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LABORATORY LOCATION: (PERMANENT LABORATORY)	Jabatan Patologi, Hospital Pulau Pinang Jalan Residensi, 10990 George Town, Pulau Pinang. , 10990, PULAU PINANG MALAYSIA
ACCREDITED SINCE :	19 MARCH 2025
FIELD(S) OF MEDICAL TESTING:	CYTOPATHOLOGY
	HISTOPATHOLOGY
	CHEMICAL PATHOLOGY
	HAEMATOLOGY
	HAEMATOLOGY (MOLECULAR)
	MEDICAL MICROBIOLOGY (BACTERIOLOGY)
	MEDICAL MICROBIOLOGY (SEROLOGY)
	MEDICAL MICROBIOLOGY (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 Communiquè, November 2021)

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CENTRAL LOCATION	Jabatan Patologi, Hospital Pulau Pinang Jalan Residensi, 10990 George Town, Pulau Pinang. , 10990, Pulau Pinang
FIELD(S) OF MEDICAL TESTING:	CYTOPATHOLOGY, HISTOPATHOLOGYCHEMICAL
	PATHOLOGYHAEMATOLOGY
	(MOLECULAR)MEDICAL MICROBIOLOGY
	(BACTERIOLOGY)MEDICAL MICROBIOLOGY
	(SEROLOGY)MEDICAL MICROBIOLOGY (VIROLOGY)

#### **SCOPE OF MEDICAL TESTING: CYTOPATHOLOGY**

Specimen Tested	Type of Test/	Test Methods, Specifications/
	Properties Measured/	Equipment/Techniques Used
Gynaecological Specimens	Gynaecological Cytology	Specimen Preparation and
	Examination	Staining
		(Manual method)
		Processing of conventional pap
		smears slides
		(HPP/PAT/CY/WI/05) +
		Papanicolaou Staining
		Automated Method
		(HPP/PAT/CY/WI/11)
		To prepare Pap smears using
		Liquid Based
		Cytology (HPP/PAT/CY/WI/09) +
		Papanicolaou
		Staining Automated Method
		(HPP/PAT/CY/WI/11)
Non-gynaecological Specimens	Non-Gynaecological Cytology	Specimen Preparation and
	Examination	Routine Staining
		(Autostainer / Manual) Method as
		documented
		Preparation of cytological smears
		from body
		fluids (excluding CSF and urine
		specimens)
		(HPP/PAT/CY/WI/02)
		Preparation of cytological smears
		from CSF and
		urine using cytocentrifugation
		method
		(HPP/PAT/CY/WI/03)
		To prepare smears from sputum using Liquid
		Based Cytology Method
		(HPP/PAT/CY/WI/06)

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	Non-Gynaecological Cytology Examination	Preparation of Carnoy's Fixative (HPP/PAT/CY/WI/19) Papanicolaou Stain (HPP/PAT/CY/WI/11)
		May Grunwald Giemsa (HPP/PAT/CY/WI/13)
Fine Needle Aspirates	FNA Cytology Examination	Specimen Preparation and Routine Staining Preparation of Carnoy's Fixative (HPP/PAT/CY/WI/19) Papanicolaou Stain (HPP/PAT/CY/WI/11)
		May Grunwald Giemsa (HPP/PAT/CY/WI/13)

#### **SCOPE OF MEDICAL TESTING: HISTOPATHOLOGY**

Specimen Tested	Type of Test/	Test Methods, Specifications/
	<b>Properties Measured/</b>	Equipment/Techniques Used
Surgical Pathology Specimens	Histology Examination	Specimen Preparation and
		Staining (Manual method)
		HPP/PAT/HP/WI/10
		Haematoxylin and Eosin
Intraoperative Frozen	Histology Examination	Specimen Preparation and
Section For Fresh Tissue		Routine Staining (Manual) Frozen
Specimens And Biopsies		Section (HPP/PAT/HP/WI/07)
		Rapid H&E Staining
		(HPP/PAT/HP/WI/11)
Histochemical Investigations	Histochemical Examination	Specimen Preparation and
		Routine Staining (Manual)
Immunohistochemical	Immunohistochemistry and	Specimen Preparation and
Investigations	Immunoflourescence	Routine Staining
		Immunohistochemical (Dako
		Omnis - Basic)
		HPP/PAT/HP/WI/46
		Immunohistochemical (Dako
		Omnis -
		Advanced) HPP/PAT/HP/WI/47
		Immunoflourescene
		(HPP/PAT/HP/WI/41)

#### SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

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

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Plasma / Serum / Urine	Electrolytes	Ion Selective Electrodes-Indirect Method as documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI-038 using
		COBAS PRO ISE analytical unit
Plasma/ Serum	Alkaline Phosphatase	P-nitrophenyl Phosphate method
	·	as documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Alanine AminoTransferase	NADH (with P-5'-P) method as
		documented in HPP/PAT/CP/WI
		038 using COBAS PRO c503
		analytical unit
	Albumin	Bromocresol Purple method as
		documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Aspartate AminoTransferase	NADH (with P-5'-P) method as
		documented in HPP/PAT/CP/WI
		038 using COBAS PRO c503
		analytical unit
	Bilirubin direct	Diazonium Salt method as
		documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Bilirubin total	Diazonium Salt method as
		documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Cholesterol	Enzymatic & colorimetric method
		Using Cholesterol Oxidase as
		documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Cholinesterase	Colorimetric using
		Butyrylthiocholine method as
		documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Creatine Kinase	NAC and IFCC recommended
		method using Immidazole buffer
	T. Control of the con	_
		method as documented in
		method as documented in HPP/PAT/CP/QP-01 and HPP/PAT/CP/WI 038 using

