

## Schedule


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Valid Until: -



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<b>LABORATORY LOCATION:</b> (PERMANENT LABORATORY) 	Medix Laboratory & Health Counselling Sdn. Bhd. 1-1-36, Ideal Avenue, Jalan Tun Dr. Awang, 11900 Bayan Lepas, Penang. , 11900, PULAU PINANG MALAYSIA
<b>ACCREDITED SINCE :</b>	19 MARCH 2025
<b>FIELD(S) OF MEDICAL TESTING :</b>	CHEMICAL PATHOLOGY HAEMATOLOGY MEDICAL LABORATORY

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)

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<b>CENTRAL LOCATION</b>	Medix Laboratory & Health Counselling Sdn. Bhd. 1-1-36, Ideal Avenue, Jalan Tun Dr. Awang, 11900 Bayan Lepas, Penang. , 11900, Pulau Pinang
<b>FIELD(S) OF MEDICAL TESTING :</b>	CHEMICAL PATHOLOGY, HAEMATOLOGYMEDICAL LABORATORY

**SCOPE OF MEDICAL TESTING : CHEMICAL PATHOLOGY**

<b>Specimen Tested</b>	<b>Type of Test/ Properties Measured/</b>	<b>Test Methods,Specifications/ Equipment/Techniques Used</b>
Urine	Screening for Morphine	Rapid Visual Immunoassay using Strip as
	None	Documented in MXL/WI- 08
	Screening for	Rapid Visual Immunoassay using Strip as
	Cannabinoids	Documented in MXL/WI-09
	Urine for Biochemistry	Urinalysis Strip using Dirui H500 analyzer as
	(Albumin & Glucose)	documented in MXL/WI-06 Urine FEME DIRUI
	None	H-500 reader & Urine FEME Visually
	Urine Pregnancy Test	Rapid Visual Immunoassay using Strip as
	(UPT)	documented in MXL/WI-07 Urine
	None	Pregnancy Test
	Pregnancy Test	Urine Pregnancy Test as documented in
	None	BPLab/UPT-01 -" Rapid chromatographic
	None	immunoassay
	Urine examination	Urine Examination as documented
	(Microscopy and	BPLab/UFEME-01 Biochemistry -" multi-
	Biochemistry)	parameter test strip
	None	Urine Microscopy as documented in
	None	BPLab/UFEME-02
	Opiates Screening	Test Strip, Cut-off: 300ng/mL Method / as
	Opiates Screening	documented in MLS/LAB/WI.1.0; Index 1.0
	Cannabinoids Screening	Test Strip, Cut-off: 50ng/mL Method / as

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Cannabinoids Screening	documented in MLS/LAB/WI.1.0; Index 1.0
Amphetamine Screening	Test Strip, Cut-off: 1000ng/mL Method / as
Amphetamine Screening	documented in MLS/LAB/WI.1.0; Index 1.0
Urine Feme	Test Strip, 10 tests parameter Method / Mission
Urine Feme	U500 Urine Analyzer as documented in
Urine Feme	MLS/LAB/WI.1.0; Index 2.0
Urine Feme	MLS/LAB/WI.1.0; Index 3.0
Urine Feme	MLS/LAB/WI.1.0; Index 6.0
Urine Feme	Microscopic Method / Microscope as
Urine Feme	documented in MLS/LAB.WI.1.0; Index 4.0
Urine Pregnancy Test	Test Strip, Sensitivity: Method / as
Urine Pregnancy Test	documented in MLS/LAB/WI.1.0; Index 5.0
Urine FEME	Test Strip, 10 tests parameter method /
Urine FEME	Mission U500 Urine Analyzer as documented
Urine FEME	in JH/WI/07-Rev 6
Urine FEME	Microscopic, 10X & 40X (low and high-power
Urine FEME	field) method / Microscope as documented in
Urine FEME	JH/WI/07-Rev 6; clause 7.1.7.2
Opiates Screening	Test Strip, Cut-off: 300ng/mL method as
Opiates Screening	documented in JH/WI/08-Rev 6; clause 8.2
Cannabinoids Screening	Test Strip, Cut-off: 50ng/mL method as
Cannabinoids Screening	documented in JH/WI/08-Rev 6; clause 8.1
Urine Pregnancy Test	Test Strip, Sensitivity: method as
Urine Pregnancy Test	documented in JH/WI/09-Rev 5
Opiate / Morphine	Opiate Assay Homogenous Enzyme
Opiate / Morphine	Immunoassay DIRUI CS-400 Auto-Chemistry
Opiate / Morphine	Analyser as documented in MTM-CP-09
Cannabinoids	Cannabinoids Assay -" Homogeneous Enzyme
Cannabinoids	Immunoassay DIRUI CS-400 Auto-Chemistry

