratories, Pusat Darah Negara Jalan Tun Razak, 50400 WP Kuala Lumpur. , 50400, Wilayah Persekutuan Kuala Lumpur
FIELD(S) OF MEDICAL TESTING :	HEMATOLOGY, HEMATOLOGY (HEMATOLOGY LABORATORY)MEDICAL MICROBIOLOGY (VIROLOGY)HEMATOLOGY(HISTOCOMPATIBILITY (HLA) LABORATORY)

SCOPE OF MEDICAL TESTING : HEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods,Specifications/ Equipment/Techniques Used
Blood Transfusion plasma / 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
Serum	Platelet antibody testing	Rapid-Monoclonal Antibody Immobilization of Platelet Antigen (MAIPA) as in document PDN/IH/PTM-33
Whole Blood	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

SCOPE OF MEDICAL TESTING : HEMATOLOGY (HEMATOLOGY LABORATORY)

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Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Blood Transfusion plasma / 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
Serum	Platelet antibody testing	Rapid-Monoclonal Antibody Immobilization of Platelet Antigen (MAIPA) as in document PDN/IH/PTM-33
Whole Blood	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

SCOPE OF MEDICAL TESTING : HEMATOLOGY(HISTOCOMPATIBILITY (HLA) LABORATORY)

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Blood Transfusion plasma / 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

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Serum	Platelet antibody testing	Rapid-Monoclonal Antibody Immobilization of Platelet Antigen (MAIPA) as in document PDN/IH/PTM-33
Whole Blood	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

SCOPE OF MEDICAL TESTING : HEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
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
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

SCOPE OF MEDICAL TESTING : HEMATOLOGY (HEMATOLOGY LABORATORY)

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used

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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
Whole Blood	Full Blood Count (FBC) <ul style="list-style-type: none"> • Red Blood Cell • White Blood Cell • Heamoglobin • 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

SCOPE OF MEDICAL TESTING : HEMATOLOGY(HISTOCOMPATIBILITY (HLA) LABORATORY)

Specimen Tested	Type of Test/ Properties Measured/	Test Methods,Specifications/ Equipment/Techniques Used
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
Whole Blood	Full Blood Count (FBC) <ul style="list-style-type: none"> • Red Blood Cell • White Blood Cell • Heamoglobin • 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

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY (VIROLOGY)

Specimen Tested	Type of Test/ Properties Measured/	Test Methods,Specifications/ Equipment/Techniques Used

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Virology(alternative Assay/ Counseling/confirmatory /supplementary Testing) Plasma/serum	HIV Ag/-Ab Anti-HCV HBsAg Anti HBs Anti HBc	Abbott Alinity System: An Automated System for Chemiluminescent Microparticle Immunoassay (CMIA) - PDN/ TM/WI-61
	Confirmatory Test	GeeniusTM HIV 1/2 Confirmatory Assay PDN/ TM/WI-60
	Confirmatory Test	HCV Line Immunoasay (LIA) – PDN/TM/WI-50

SCOPE OF MEDICAL TESTING : HEMATOLOGY

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 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 : HEMATOLOGY (HEMATOLOGY LABORATORY)

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 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 : HEMATOLOGY(HISTOCOMPATIBILITY (HLA) LABORATORY)

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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 Manual DNA Extraction and Quantitation as Documented in PDN/HI/WI-01 Automated DNA Extraction and Quantitation as Documented in PDN/HI/WI-19

SITE LOCATION (HQ)	1. CLINICAL TRANSFUSION LABORATORY HOSPITAL TUNKU AZIZAH LOT 25, JALAN RAJA MUDA ABDUL AZIZ, KAMPUNG BARU, MALAYSIA
FIELD(S) OF MEDICAL TESTING :	HAEMATOLOGY

FIELD(S) 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

NOTE :

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-mt/3000882> for the current scope of accreditation