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Complement	Immunoturbidimetric method as
Component C3	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Complement	Immunoturbidimetric method as
Component C4	documented in
·	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
C-Reactive Protein	Particle enhanced
	immunoturbidimetric method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Gamma	IFCC Enzymatic colorimetric
Glutamyltransferase	assay with ?-glutamyltransferase
Giulaniyillansierase	as documented in
	HPP/PAT/CP/AVI 000 verification
	HPP/PAT/CP/WI 038 using
LIDI	COBAS PRO c503 analytical unit
HDL-C	Direct measuring of HDL with
	Enzymatic method (without pre-
	treatment) as documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Iron	FerroZine method (without
	deproteinization) as documented
	in HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Lactate Dehydrogenase	IFCC Lactate to pyruvate method
	as documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Triglycerides	Enzymatic, colorimetric method
	as documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Total Protein	Biuret method as documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
	CODACT NO 6000 analytical utilit

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Transferrin	Immunoturbidimetric method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Free Triiodothyronine	ECL/Competition method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
Free Thyroxine	ECL/Competition method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
Thyroid Stimulating Hormones	ECL/Sandwich method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
Ferritin	ECL/Sandwich method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
?HCG	ECL/Sandwich method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
Luteinizing Hormone	ECL/Sandwich method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
Follicle-Stimulating Hormone	ECL/Sandwich method as
C C	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
Prolactin	ECL/Sandwich method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
?1-Fetoprotein	ECL/Sandwich method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
	232/10 1 110 0001 analytical unit

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	E01 (0 1 : 1
Carcinoembryonic	ECL/Sandwich method as
Antigen	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
Cancer Antigen 125	ECL/Sandwich method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
Total Prostate-Specific Antigen	ECL/Sandwich method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
Cortisol	ECL/Competition method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
CA 19.9	ECL/Sandwich method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit
Acetaminophen	Homogenous enzyme
·	immunoassay method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Amikacin	KIMS as documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Carbamazepine	Homogeneous microparticle
' '	agglutination immunoassay as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Digoxin	KIMS as documented in
- · <del>9</del> - · ····	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 COBAS
	PRO c503 analytical unit
Gentamicin	KIMS as documented in
Contamon	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
	CODAS FINO 6505 analytical unit

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Lithium	Colorimetric test method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analyzer
Methotrexate	Homogeneous enzyme
	immunoassay as documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Phenobarbital	KIMS as documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Phenytoin	KIMS as documented in
, , ,	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Salicylate	Enzymatic Salicylate hydroxylase
	method as documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Theophylline	KIMS as documented in
Theophylline	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical unit
Valproic Acid	Homogeneous enzyme
Valproic Acid	, ,
	immunoassay as documented in HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
Vanaganyain	COBAS PRO c503 analytical unit
Vancomycin	KIMS as documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
<del>-</del>	COBAS PRO c503 analytical unit
Thyroglobulin	ECL/Sandwich method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038
	using COBAS PRO e801
	analytical unit
Anti Thyroglobulin	ECL/Competitive method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical unit

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Anti Thyroid specific peroxidase	ECL/Competitive method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical ur
Vitamin B12	ECL/Competitive method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical ur
Folate	ECL/Competitive method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical ur
High sensitivity Troponin T	ECL/Sandwich method as
1100011111	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
Procalcitonin	COBAS PRO e801 analytical ur ECL/Sandwich method as
Procalcitoriin	
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical ur
Estradiol	ECL/Competitive method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical ur
Progesterone	ECL/Competitive method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical ur
Testosterone	ECL/Competitive method as
	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO e801 analytical ur
Albumin	Immunoturbidimetric method as
·	documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI 038 using
	COBAS PRO c503 analytical ur

Urine/ Csf

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Plasma/ Serum/ Urine	Amylase	Enzymatic using
i iasilia/ Sciulii/ Ulille	Alliyiase	4,6-ethylidene-(G7) pnitrophenyl-
		(G1)-alpha-D-Maltoheptaoside
		method as documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Magnesium	Xylidyl blue method as
		documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Phosphate	Phosphomolydate method as
		documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
Plasma	Ammonia	Enzymatic using Glutamate
. Idoma	,a	Dehydrogenase method as
		documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
Plasma/ Serum/ Urine	Calcium	
Plasma/ Serum/ Unine	Calcium	NM-BAPTA method as
		documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Creatinine	Kinetic Alkaline Picrate method
		as documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Urea	Urease method as documented
		in HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Uric Acid	Uricase method as documented
		in HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	Osmolality	Freezing point as documented in
	Comoranty	HPP/PAT/CP/WI-037 using
		Advanced MicroOsmometer
		Model Osmo1
Diagna/ Source/ Living/ Cof	Chiana	
Plasma/ Serum/ Urine/ Csf	Glucose	Enzymatic UV, Hexokinase
		method as documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
	1	