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Cannabinoids	Analyser as documented in MTM-CP-10
Urine Chemistry (Protein & Glucose)	Manual method with DIRUI 2 items (Protein & Glucose) test strips as documented in MTM-CP-12
Urine Pregnancy Test	Manual method with the Ecotest HCG-U11
Urine Pregnancy Test	Human Chorionic Gonadotropin Rapid Test
Urine Pregnancy Test	Strips as documented in MTM-CP-11
Cannabinoids drug test	Dipstick
Morphine drug test	Dipstick
Urine Full Examination (FEME)	Analyzer ACON MISSION U-500 nan
Urine Pregnancy Test	HCG Rapid Test Device
Urine Biochemistry -"	Immunochromatographic Principle (Dipstick) /
Glucose & Albumin	Manual method as documented in Q
Glucose & Albumin	LAB_SOP_08
Urine Pregnancy Test	Rapid Chromatographic Immunoassay / Visual
Urine Pregnancy Test	Observation of Strip Test as documented in Q
Urine Pregnancy Test	LAB_SOP_11
Urine Drugs -" Morphine and Cannabinoids	Immunochromatographic / Visual Observation of strip test as documented in Q LAB_SOP_09
and Cannabinoids	(MORPHINE) and Q LAB_SOP_10
and Cannabinoids	(CANNABINOIDS)
Benzodiazepines	Rapid Chromatographic Competitive Binding
Benzodiazepines	mmunoassay Method/Manual as documented in
Benzodiazepines	GPQD/BI/SOP-21
Barbiturates	Rapid Chromatographic Competitive Binding
Barbiturates	mmunoassay Method/Manual as documented in
Barbiturates	GPQD/BI/SOP-21
Cocaine	Rapid Chromatographic Competitive Binding
Cocaine	mmunoassay Method/Manual as documented in
Cocaine	GPQD/BI/SOP-21

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Propoxyphene	Rapid Chromatographic Competitive Binding
Propoxyphene	Immunoassay Method/Manual as documented in
Propoxyphene	GPQD/BI/SOP-21
Amphetamines	Kinetic interaction of microparticles in a
Amphetamines	solution/Cobas c502 as documented electronically
Amphetamines	in Roche Cobas c502
Cannabinoids	Kinetic interaction of microparticles in a
Cannabinoids	solution/Cobas c502 (4) documented as
Cannabinoids	electronically in Roche Cobas c502
Opiates	Kinetic interaction of microparticles in a
Opiates	solution/Cobas c502 (4) documented as
Opiates	electronically in Roche Cobas c502
Microalbumin	Immunoturbidimetric/Cobas c502 as documented
Microalbumin	electronically in Roche Cobas LINK/Cobas c502
Phencyclidine	Rapid Chromatographic Competitive Binding
Phencyclidine	Immunoassay Method/Manual as documented in
Phencyclidine	GPQD/BI/SOP-21
Total Protein	Turbidimetric (Benzethonium chloride)/Cobas c502
Total Protein	(4) documented electronically in Roche Cobas LINK/
Total Protein	Cobas c702
Urine Pregnancy Test	Rapid Chromatographic immunoassay/Manual
Urine Pregnancy Test	as documented in Processing Urine Pregnancy
Urine Pregnancy Test	Test (GPQD/MIC/SOP-33)
Urine Culture and	Conventional method as documented in Urine
Sensitivity	Culture -" (GPQD/MIC/SOP-56)
Sensitivity	Culture by Laser Nephelometry Automated by
Sensitivity	Analyzer Alfred 60 (1) (GPQD/MIC/SOP-102)
Cannabinoids	Rapid competitive binding
Cannabinoids	Immunochromatography/Manual as documented in

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Cannabinoids	GPQD/BI/SOP-4
Opiates	Rapid competitive binding
Opiates	Immunochromatography/Manual as documented in
Opiates	GPQD/BI-SOP-4
FEME	Urine dipstick on Roche Cobas U411 as documented
Dipstick (chemistry)	electronically in Roche COBAS LINK/COBAS U411
Microscopy	and microscopy based on manual method as
Microscopy	documented in GPQD/MIC/SOP-12,
Microscopy	GPQD/MIC/SOP-43, GPQD/MIC/SOP-58
Urine pregnancy Test	Rapid Chromatographic Immunoassay/Manual Test
Urine pregnancy Test	strip based on as documented in GPQD/MIC/SOP-
Urine pregnancy Test	11
Culture and Sensitivity	Disc diffusion susceptibility method as documented
Culture and Sensitivity	in GPQD/MIC/SOP-83, GPQD/MIC/WI-5
Bacterial Identification	FCommerical Kits documented in as
Bacterial Identification	GPQD/MIC/IS-3
Bacterial Identification	Test Identification with API System as documented
Bacterial Identification	in GPQD/MIC/SOP-28
Staining Techniques	Manual method as documented in GPQD/MIC/SOP-
Gram Stain	48
FEME	Urine dipstick and microscopy based on manual
FEME	method as documented in GPQD/MIC/SOP-12,
FEME	GPQD/MIC/SOP-43, GPQD/MIC/SOP-58
Malarial parasite	Microscopy as documented in GPQD/HAE/SOP-
Malarial parasite	22, GPQD/HAE/SOP-28
Dengue Ab IgG/IgM	Fluorescence Immunoassay/F200 as
Dengue Ab IgG/IgM	documented in GPQD/HAE/SOP-30
Dengue NS1	Fluorescence Immunoassay/F200 as
Dengue NS1	documented in GPQD/HAE/SOP-29