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Plasma/ Csf	Lactate	Enzymatic (L-lactate is oxidized
i lasilla/ Osi	Laciale	to pyruvate) method as
		documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
Urine/ Csf	Total Protein	Benzethonium Chloride method
Office CSI	Total Flotelli	as documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO c503 analytical unit
Edta Whole Blood	Cyclosporine	ECL/Competition method as
Lata Whole Blood	Сустозротте	documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO e801 analytical unit
	Tacrolimus	ECL/Competition method as
	Taciolillus	documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI 038 using
		COBAS PRO e801 analytical unit
Whole Blood	Glycated Hemoglobin	HPLC method as documented in
Whole Blood	Glycaled Hemoglobin	HPP/PAT/CP/WI-034 using
		Biorad D100
	Blood Gases, Arterial (ABG)	Electrode as documented in
	blood Gases, Alterial (AbG)	HPP/PAT/CP/WI063 Using
		Radiometer ABL 90 Flex Plus
	Blood Gases, Venous (VBG)	Electrode as documented in
	blood Gases, Verious (VBG)	HPP/PAT/CP/WI063 Using
		Radiometer ABL 90 Flex Plus
Urine	Urine Biochemistry	Semi-automated using
Office	Office Biochemistry	reflectance photometry method
		as documented in HPP/CP/WI/-
		058 by using ERBA Laura
		analyzer and automated using
		image analysis method as
		documented in HPP/PAT/CP/WI
		– 059 by using ERBA Laura XL
		analyzer
	Urine Microscopy	Automated using sedimentation
	Office Wildroscopy	and digital Imaging method as
		documented in HPP/PAT/CP/WI
		– 059 by using ERBA Laura XL
		analyzer
Serum	Protein Electrophoresis	Agarose gel
	(Paraprotein)	electrophoresis/densitometry
	(i diapiotolii)	method as documented in
		HPP/PAT/CP/QP-01 and
		HPP/PAT/CP/WI-053 using
		SebiaHydrasis 2 Scan Analyser
		Josiai iyaradid 2 Joan Anaiyati

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Paraprotein Typing	Agarose gel
(Immunofixation)	immunoelectrophoresis method
	as documented in
	HPP/PAT/CP/QP-01 and
	HPP/PAT/CP/WI-053 using
	SebiaHydrasis 2 Scan Analyser

#### **SCOPE OF MEDICAL TESTING: HAEMATOLOGY**

Specimen Tested	Type of Test/	Test Methods, Specifications/
W/ 1 DI 1	Properties Measured/	Equipment/Techniques Used
Whole Blood	Full Blood Count Reticulocyte Counts NRBC Counts	Analysis of WBCs with Flow Cytometer, Haemoglobin using colorimetric Method, RBC and PLT Using electrical impedance method with Mindray BC6200 method as documented in
	Full Blood Picture	HPP/PAT/HM/WI/71 Procedure as documented in HPP/PAT/HM/WI/04
	Hb Analysis	Capillary electrophoresis using Sebia Capillary 2 Flex-Piercing Method as documented in HPP/PAT/HM/WI/50) HPLC method using HPLC Biorad Variant II Method as documented in HPP/PAT/HM/WI/52)
	Erythrocyte Sedimentation Rate	Erythrocyte Sedimentation Rate using MIX-RATE ESR Analyzer A modification base on the Westergren Method as documented in HPP/PAT/HM/WI/26 and HPP/PAT/HM/WI41
	CD4/CD8 Enumeration	Flow Cytometry Quantitation of CD4/CD8 in absolute and percentage count using Beckman Coulter AQUIOS CL Flow Cytometer Method as documented in HPP/PAT/HM/WI/70
Plasma	PT/APTT Fibrinogen	Optical Clot Detection Method by using ACL Top 550 as documented in HPP/PAT/HM/WI/80

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	Manual PT/APTT	Manual method as documented in HPP/PAT/HM/WI/54
	Factor VIII Assay Factor IX Assay	Optical Clot Detection Method by using ACL TOP 550 as documented in HPP/PAT/HM/WI/11
	Lupus Anticoagulant Assay	Optical Clot Detection Method by using ACL TOP 550 as documented in HPP/PAT/HM/WI/55
	Mixing Test Inhibitor Assay	Optical Clot Detection Method by using ACL TOP 550 as documented in: i) HPP/PAT/HM/WI/56 ii) HPP/PAT/HM/WI/12
	Von Willebrand Factor (Antigen & Ristocetin Cofactor)	Turbidimetric Immunoassay method for vWF:Ag and Agglutination method for vWF: Ricof by using ACL TOP 550 as documented in HPP/PAT/HM/WI/63
	D-Dimer Quantitative Assay	Turbidimetric Immunoassay method by using ACL TOP 550 as documented in HPP/PAT/HM/WI/81
Bone Marrow Aspirate	ВМА	Routine Staining (MGG and Perls), Cytochemical Staining and Other Special Staining Procedures as documented in: i) HPP/PAT/HM/WI/05 ii) HPP/PAT/HM/WI/07 iii) HPP/PAT/HM/WI/08
Blood On Filter Paper/ Edta Whole Blood	G6PD Screening Tests	Fluorescence Spot Test as documented in the HPP/PAT/HM/WI/24
Whole Blood Bone Marrow Aspirate	Leukaemia and Lymphoma Immunophenotyping	Flowcytometry method using Facs Canto II as documented in HPP/PAT/HM/WI/58

### SCOPE OF MEDICAL TESTING: HAEMATOLOGY (MOLECULAR)

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

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Whale Disast	Full Discard County Darks Town	Analysis of M/DO: 10 Fl
Whole Blood	Full Blood Count Reticulocyte Counts NRBC Counts	Analysis of WBCs with Flow Cytometer, Haemoglobin using colorimetric Method, RBC and PLT Using electrical impedance method with Mindray BC6200 method as documented in HPP/PAT/HM/WI/71
	Full Blood Picture	Procedure as documented in HPP/PAT/HM/WI/04
	Hb Analysis	Capillary electrophoresis using Sebia Capillary 2 Flex-Piercing Method as documented in HPP/PAT/HM/WI/50) HPLC method using HPLC Biorad Variant II Method as documented in HPP/PAT/HM/WI/52)
	Erythrocyte Sedimentation Rate	Erythrocyte Sedimentation Rate using MIX-RATE ESR Analyzer A modification base on the Westergren Method as documented in HPP/PAT/HM/WI/26 and HPP/PAT/HM/WI41
	CD4/CD8 Enumeration	Flow Cytometry Quantitation of CD4/CD8 in absolute and percentage count using Beckman Coulter AQUIOS CL Flow Cytometer Method as documented in HPP/PAT/HM/WI/70
Plasma	PT/APTT Fibrinogen	Optical Clot Detection Method by using ACL Top 550 as documented in HPP/PAT/HM/WI/80
	Manual PT/APTT	Manual method as documented in HPP/PAT/HM/WI/54
	Factor VIII Assay Factor IX Assay	Optical Clot Detection Method by using ACL TOP 550 as documented in HPP/PAT/HM/WI/11
	Lupus Anticoagulant Assay	Optical Clot Detection Method by using ACL TOP 550 as documented in HPP/PAT/HM/WI/55
	Mixing Test Inhibitor Assay	Optical Clot Detection Method by using ACL TOP 550 as documented in: i) HPP/PAT/HM/WI/56 ii) HPP/PAT/HM/WI/12

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	Von Willebrand Factor	Turbidimetric Immunoassay
	(Antigen & Ristocetin	method for vWF:Ag and
	Cofactor)	Agglutination method for vWF:
		Ricof by using ACL TOP 550 as
		documented in
		HPP/PAT/HM/WI/63
	D-Dimer Quantitative Assay	Turbidimetric Immunoassay
		method by using ACL TOP 550
		as documented in
		HPP/PAT/HM/WI/81
Bone Marrow Aspirate	BMA	Routine Staining (MGG and
		Perls),
		Cytochemical Staining and Other
		Special
		Staining Procedures as
		documented in:
		i) HPP/PAT/HM/WI/05
		ii) HPP/PAT/HM/WI/07
		iii) HPP/PAT/HM/WI/08
Blood On Filter Paper/ Edta Whole	G6PD Screening Tests	Fluorescence Spot Test as
Blood		documented in the
		HPP/PAT/HM/WI/24
Whole Blood Bone Marrow	Leukaemia and Lymphoma	Flowcytometry method using
Aspirate	Immunophenotyping	Facs Canto II as documented in HPP/PAT/HM/WI/58

#### **SCOPE OF MEDICAL TESTING: HAEMATOLOGY**

Specimen Tested	Type of Test/	Test Methods, Specifications/
	<b>Properties Measured/</b>	Equipment/Techniques Used
Whole Blood	Molecular Quantitation Major BCR-	Quantitative detection of BCR-
	ABL (p210)	ABL1 chromosomal translocation
		mRNA transcript (types
		e13a2/b2a2 or e14a2/b3a2) by
		using polymerase chain reaction
		using Cepheid Genexpert System
		as documented in
		HPP/PAT/HM/WI/77

### SCOPE OF MEDICAL TESTING: HAEMATOLOGY (MOLECULAR)

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

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Whole Blood	Molecular Quantitation Major BCR-	Quantitative detection of BCR-
	ABL (p210)	ABL1 chromosomal translocation
		mRNA transcript (types
		e13a2/b2a2 or e14a2/b3a2) by
		using polymerase chain reaction
		using Cepheid Genexpert System
		as documented in
		HPP/PAT/HM/WI/77

### SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (BACTERIOLOGY)

Properties Measured/ Macroscopy	Equipment/Techniques Used
Macroscopy	
Madroscopy	Processing Cerebrospinal Fluid
	as
	documented in
	HPP/PAT/MM/WI/001
	Gram stain and Indian Ink as
	documented in
	HPP/PAT/MM/WI/020
Culture	As documented in
	HPP/PAT/MM/WI/001
Microscopy	Gram Stain and Indian Ink as
	documented in
	HPP/PAT/MM/WI/020
Culture	As documented in
	HPP/PAT/MM/WI/002
Cell Count	As documented in
	HPP/PAT/MM/WI/116
Macroscopy	Visual Observation
	Gram Stain as documented in
	HPP/PAT/MM/WI/020
Culture	As documented in
	HPP/PAT/MM/WI/003
Microscopy	Direct Smear and Gram Stain as
	documented
	in HPP/PAT/MM/WI/020
Culture	As documented in
	HPP/PAT/MM/WI/004
	Visual Observation
Culture	As documented in
	HPP/PAT/MM/WI/005
Clostridium Difficile Toxin	Detection of Toxin A&B of
	Clostridium Difficile Using
	Immunochromatographic Rapid
	Test as documented in
	HPP/PAT/MM/WI/005
	Culture  Cell Count