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nan	Agilent 1260 HPLC with Fluorescence
nan	Detector
Culture & Sensitivity Testing	Manual Method As Documented in HSNI/PAT/MB/AK-12
Urinalysis	Dipstick on IRICELL iChem VELOCITY as documented in
Urinalysis	HS/JP/W1 (CP;07)-016 Urine Full Examination on IRICELL iChem
Urinalysis	VELOCITY Analyzer
Urinalysis	Sediment Urine microscopy as documented in HS/JP/W1 (CP; 07)- 017 Urine Full Examination on Iris lo-
Urinalysis	200 SPRINTAutomated Urine
Urinalysis	Microscopic Analyser
Urine Pregnancy Test	Immunochromatographic Test Kit as documented in HS/JP/W1
Urine Pregnancy Test	(CP;07)-025 Urine One Step Pregnancy Test
URINE DRUG OPIATE ASSAY (RAPID TEST)	Rapid visual Immunoassay as. documented in DS/LAB/LW 1/003
URINE DRUG THC ASSAY (RAPID TEST)	Rapid visual Immunoassay as. documented in DS/LAB/LW 1/003
Urine Pregnancy Test (HCG Rapid Test Strip)	Rapid test strip method by visual interpretation as documented in DS/LAB/LW 1/003
UFEME	Test strip method using DiaLab Urine Analyser based on reagent strip method and microscopic method as documented in DS/LAB/LW 1/003
Culture & Sensitivity	Semi Quantitative Using Dip Strips As documented in HTPG/JP/MIC/AK-05, HTPG/JP/MIC/AK-24, HTPG/JP/MIC/AK-29 and HTPG/JP/MIC/AK-32
Creatinine	Picrate method as documented in LWICP11



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Urine Protein	Architect ci8200 based on Benzethonium Chloride method as documented in LWI CP47
Microalbumin	Architect ci8200 based on the Turbidimetric / Immunoturbidimetric method as documented in LWI-CP36
Microscopy ? Gram Stain	Gram staining method as documented in SASMEC@IIUM/ PALM/MIC-WI1313
Culture, identification and Sensitivity	Culture, identification and Sensitivity methods as documented in; SASMEC@IIUM/ PALM/MIC-W10302 SASMEC@IIUM/ PALM/MIC-W10202 SASMEC@IIUM/ PALM/MIC-W10314 SASMEC@IIUM/ PALM/MIC-W10315 SASMEC@IIUM/ PALM/MIC-W10205

**SCOPE OF MEDICAL TESTING : HAEMATOLOGY**

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Whole Blood	ABO & Rhesus Blood	Tube Method as documented in MXL/WI-04
	Grouping	Blood Grouping
	Malaria Antigen	ELISA method / ELISA reader (Chromate) as
	None	documented in MXL/WI-05 Malaria Parasite
	ABO & Rh D Blood	Manual tube method as documented in Blood
	Grouping	Bank Procedure Manual chapter BP020
	Cross-matching	Column Agglutination (gel card) method as
	Cross-matching	documented in Blood Bank Procedure Manual
	Cross-matching	chapter BP026
	Direct Antiglobulin Test	Column agglutination (gel card) method as
	Direct Antiglobulin Test	documented in Blood Bank procedure Manual
	Direct Antiglobulin Test	chapter BP085
	Antibody screening /	Column agglutination (gel card) method as

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Indirect Antiglobulin Test	documented in Blood Bank Procedure manual
Indirect Antiglobulin Test	chapter
Full Blood Count (FBC)	Fluorescent flow cytometry, hydrodynamic
Full Blood Count (FBC)	focusing and Cyanide-free SLS method using
Full Blood Count (FBC)	Sysmex XN 1000 analyzer as
Full Blood Count (FBC)	documented in Haematology Procedure
Full Blood Count (FBC)	Manual, YP037
ABO & Rh Blood	Test Tube Method / Centrifuge as documented
Grouping	in
Grouping	MLS/LAB/WI.3.0; Index 1.0
Grouping	MLS/LAB/WI.3.0; Index 2.0
Grouping	MLS/LAB/WI.3.0; Index 3.0
Malaria Parasite	ELISA Method / Microplate washer, Incubator
Malaria Parasite	37°C and Reader as documented in
Malaria Parasite	MLS/LAB/WI.2.0; Index 1.0
Malaria Parasite	Blood Smear Thick and Thin Method as
Malaria Parasite	documented in MLS/LAB/WI.2.0; Index 2.0
ABO & Rhesus Blood	Test Tube method / Centrifuge as documented
Grouping	in JH/WI/01-Rev 6
Malaria Parasite	ELISA -" Qualisa MalariaTM Method /
Malaria Parasite	Incubator 37°C, Microplate washer and Reader
Malaria Parasite	as documented in JH/WI/04-Rev 4
Malaria Parasite	Blood smear thick and thin method as
Malaria Parasite	documented in JH/WI/04-Rev 4; clause 4.2
iii Hematocrit	None
iv. Mean Cell Volume Mean Vv	b Coulter Principle, CN-Free Hemoglobinometry, Flowcytometry / UniCel DxH 800 Coulter as documented in
Corpuscular	None
Haemoglobin	None
Mean Cell vi	None
Haemoglobin	None
Concentration	None
vii Platelet	None
viii Red Cell	None