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Respiratory Tract Specimens	Microscopy	Direct Smear and Gram Stain as documented in
		HPP/PAT/MM/WI/020
	Culture	As documented in
		HPP/PAT/MM/WI/006
Blood	Microscopy	Direct Smear and Gram stain as
		documented in
	Cultura	HPP/PAT/MM/WI/020
	Culture	Processing Blood Specimens and Body Fluids (BACTEC FX) as
		documented in HPP/PAT/MM/WI/127
Ear Swabs	Culture	As documented in HPP/PAT/MM/WI/010
Urine	Culture	As documented in HPP/PAT/MM/WI/011
Pus/swab	Microscopy	Direct Smear and Gram Stain as
		documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/012
Urogenital Swabs	Microscopy	Direct smear and Gram stain as
		documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/014
Genital Swabs	Microscopy	Direct smear and Gram stain as
	,,	documented in HPP/PAT/MM/WI/020
	Culture	As documented in
		HPP/PAT/MM/WI/015
Tissue	Microscopy	Direct smear and Gram stain as
		documented in
	0.11	HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/013
	Anaerobic Culture	As documented in HPP/PAT/MM/WI/088
Positive Cultures From Specimens	Identification of Bacteria	Biochemical Tests as
		documented in
		HPP/PAT/MM/WI/021
		Identification using MALDI-TOF of as
		documented in
		HPP/PAT/MM/WI/155
		Serotyping as documented in HPP/PAT/MM/WI/022
	In Vitro Antibiotic Susceptibility	Antibiotic Sensitivity Testing as
	Testing	documented in HPP/PAT/MM/WI/026

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Serum	Serology Detection of Antibodies	In vitro Passive Particle
	to Treponema pallidum	Agglutination Assay
		as documented in
		HPP/PAT/MM/WI/048
		Macroscopic non-treponemal
		flocculation
		card test as in Rapid Plasma
		Reagin (RPR)
		Test as documented in
		HPP/PAT/MM/WI/039.

### SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (SEROLOGY)

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Cerebrospinal Fluid	Macroscopy	Processing Cerebrospinal Fluid as documented in HPP/PAT/MM/WI/001
		Gram stain and Indian Ink as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/001
Body Fluid	Microscopy	Gram Stain and Indian Ink as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/002
	Cell Count	As documented in HPP/PAT/MM/WI/116
Peritoneal Dialysis Fluid	Macroscopy	Visual Observation Gram Stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/003
Eye Swab	Microscopy	Direct Smear and Gram Stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/004
Stool/rectal Swab	Macroscopy	Visual Observation
	Culture	As documented in HPP/PAT/MM/WI/005

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	Clostridium Difficile Toxin	Detection of Toxin A&B of Clostridium Difficile Using Immunochromatographic Rapid Test as documented in HPP/PAT/MM/WI/005
Respiratory Tract Specimens	Microscopy	Direct Smear and Gram Stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/006
Blood	Microscopy	Direct Smear and Gram stain as documented in HPP/PAT/MM/WI/020
	Culture	Processing Blood Specimens and Body Fluids (BACTEC FX) as documented in HPP/PAT/MM/WI/127
Ear Swabs	Culture	As documented in HPP/PAT/MM/WI/010
Urine	Culture	As documented in HPP/PAT/MM/WI/011
Pus/swab	Microscopy	Direct Smear and Gram Stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/012
Urogenital Swabs	Microscopy	Direct smear and Gram stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/014
Genital Swabs	Microscopy	Direct smear and Gram stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/015
Tissue	Microscopy	Direct smear and Gram stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/013
	Anaerobic Culture	As documented in HPP/PAT/MM/WI/088

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Positive Cultures From Specimens	Identification of Bacteria	Biochemical Tests as documented in HPP/PAT/MM/WI/021 Identification using MALDI-TOF of as documented in HPP/PAT/MM/WI/155 Serotyping as documented in HPP/PAT/MM/WI/022
	In Vitro Antibiotic Susceptibility Testing	Antibiotic Sensitivity Testing as documented in HPP/PAT/MM/WI/026
Serum	Serology Detection of Antibodies to Treponema pallidum	In vitro Passive Particle Agglutination Assay as documented in HPP/PAT/MM/WI/048 Macroscopic non-treponemal flocculation card test as in Rapid Plasma Reagin (RPR) Test as documented in HPP/PAT/MM/WI/039.

# SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (VIROLOGY)

Specimen Tested	Type of Test/	Test Methods, Specifications/
	<b>Properties Measured/</b>	<b>Equipment/Techniques Used</b>
Cerebrospinal Fluid	Macroscopy	Processing Cerebrospinal Fluid
		as
		documented in
		HPP/PAT/MM/WI/001
		Gram stain and Indian Ink as
		documented in
		HPP/PAT/MM/WI/020
	Culture	As documented in
		HPP/PAT/MM/WI/001
Body Fluid	Microscopy	Gram Stain and Indian Ink as
		documented in
		HPP/PAT/MM/WI/020
	Culture	As documented in
		HPP/PAT/MM/WI/002
	Cell Count	As documented in
		HPP/PAT/MM/WI/116
Peritoneal Dialysis Fluid	Macroscopy	Visual Observation
		Gram Stain as documented in
		HPP/PAT/MM/WI/020
	Culture	As documented in
		HPP/PAT/MM/WI/003

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Eye Swab	Microscopy	Direct Smear and Gram Stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/004
Stool/rectal Swab	Macroscopy	Visual Observation
	Culture	As documented in HPP/PAT/MM/WI/005
	Clostridium Difficile Toxin	Detection of Toxin A&B of Clostridium Difficile Using Immunochromatographic Rapid Test as documented in HPP/PAT/MM/WI/005
Respiratory Tract Specimens	Microscopy	Direct Smear and Gram Stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/006
Blood	Microscopy	Direct Smear and Gram stain as documented in HPP/PAT/MM/WI/020
	Culture	Processing Blood Specimens and Body Fluids (BACTEC FX) as documented in HPP/PAT/MM/WI/127
Ear Swabs	Culture	As documented in HPP/PAT/MM/WI/010
Urine	Culture	As documented in HPP/PAT/MM/WI/011
Pus/swab	Microscopy	Direct Smear and Gram Stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/012
Urogenital Swabs	Microscopy	Direct smear and Gram stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/014
Genital Swabs	Microscopy	Direct smear and Gram stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/015
Tissue	Microscopy	Direct smear and Gram stain as documented in HPP/PAT/MM/WI/020
	Culture	As documented in HPP/PAT/MM/WI/013
	Anaerobic Culture	As documented in HPP/PAT/MM/WI/088

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Positive Cultures From Specimens	Identification of Bacteria	Biochemical Tests as documented in HPP/PAT/MM/WI/021 Identification using MALDI-TOF
		of as documented in
		HPP/PAT/MM/WI/155
		Serotyping as documented in HPP/PAT/MM/WI/022
	In Vitro Antibiotic Susceptibility	Antibiotic Sensitivity Testing as
	Testing	documented in
		HPP/PAT/MM/WI/026
Serum	Serology Detection of Antibodies	In vitro Passive Particle
	to Treponema pallidum	Agglutination Assay
		as documented in
		HPP/PAT/MM/WI/048
		Macroscopic non-treponemal
		flocculation
		card test as in Rapid Plasma
		Reagin (RPR)
		Test as documented in
		HPP/PAT/MM/WI/039.

### SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (BACTERIOLOGY)

Specimen Tested	Type of Test/	Test Methods, Specifications/
	<b>Properties Measured/</b>	<b>Equipment/Techniques Used</b>
Parasitology Blood For Malaria Parasites	BFMP	As documented in HPP/PAT/MM/WI/115
Serum	Qualitative Determination of IgM or IgG Antibodies to Toxoplasma Gondii	ECLIA (electrochemiluminescence immunoassay) for IgM and IgG assay using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/134 ii) HPP/PAT/MM/WI/135 iii) HPP/PAT/MM/WI/176

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Mycobacteriology	Microscopy	Direct Smear Staining as
Suspected Tb, Infection		documented in
Specimens		HPP/PAT/MM/WI/0112
		Acid Fast Bacili Smear
		Fluorescent
		Microscopy in
		HPP/PAT/MM/WI/124
		Direct Smear Staining using
		AS-316T BASO
		autostainer equipment as
		documented in
		Operation of TB Autostainer in
		HPP/PAT/MM/WI/178
	Culture	Using BD MGIT 960 as
		documented in
		HPP/PAT/MM/WI/113
		Using conventional method as
		documented in
		HPP/PAT/MM/WI/O27

# SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (SEROLOGY)

Parasitology Blood For Malaria Parasites  Qualitative Determination of IgM or IgG Antibodies to Toxoplasma Gondii  EQUALITATION AS documented in HPP/PAT/MM/WI/115  ECLIA (electrochemiluminescence immunoassay) for IgM and IgG assay using COBAS PRO e801 analytical unias documented in: i) HPP/PAT/MM/WI/134 ii) HPP/PAT/MM/WI/135 iii) HPP/PAT/MM/WI/176	Specimen Tested	Type of Test/	Test Methods, Specifications/
Blood For Malaria Parasites  Serum  Qualitative Determination of IgM or IgG Antibodies to Toxoplasma Gondii  ECLIA (electrochemiluminescence immunoassay) for IgM and IgG assay using COBAS PRO e801 analytical unias documented in: i) HPP/PAT/MM/WI/134 ii) HPP/PAT/MM/WI/135		Properties Measured/	Equipment/Techniques Used
Serum  Qualitative Determination of IgM or IgG Antibodies to Toxoplasma Gondii  ECLIA (electrochemiluminescence immunoassay) for IgM and IgG assay using COBAS PRO e801 analytical uni as documented in: i) HPP/PAT/MM/WI/134 ii) HPP/PAT/MM/WI/135	Parasitology	BFMP	As documented in
or IgG Antibodies to Toxoplasma Gondii  (electrochemiluminescence immunoassay) for IgM and IgG assay using COBAS PRO e801 analytical unias documented in: i) HPP/PAT/MM/WI/134 ii) HPP/PAT/MM/WI/135	Blood For Malaria Parasites		HPP/PAT/MM/WI/115
		or IgG Antibodies to Toxoplasma	ECLIA (electrochemiluminescence immunoassay) for IgM and IgG assay using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/134 ii) HPP/PAT/MM/WI/135

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Mycobacteriology	Microscopy	Direct Smear Staining as
Suspected Tb, Infection		documented in
Specimens		HPP/PAT/MM/WI/0112
		Acid Fast Bacili Smear
		Fluorescent
		Microscopy in
		HPP/PAT/MM/WI/124
		Direct Smear Staining using
		AS-316T BASO
		autostainer equipment as
		documented in
		Operation of TB Autostainer in
		HPP/PAT/MM/WI/178
	Culture	Using BD MGIT 960 as
		documented in
		HPP/PAT/MM/WI/113
		Using conventional method as
		documented in
		HPP/PAT/MM/WI/O27

# SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (VIROLOGY)

Specimen Tested	Type of Test/	Test Methods, Specifications/
	Properties Measured/	Equipment/Techniques Used
Parasitology	BFMP	As documented in
Blood For Malaria Parasites		HPP/PAT/MM/WI/115
Serum	Qualitative Determination of IgM or IgG Antibodies to Toxoplasma Gondii	ECLIA (electrochemiluminescence immunoassay) for IgM and IgG assay using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/134 ii) HPP/PAT/MM/WI/176