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Distribution	None
Width (CV)	None
Full Blood Picture	Fully automated preparation / Sysmex XN3000
(FBP)	(Sysmex XN-20 Integrated with Automated Slide Maker SP10) as documented in
Haemoglobin	Capillary Electrophoresis (CE) / SEBIA Flex2
Analysis	Cap Piercing Analyser as documented in
None	HA/HAEM/MRKH/RC/WI-23
None	Gel Electrophoresis (acid) / Hydrasis Gel
None	Electrophoresis Analyser as documented in
None	Gel Electrophoresis (alkaline) / Hydrasis Gel
None	Electrophoresis Analyser as documented in
None	HA/HAEM/MRKH/RC/WI-25
Blood Count (FBC)	Electrical resistance for counting WBC, RBC and
White Cell	PLT and cyanide free method for hemoglobin /
None	as documented in
None	HA/HAEM/MRKH/CYT/WI-11v1
Karyotyping	G-banding technique / MetaSystem: IKAROS imaging as documented in
None	HA/HAEM/MRKH/CYT/WI-05-1v2
None	HA/HAEM/MRKH/CYT/WI-11v1
None	HA/HAEM/MRKH/CYT/WI-12v2
Hybridization (FISH)	/MetaSystem ISIS imaging as documented in
None	HA/HAEM/MRKH/CYT/WI-13v1
None	HA/HAEM/MRKH/CYT/WI-17v2
None	HA/HAEM/MRKH/CYT/WI-18v2
None	HA/HAEM/MRKH/CYT/WI-19 v1
None	HA/HAEM/MRKH/CYT/WI-20v1
Fluorescence In-situ	FISH method /Thermobrite-StatSpin,Abbott Molecular
Hybridization (FISH)	/MetaSystem ISIS imaging as documented in
None	HA/HAEM/MRKH/CYT/WI-13v1
None	HA/HAEM/MRKH/CYT/WI-17v2
None	HA/HAEM/MRKH/CYT/WI-18v2
None	HA/HAEM/MRKH/CYT/WI-19 v1
None	HA/HAEM/MRKH/CYT/WI-20v1
ABO Blood Grouping / Rh (D)	Tube Method as documented in MTM-IH-06

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Malarial Antigen	ELISA Method as documented in MTM-IH-03
Malarial Antigen	ROBONIK Washwell plate Elisa Washer
Malarial Antigen	ROBONIK Readwell touch Elisa Plate
Malarial Antigen	Analyser
Blood Film Malaria	Microscopy -" Thick and Thin Blood Film as
Parasite (BFMP)	documented in MTM-IH 07
Parasite (BFMP)	Giemsa stain
Full Blood Count	Cell count using Sysmex XN 550 and XN 1000
(FBC)	analyzers as documented in Haematology
None	Procedure Manual Chapter and YP037
ABO and RhD Blood	Manual tube method as documented in Blood
Grouping	Bank Procedure Manual Chapter BP020
Cross-matching	Column Agglutination Technology method as
None	documented in Blood Bank Procedure Manual
None	Chapter BP026
ABO Blood Grouping /	Test Tube
Rhesus	nan
Full Blood Count (FBC) White Blood Cell	Mythic-,,¢ 22 AL
Lymphocyte	nan
Monocytes	nan
Neutrophils	nan
Eosinophils	nan
Basophils	nan
Red Blood Cell	nan
Hemoglobin	nan
Hematocrit	nan
Mean Cell	nan
Volume	nan
Mean	nan
Corpuscular	nan
Hemoglobin	nan
Concentration	nan
Red Cell	nan
Distribution Width	nan
Platelets	nan
Mean Platelet	nan
Volume	nan
Malaria Antigen	Reader and Washer (ELISA Method)

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Malaria Antigen	GBLISA-R Microplate Reader
Malaria Antigen	GBLISA-W Microplate Washer
Malaria Slide	Thick & Thin Blood Film by Microscopy Method
(Outsource)	nan
Glycated Haemoglobin	Clover A1c- <sub>8</sub> Self
Glycated Haemoglobin	On-Call Multipro Analyzer
Malaria Antigen	Malaria ELISA Enzyme Linked Immunosorbent
Screening Test (ELISA)	Assay / ELISA Semi Automated Instrument -"
Screening Test (ELISA)	Washer, Reader and Incubator as documented
Screening Test (ELISA)	in Q@LAB_SOP_04
Blood film for Malaria	Blood Film Malaria Parasite (Thick and Thin
Parasite	Film) / Giemsa Staining of Thick and Thin Blood
Parasite	Film as documented in Q LAB_SOP_05
Cyclosporin	Immuno-electrochemiluminescence/Cobas e801
Cyclosporin	(6) as documented in electronically in Cobas e801
G6PD screen	Fluorescence Method/Manual as documented in G6PD
G6PD screen	SOP (GPQD/HAE/SOP-55)
Cytomegalovirus PCR	as documented in GPQD/MOL/SOP-14
Mumps IgG & IgM	Chemiluminescence Immunoassay/Diasorin XL (2)
Mumps IgG & IgM	as documented in Operator Manual
Measles IgG & IgM	Chemiluminescence Immunoassay/Diasorin XL (2)
Measles IgG & IgM	as documented in Operator Manual
Varicella IgG & IgM	Chemiluminescence Immunoassay/Diasorin XL (2)
Varicella IgG & IgM	as documented in Operator Manual
HBA1C	DCCT/NGSP/ Roche Cobas (c501, c311) as
HBA1C	documented electronically in Roche COBAS
HBA1C	LINK/Roche COBAS
Urine Pregnancy Test	UPT Test strip method as documented in
Urine Pregnancy Test	GPQD/BI/SOP-11

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HBA1C	TTAB-Tetradecyltrimethylammonium bromide
HBA1C	Turbidimetric/Cobas c501 documented as
HBA1C	electronically in Roche COBAS LINK/COBAS 6000
HbA1C	Spectrophotometry/Cobas c311 as documented electronically in Roche C311
Troponin T (POCT)	Quantitative immunological method as documented in Roche H232 (Cobas H232 Operator Manual)
Full Blood Count (FBC)	Fluorescence Flow Cytometry, Hydro Dynamic Focusing & SLS Hemoglobin determination / Sysmex XN1000 as documented in HSNI/PAT/HM/TPM/VER3/01
Full Blood Count (FBC)	HSNI/PAT/HM/AK/VER3/01
D-Dimer	Antigen-antibody interaction/Cobas H232 As documented in
D-Dimer	HSNI/PAT/HM/TPM/VER2/04
D-Dimer	HSNI/PAT/HM/AK/VER2/05
Peripheral Blood Film (PBF)	Manual peripheral blood slide preparation (smearing & staining) As documented in HSNI/PAT/HM/TPM/VER3/05
Peripheral Blood Film (PBF)	HSNI/PAT/HM/AK/VER2/06
ABO Grouping	Manual method (tube method) As documented in HSNI/PAT/AK/TD/31
Blood Gases	Flow through electrode sensors as documented in HS/JP/WI (CP ;07)-020 pH and Blood Gases on GEM PREMIER 3500

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Cyclosporine	EMIT on Viva E (Siemens) as documented in HS/JP/WI (CP:07)- 014 Test on VIVA E (Siemens)
Everolimus	Immunoturbidimetry on Beckman Coulter AU5800 as documented in HS/JP/WI (CP:07)- 024 Test on Beckman Coulter AU 5800
HbA1c	HLPC on Variant II Turbo (Biorad) as documented in HS/JP/WI (CP:07)-011 HbA1c on Variant II Turbo (Biorad)
Tacrolimus	EMIT on Viva E (Siemens) as documented in HS/JP/WI (CP:07)- 014 Test on VIVA E (Siemens)
Full Blood Count	Flowcytometry Method Hydrodynamic Focusing method SLS-Hemoglobin Method.
Full Blood Count	HS/JP/WI(HM:08)-004
Erythrocyte Sedimentation Rates (ESR)	Westergren Method HS/JP/W1(HM:08)- 005
Full Blood Picture (FBP)	Flowcytometry and Microscopic Examination HS/JP/W1(HM:08)- 011
Reticulocytes	Flowcytometry method
Reticulocytes	HS/JP/W1(HM:08)- 004
Hb Analysis	1. High Performance Liquid Chromatography HS/JP/W1(HM:08)-21 2. Capillary Electrophoresis
ABO and RhD Blood Grouping	Manual tube method as documented in Blood Bank Operation Procedure Manual BP020.
Cross-matching	Column Agglutination Technology method as documented in Blood Bank Operation Procedure Manual BP026.
Direct Antiglobulin Test	Column Agglutination Technology method as documented in Blood Bank Procedure Manual, BP085
Full blood Count (FBC)	Cell count using Sysmex XS 500i analyzer as documented in Haematology Procedure Manual YP036.
Full Blood Count	Method: Combination of
(5-part hematology analyser)	Impedence, SLS Hb, Flowcytometry, and calculation
(5-part hematology analyser)	Analyser: Sysmex XN-1000

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(5-part hematology analyser)	All methods and specifications as documented in HTPG/JP/HEM/AK-01
(5-part hematology analyser)	Manual Differential count as documented in
(5-part hematology analyser)	HTPG/JP/HEM/AK-11
Reticulocyte count	Flowcytometry method Analyser: Sysmex XN-1000 All methods and specifications as documented in HTPG/JP/HEM/AK-01
Full Blood Picture	Manual blood smear and staining method using Leishman stain All methods and specifications as documented in HTPG/JP/HEM/AK-10 & AK-12
WBC?s Count	Aperture Impedance. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
WBC?s Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/I NT-W10205
RBC?s Count	Aperture Impedance. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
RBC?s Count	SASMEC@IIUM/PALM/INT-W10204
Hemoglobin?s Count	Photometric Impedance. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented
Hemoglobin?s Count	in SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/I NT-W10205
Hematocrit?s Count	Photometric Impedance. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented
Hematocrit?s Count	in SASMEC@IIUM/PALM/INT-W10204
Mean Corpuscular Volume?s Count	Aperture Impedance. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
Mean Corpuscular Volume?s Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/I NT-W10205



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Mean Corpuscular Hemoglobin?s Count	Aperture Impedance. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in SAS MEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/INT-W10205
Mean Corpuscular Hemoglobin Concentration?s Count	Aperture Impedance. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in SAS MEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/INT-W10205
RDW?s Count	Aperture Impedance. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
RDW?s Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/INT-W10205
Platelet?s Count	Aperture Impedance. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
Platelet?s Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/INT-W10205
Neutrophils?s Count	Aperture Impedance. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
Neutrophils?s Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/INT-W10205
Lymphocytes?s Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
Lymphocytes?s Count	SASMEC@IIUM/PALM/INT-W10204
Monocytes?s Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
Monocytes?s Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/INT-W10205
Eosinophil?s Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
Eosinophil?s Count	SASMEC@IIUM/PALM/INT-W10204
Basophils?s Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in

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Basophils?s Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/I NT-W10205
NE# Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
NE# Count	SASMEC@IIUM/PALM/INT-W10204
LY# Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
LY# Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/I NT-W10205
MO# Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
MO# Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/I NT-W10205
EO# Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
EO# Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/I NT-W10205
BA# Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
BA# Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/I NT-W10205
Nucleated Red Blood Cell?s Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
Nucleated Red Blood Cell?s Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/I NT-W10205
NRBC# Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
NRBC# Count	SASMEC@IIUM/PALM/INT-W10204
MDW?s Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
MDW?s Count	SASMEC@IIUM/PALM/INT-W10204 SASMEC@IIUM/PALM/I NT-W10205

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Retic?s Count	VCSn Analysis. Analyzer Beckman Coulter DXH 800 and DXH 900 as documented in
Retic?s Count	SASMEC@IIUM/PALM/INT-W10204
Glucose-6-phosphate dehydrogenase deficiency (G6PD) screening	Spot fluorescence test method as documented in; SASMEC@IIUM/PALM/HAE-WP01 SASMEC@IIUM/PALM/HAE-W10102
Full blood picture with clinical interpretation	Slide preparation and routine staining: (Automated) as documented in; SASMEC@IIUM/PALM/HAE-W10101/W10105 Haematology Slide Stainer Cytocentrifuge User's Manual
Haemoglobin analysis (HbA, HbA2, HbF, Hb variant)	Quantitation of HbA, HbA2, HbF, Hb variant: High Performance Liquid Chromatography (HPLC) method as documented in SASMEC@IIUM/PALM/HAE-WP02 SASMEC@IIUM/PALM/HAE-W10203/ BioRad Variant II Haemoglobin Testing System User?s Manual
Haemoglobin analysis (HbA, HbA2, HbF, Hb variant)	Capillary?s electrophoresis (CE) method as documented in SASMEC@IIUM/PALM/HAE-WP02 SASMEC@IIUM/PALM/HAE-W10202/ Sebia Capillarys 2 Flex Piercing User?s Manual
Haemoglobin analysis (HbA, HbA2, HbF, Hb variant)	Hb H inclusion bodies
Haemoglobin analysis (HbA, HbA2, HbF, Hb variant)	Specimen preparation and staining (manual) as documented in SASMEC@IIUM/PALM/HAE-
Haemoglobin analysis (HbA, HbA2, HbF, Hb variant)	Blood cell morphology; Slide preparation and routine staining: (Automated) as documented in SASMEC@IIUM/PALM/HAE-W10101/ Haematology Slide Stainer Cytocentrifuge User's Manual

## SCOPE OF MEDICAL TESTING : MEDICAL LABORATORY

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Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Plasma	Syphilis Serology -RPR	RPR Carbon Antigen Method as documented
	(Rapid Plasma Reagin)	in MXL/WI-01 VDRL
	Hepatitis B Surface	ELISA method / ELISA reader (Chromate) as
	Antigen (HBsAg )	documented in MXL/WI-02 Hepatitis B Surface Antigen (HBsAg)
	HIV Ag/Ab Combo	ELISA method / ELISA reader (Chromate) as
	None	documented in MXL/WI-03 HIV 1+2 Ab.
	APTT	Turbodensitometric measuring method using
	APTT	Sysmex CA 104 Analyzer as documented in
	APTT	Haematology Procedure Manual chapter
	APTT	YP151
	PT	Turbodensitometric Measuring method using
	PT	Sysmex CA 104 Analyzer as documented in
	PT	Haematology Procedure Manual chapter
	PT	YP152
	Prothrombin	Viscosity-based detection / STA Compact a
	Time (PT)	Analyzer as documented in
	Activated Partial	None
	Thromboplastin	None
	Time (APTT)	b Turbidimetric immunoassay / ACL TOP CTS 500
	iii Fibrinogen	as documented in
	(Clauss	None
	Technique)	None
	Factor Assays Iv	None
	(Based on	None
	APTT)	None
	Factor Assays Vv	None
	(Based on PT)	None
	Collagen Binding	ELISA method / TECAN Sunrise Microplate Reader
	Assay (CBA)	as documented in
	None	HA/HAEM/MRKH/RCH/W118
	Factor Inhibitors	Coagulation method / ACL TOP CTS 500 as
	(Bethesda Unit)	documented in
	None	HA/HAEM/MRKH/RCH/WI-09

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Lupus Anticoagulant	Viscosity-based detection / STA Compact Analyzer
(Screening test)	as documented in
None	HA/HAEM/MRKH/RCH/WI-02
Anti-Xa (Low	Viscosity-based detection / STA Compact Analyzer
Molecular Weight	as documented in
Heparin)	HA/HAEM/MRKH/RCH/WI-02
Lupus Anticoagulant	Viscosity-based detection / STA Compact Analyzer
(Confirmation Test)	as documented in
None	HA/HAEM/MRKH/RCH/WI-11
Von-Williebrand	Turbidimetric immunoassay / ACL TOP CTS 500 as
(VWF) Assays	documented in
None	HA/HAEM/MRKH/RCH/WI-22
Glucose	Automation / Cobas 6000 analyzer series module C501 as documented in MKAI/SP/BKM/WI-01
Activated Partial	Clotting method by Sysmex CA104 as
Thromboplastin Time	documented in Haematology Procedure Manual
(APTT)	Chapter YP151
Prothrombin Time (PT)	Clotting method by Sysmex CA104 as
None	documented in Haematology Procedure Manual
None	Chapter YP152
INR	Photo-optical clot reaction/CS2500 (2) as documented in PT/INR SOP (GPQD/HAE/SOP-33)
APTT	Photo-optical clot reaction/CS2500 (2) as documented in APTT SOP (GPQD/HAE/SOP-37)
Fibrinogen	Photo-optical clot reaction/CS2500 (2) as documented
Fibrinogen	in Fibrinogen SOP (GPQD/HAE/SOP-35)
Lupus Anticoagulant	Photo-optical clot reaction/CS2500 (2) as documented
Lupus Anticoagulant	in SOP (GPQD/HAE/SOP-1)
Antithrombin III	Photo-optical clot reaction/CS2500 (2) as documented

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Antithrombin III	in Antithrombin II] GPQD/HAE/SOP-2
Protein C	Photo-optical clot reaction/CS2500 (2) as documented
Protein C	in Protein C GPQD/HAE/SOP-4
Protein S	Photo-optical clot reaction/CS2500 (2) as documented
Protein S	in Protein S GPQD/HAE/SOP-3
Factor V Leiden	Photo-optical clot reaction/CS2500 (2) as documented
Mutation	in Factor V Leiden GPQD/HAE/SOP-6
HIV-1 RNA Quantitative	Real-Time PCR/Alinity M System (1 as
HIV-1 RNA Quantitative	documented in SOP (GPQD/MOL/SOP-19
HBV DNA Quantitative	Real-Time PCR/Alinity M System (1 as
HBV DNA Quantitative	documented in SOP (GPQD/MOL/SOP-19
HCV RNA Quantitative	Real-Time PCR/Alinity M System (1 as
HCV RNA Quantitative	documented in SOP (GPQD/MOL/SOP-19
HCV RNA	Real-Time PCR/Alinity M System (1 as
HCV RNA	documented in SOP (GPQD/MOL/SOP-19
Iron	Photometry hexokinase/Cobas c311 as
Iron	documented electronically in Roche COBAS
Iron	LINK/COBAS c311
Glucose	Photometry hexokinase/Cobas c311 as
Glucose	documented electronically in Roche COBAS
Glucose	LINK/COBAS c311
INR	Clotting scattered light detection method/Sysmex
APTT	Ca-660 as documented in GPQD/HAE-SSOP-
APTT	43/CA600 Operating Procedure
Blood Group	GPQD/HAE/SOP-47 and GPQD/HAE/SOP-48
DAT	Direct agglutination/Diamed Gel- card as

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DAT	documented in GPQD/HAE/SOP-45 and
DAT	GPQD/HAE/SOP-48
Antibody Screen	Agglutination with Panel cells/ Diamed Gel-card as
Antibody Screen	documented in GPQD/HAE/SOP-53 and
Antibody Screen	GPQD/HAE/SOP-48
Cross-match	Major cross match/ Diamed Gel-card as documented
Cross-match	in GPQD/HAE/SOP-46 and GPQD/HAE/SOP-48
Glucose	Colourimetric hexokinase/Cobas c501 as =
Glucose	documented electronically in Roche COBAS
Glucose	LINK/COBAS 6000
Lactate	Colourimetry Enzymatic/Cobas c501 as
Lactate	documented electronically in Roche COBAS
Lactate	LINK/COBAS 6000
INR	Electromagnetic sensor/CA104 as documented in
INR	ST art4 SOP (GPQD/HAE/SOP-42)
APTT	Electromagnetic sensor/CA 104 as documented in
APTT	ST art4 SOP (GPQD/HAE/SOP-42)
Glucose	Spectrophotometry/Cobas c311 as documented
Glucose	electronically in Roche C311
Procalcitonin	Immunoelectrochemiluminescence/Cobas e144 as
Procalcitonin	documented electronically in Roche COBAS
INR	Clotting method-turbo densitometric photo-optical
INR	measuring principle/Sysmex CA 104 as
INR	documented in (GPQD/HAE/SOP-42)
G6PD Screen	nan
G6PD Screen	Fluorescence Immunoassay as documented in D
D-Dimer	Dimer SOP (GPQD/HAE/SOP-36)
Blood Culture	9240) fluorescent method as documented in



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Blood Culture	SL/LAB/S3.1 and BD BACTEC 9240 Manual
HIV Genotypic Resistance -"	Polymerase Chain Reaction (PCR) and
Protease and Reverse	Population-based Genome Sequencing /
Transcriptase	Eppendorf Mastercycler X50s thermal cycler
Transcriptase	as documented in
Transcriptase	IMR/IDRC/VIRO/SOP/HIV/10
HIV Genotypic Resistance -"	Polymerase Chain Reaction (PCR) and
Integrase	Population-based Genome Sequencing /
Integrase	Eppendorf Mastercycler X50s thermal cycler
Integrase	as documented in
Integrase	IMR/IDRC/VIRO/SOP/HIV/11
Homocysteine (Total)	Documented in IMR/SDC/BC/SOP-4 / Agilent 1260 HPLC
Homocysteine (Total)	with Fluorescence Detector
Carnitine (Total & Free)	Enzymatic end-point as documented in
Carnitine (Total & Free)	IMR/SDC/BC/SOP-3/ Spectrophotometer
Glycosaminoglycans	Complex with Dimethylmethylene Blue (DMB)
(GAG) Quantitation	as documented in IMR/SDC/BC/SOP-5/ Spectrophotometer
GAG Separation	High Resolution Electrophoresis as
GAG Separation	documented in IMR/SDC/BC/SOP-6/ Multiphor
GAG Separation	II Electrophoresis System
Organic Acids	Derivatisation with BSTFA as documented in
Organic Acids	IMR/SDC/BC/SOP-9/GCMS Agilent 7890B
Orotic Acids	Reverse-phase Chromatography as
Orotic Acids	Documented in IMR/SDC/BC/SOP-10/ Agilent 1200 HPLC
Orotic Acids	with Diode Array Detector



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Coagulation:	Clotting (optical) Method/Sysmex CS1600 As documented in
Prothrombin time (PT)	HSNI/PAT/HM/TPM/VER3/2019/02 HSNI/PAT/HM/AK/VER3/2019/04
Activated Partial	HSNI/PAT/HM/TPM/VER3/2019/03
Thromboplastin Time (APTT)	HSNI/PAT/HM/AK/VER3/2019/04
Ammonia	GLDH ? UV on Beckman Coulter AU5800 as documented in HS/JP/W1 (CP;07)-024 Test on Beckman Coulter AU5800
Lactate	Enzymatic LOD-POD on Beckman Coulter AU5800 as documented in HS/JP/W1 (CP;07)- 024 Test on Beckman Coulter AU 5800
Mycophenolic Acid	EMIT on Viva E (Siemens) as documented in HS/JP/W1 (CP;07)- 014 Test on VIVA E (Siemens)
Prothrombin Time (PT)	Clotting Activity HS/JP/W1(HM:08)- 007
Activated Partial Thromboplastin Time (APTT)	Clotting Activity HS/JP/W1(HM:08)- 007
Fibrinogen Estimations (FIB)	Clotting Activity HS/JP/W1(HM:08)- 007
International Normalised Ratio (INR)	Clotting Activity HS/JP/W1(HM:08)- 007
D-Dimer Quantitative	Change in turbidity of a microparticle suspension measured by photometry
Coagulation Mixing Test: APTT/PT	Clotting Activity HS/JP/W1(HM:08)- 017
Ammonia	Glutamate Dehydrogenase as documented in Arahan Kerja Pengendalian Ujian Pada Alinity (HTPG/JP/CHM/AK-02)
Lactate (LacticAcid)	Lactic Acid to Pyruvate (L to P) as documented in Arahan Kerja Pengendalian Ujian Pada Alinity (HTPG/JP/CHM/AK-02)
PT/ INR	Mechanical clot detection
PT/ INR	Analyser: Stago Compact/ Max All methods and specifications as documented in HTPG/JP/HEM/AK-04
APTT	Mechanical clot detection

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	APTT	Analyser: Stago Compact/ Max All methods and specifications as documented in HTPG/JP/HEM/AK-05
	Fibrinogen	Clauss method Analyser: Stago Compact/ Max All methods and specifications as documented in HTPG/JP/HEM/AK-06
	D-Dimer	Turbidimetry Analyser: Stago Compact/ Max All methods and specifications as documented in HTPG/JP/HEM/AK-07
	Glucose (Plasma)	Hexokinase Method. Analyzer Beckman Coulter AU680 (labelled as AU680-A and AU680-B) as documented in SASMEC@IIUM/PALM/INT- WI0203
Virology	None	None
	(TPHA) Test	None
	PCR	nan
	Blood Culture	None

**NOTE :**