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Mycobacteriology	Microscopy	Direct Smear Staining as
Suspected Tb, Infection		documented in
Specimens		HPP/PAT/MM/WI/0112
		Acid Fast Bacili Smear
		Fluorescent
		Microscopy in
		HPP/PAT/MM/WI/124
		Direct Smear Staining using
		AS-316T BASO
		autostainer equipment as
		documented in
		Operation of TB Autostainer in
		HPP/PAT/MM/WI/178
	Culture	Using BD MGIT 960 as
		documented in
		HPP/PAT/MM/WI/113
		Using conventional method as
		documented in
		HPP/PAT/MM/WI/O27

# SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (BACTERIOLOGY)

Specimen Tested	Type of Test/	Test Methods, Specifications/
	Properties Measured/	Equipment/Techniques Used
Serum	Dengue Combo NS1, IgG/IgM	Dengue Rapid Test RVR as
	Rapid Test	documented in:
		i) HPP/PAT/MM/WI/128
		ii) HPP/PAT/MM/WI/162
		iii) HPP/PAT/MM/WI/179
	Qualitative detection of Antibodies	Non cultural Methods Using
	to Human Immunodeficiency Virus	Passive Particle Agglutination for
	type 1 (HIV-1) and/or type 2	Detection of Antibodies to HIV 1
	(HIV-2)	and HIV 2 as documented in
		HPP/PAT/MM/WI/037
Plasma/serum	Qualitative Determination of HIV-1	ECLIA
	p24 Antigen and Antibodies to	(Electrochemiluminescence
	HIV-1 and HIV-2	immunoassay) for HIV using
		COBAS PRO
		e801 analytical unit as
		documented in:
		i) HPP/PAT/MM/WI/150
		ii) HPP/PAT/MM/WI/176
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Qualitative Detection of Hepatitis B Surface Antigen (HBsAg), Hepatitis B e Antigen (HBeAg), and Antibodies to Hepatitis B e Antigen (anti-HBe)  Qualitative determination of IgG	ECLIA (Electrochemiluminescence Immunoassay) for, HBsAg Anti HBe & HBeAg using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/138 ii) HPP/PAT/MM/WI/148 iii) HPP/PAT/MM/WI/149 iv) HPP/PAT/MM/WI/176 ECLIA
and IgM antibodies to the Hepatitis B Core Antigen (anti- HBc)	(Electrochemiluminescence Immunoassay) for Anti-HBc using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/M/WI/166 ii) HPP/PAT/MM/WI/176
Quantitative Determination of Human Antibodies to Hepatitis B Surface Antigen (Anti-HBs)	ECLIA (Electrochemiluminescence Immunoassay) for Anti-HBs using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/137 ii) HPP/PAT/MM/WI/176
Qualitative Detection of Antibodies to Hepatitis C Virus (Anti-HCV)	ECLIA (Electrochemiluminescence Immunoassay) for HCV test using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/141 ii) HPP/PAT/MM/WI/176
Qualitative Determination of IgM or IgG Antibodies to Cytomegalovirus	ECLIA (Electrochemiluminescence Immunoassay) with Cytomegalovirus IgM and IgG test with COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/140 ii) HPP/PAT/MM/WI/142 iii) HPP/PAT/MM/WI/176
Quantitative Determination of Rheumatoid Factor	Immunoturbidimetric assay for Rheumatoid Factors-II test with COBAS PRO c503 analytical unit as documented in: i) HPP/PAT/MM/WI/163 ii) HPP/PAT/MM/WI/176

**Immunology** Serum

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Molecular	Quantitative Detection of Human	Using ALINITY M Instrument and
Plasma	Immunodeficiency Virus Type1	System Operation for detection of
	(HIV-1) RNA, Hepatitis B Virus	nucleic acid sequences & HIV-1,
	(HBV) DNA, Hepatitis C Virus	HBV, HCV viral load and SARS-
	(HCV) RNA	CoV-2 PCR as documented in
		HPP/PAT/MM/WI/169

### SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (SEROLOGY)

Specimen Tested	Type of Test/	Test Methods, Specifications/
	Properties Measured/	Equipment/Techniques Used
Serum	Dengue Combo NS1, IgG/IgM Rapid Test	Dengue Rapid Test RVR as documented in: i) HPP/PAT/MM/WI/128 ii) HPP/PAT/MM/WI/162 iii) HPP/PAT/MM/WI/179
	Qualitative detection of Antibodies to Human Immunodeficiency Virus type 1 (HIV-1) and/or type 2 (HIV-2)	Non cultural Methods Using Passive Particle Agglutination for Detection of Antibodies to HIV 1 and HIV 2 as documented in HPP/PAT/MM/WI/037
Plasma/serum	Qualitative Determination of HIV-1 p24 Antigen and Antibodies to HIV-1 and HIV-2	ECLIA (Electrochemiluminescence immunoassay) for HIV using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/150 ii) HPP/PAT/MM/WI/176
	Qualitative Detection of Hepatitis B Surface Antigen (HBsAg), Hepatitis B e Antigen (HBeAg), and Antibodies to Hepatitis B e Antigen (anti-HBe)	ECLIA (Electrochemiluminescence Immunoassay) for, HBsAg Anti HBe & HBeAg using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/138 ii) HPP/PAT/MM/WI/149 iv) HPP/PAT/MM/WI/176
	Qualitative determination of IgG and IgM antibodies to the Hepatitis B Core Antigen (anti-HBc)	ECLIA (Electrochemiluminescence Immunoassay) for Anti-HBc using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/M/WI/166 ii) HPP/PAT/MM/WI/176

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	Quantitative Determination of	ECLIA
	Human Antibodies to Hepatitis B	(Electrochemiluminescence
	Surface Antigen (Anti-HBs)	Immunoassay) for Anti-HBs using
	carrier carriger (carrier sy	COBAS PRO e801 analytical unit
		as documented in: i)
		HPP/PAT/MM/WI/137 ii)
		HPP/PAT/MM/WI/176
	Qualitative Detection of Antibodies	ECLIA
	to Hepatitis C Virus (Anti-HCV)	(Electrochemiluminescence
	le riepanie e vii de (i iiii rie v)	Immunoassay) for HCV test using
		COBAS PRO e801 analytical unit
		as documented in: i)
		HPP/PAT/MM/WI/141 ii)
		HPP/PAT/MM/WI/176
	Qualitative Determination of IgM	ECLIA
	or IgG Antibodies to	(Electrochemiluminescence
	Cytomegalovirus	Îmmunoassay)
		with Cytomegalovirus IgM and
		IgG test with
		COBAS PRO e801 analytical unit
		as documented
		in:
		i) HPP/PAT/MM/WI/140
		ii) HPP/PAT/MM/WI/142
		iii) HPP/PAT/MM/WI/176
Immunology	Quantitative	Immunoturbidimetric assay for
Serum	Determination of	Rheumatoid
	Rheumatoid Factor	Factors-II test with COBAS PRO
		c503 analytical
		unit as documented in:
		i) HPP/PAT/MM/WI/163
		ii) HPP/PAT/MM/WI/176
Molecular	Quantitative Detection of Human	Úsing ALINITY M Instrument and
Plasma	Immunodeficiency Virus Type1	System Operation for detection of
	(HIV-1) RNA, Hepatitis B Virus	nucleic acid sequences & HIV-1,
	(HBV) DNA, Hepatitis C Virus	HBV, HCV viral load and SARS-
	(HCV) RNA	CoV-2 PCR as documented in
		HPP/PAT/MM/WI/169

#### SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY (VIROLOGY)

Specimen Tested	Type of Test/	Test Methods, Specifications/
	<b>Properties Measured/</b>	<b>Equipment/Techniques Used</b>
Serum	Dengue Combo NS1, IgG/IgM	Dengue Rapid Test RVR as
	Rapid Test	documented in:
		i) HPP/PAT/MM/WI/128
		ii) HPP/PAT/MM/WI/162
		iii) HPP/PAT/MM/WI/179

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	Qualitative detection of Antibodies to Human Immunodeficiency Virus type 1 (HIV-1) and/or type 2 (HIV-2)	Non cultural Methods Using Passive Particle Agglutination for Detection of Antibodies to HIV 1 and HIV 2 as documented in HPP/PAT/MM/WI/037
Plasma/serum	Qualitative Determination of HIV-1 p24 Antigen and Antibodies to HIV-1 and HIV-2	ECLIA (Electrochemiluminescence immunoassay) for HIV using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/150 ii) HPP/PAT/MM/WI/176
	Qualitative Detection of Hepatitis B Surface Antigen (HBsAg), Hepatitis B e Antigen (HBeAg), and Antibodies to Hepatitis B e Antigen (anti-HBe)	ECLIA (Electrochemiluminescence Immunoassay) for, HBsAg Anti HBe & HBeAg using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/138 ii) HPP/PAT/MM/WI/149 iv) HPP/PAT/MM/WI/176
	Qualitative determination of IgG and IgM antibodies to the Hepatitis B Core Antigen (anti-HBc)	ECLIA (Electrochemiluminescence Immunoassay) for Anti-HBc using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/M/WI/166 ii) HPP/PAT/MM/WI/176
	Quantitative Determination of Human Antibodies to Hepatitis B Surface Antigen (Anti-HBs)	ECLIA (Electrochemiluminescence Immunoassay) for Anti-HBs using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/137 ii) HPP/PAT/MM/WI/176
	Qualitative Detection of Antibodies to Hepatitis C Virus (Anti-HCV)	ECLIA (Electrochemiluminescence Immunoassay) for HCV test using COBAS PRO e801 analytical unit as documented in: i) HPP/PAT/MM/WI/141 ii) HPP/PAT/MM/WI/176

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	Qualitative Determination of IgM	ECLIA
	or IgG Antibodies to	(Electrochemiluminescence
	Cytomegalovirus	Immunoassay)
		with Cytomegalovirus IgM and
		IgG test with
		COBAS PRO e801 analytical unit
		as documented
		in:
		i) HPP/PAT/MM/WI/140
		ii) HPP/PAT/MM/WI/142
		iii) HPP/PAT/MM/WI/176
Immunology	Quantitative	Immunoturbidimetric assay for
Serum	Determination of	Rheumatoid
	Rheumatoid Factor	Factors-II test with COBAS PRO
		c503 analytical
		unit as documented in:
		i) HPP/PAT/MM/WI/163
		ii) HPP/PAT/MM/WI/176
Molecular	Quantitative Detection of Human	Using ALINITY M Instrument and
Plasma	Immunodeficiency Virus Type1	System Operation for detection of
	(HIV-1) RNA, Hepatitis B Virus	nucleic acid sequences & HIV-1,
	(HBV) DNA, Hepatitis C Virus	HBV, HCV viral load and SARS-
	(HCV) RNA	CoV-2 PCR as documented in
		HPP/PAT/MM/WI/169

NOTE: