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LABORATORY LOCATION: (PERMANENT LABORATORY) 回院 知道 1000000000000000000000000000000000000	Department of Pathology, Hospital Melaka Jalan Mufti Haji Khalil 75400 Melaka. , 75400, MELAKA MALAYSIA
ACCREDITED SINCE :	04 FEBRUARY 2025
FIELD(S) OF MEDICAL TESTING:	CYTOPATHOLOGY
	HISTOPATHOLOGY
	CHEMICAL PATHOLOGY
	HAEMATOLOGY
	MEDICAL MICROBIOLOGY

The standard used for assessment of this laboratory is MS ISO 15189:2022 (ISO 15189:2022, IDT).

A medical laboratory's fulfilment of the requirements of ISO 15189 means the laboratory meets both the technical competence requirements and the management system requirements necessary for it to consistently deliver technically valid test results. The management system requirements in ISO 15189 are written in language relevant to a medical laboratory's operations. Medical laboratories that implement ISO 15189 operate generally in accordance with the principles of ISO 9001. (See Joint IAF-ILAC-ISO Communiquè, November 2021)

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CENTRAL LOCATION	Department of Pathology, Hospital Melaka Jalan Mufti Haji Khalil 75400 Melaka. , 75400, Melaka
FIELD(S) OF MEDICAL TESTING:	CYTOPATHOLOGY, HISTOPATHOLOGYCHEMICAL PATHOLOGYHAEMATOLOGYMEDICAL MICROBIOLOGY

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

Specimen Tested	Type of Test/	Test Methods, Specifications/
	Properties Measured/	Equipment/Techniques Used
Gynaecological Specimens	Conventional	Manual handling as documented
	Gynaecological	in
	Cytology Examination	1. HM/JP/CYTO/PK-06
		(Pengendalian spesimen Pap
		Smear.
		2. HM/JP/CYTO/AK-05
		(Mounting)
		3. HM/JP/CYTO/AK-06 (Label)
		4. HM/JP/CYTO/TPM-04
		(Papanicolaou Stain)
		Automated staining / Leica
		Autostainer XL as documented in
		HM/JP/CYTO/AK-04
		(Pencelupan Sitologi)
	Liquid based	Automated Liquid based
	Gyaecological	processor as documented in
	Examination	HM/JP/CYTO/AK-20
		(PathTezt Liquid based
		processor)
		Automated staining / Leica
		Autostainer XL as documented in
		HM/JP/CYTO/AK-04
		(Pencelupan Sitologi)
		Manual handling as documented
		in
		1. HM/JP/CYTO/PK-06
		(Pengendalian spesimen Pap
		Smear.
		2. HM/JP/CYTO/AK-05
		(Mounting)
		3. HM/JP/CYTO/AK-06 (Label)
		HM/JP/CYTO/TPM-04
		(Papanicolaou Stain)

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Non-gynaecological Specimens	Non-Gynaecological Cytology Examination	Manual handling as documented in :
		1. HM/JP/CYTO/PK-07
		(Pengendalian spesimen Non-
		Gynae)
		2. HM/JP/CYTO/AK-05
		(Mounting)
		3. HM/JP/CYTO/AK-06 (Label) 4. HM/JP/CYTO/AK-07
		(Pengawetan Spesimen Sitologi)
		5. HM/JP/CYTO/AK-12 (Imprint
		dari spesimen tisu) 6. HM/JP/CYTO/TPM-01 (Ziehl-
		Neelson)
		7. HM/JP/CYTO/TPM-02 (Diff-
		Quik)
		8. HM/JP/CYTO/TPM-03 (MGG
		Stain)
		9. HM/JP/CYTO/TPM-04
		(Papanicolaou Stain)
		Automated staining/ Leica
		Autostainer XL as documented in HM/JP/CYTO/AK-04
		(Pencelupan Sitologi)
Fine Needle Aspirates	FNA Cytology Examination	Manual handling as documented
-		in :
		1. HM/JP/CYTO/PK-08
		(Pengendalian FNAC).
		2. HM/JP/CYTO/AK-05
		(Mounting)
		3. HM/JP/CYTO/AK-06 (Label)
		4. HM/JP/CYTO/AK-07
		(Pengawetan Spesimen Sitologi)
		5. HM/JP/CYTO/TPM-02 (Diff-
		Quik)
		6. HM/JP/CYTO/TPM-03 (MGG
		Stain)
		7. HM/JP/CYTO/TPM-04
		(Papanicolaou Stain)
		Automated staining /Leica
		Autostainer XL as documented in
		HM/JP/CYTO/AK-04
		(Pencelupan Sitologi)

SCOPE OF MEDICAL TESTING: HISTOPATHOLOGY

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Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Surgical Pathology Specimens	Histopathology Examination (HPE)	Manual handling as documented in:  1. HM/JP/HISTO/PK-01 (Pengendalian Spesimen Tisu) 2. HM/JP/HISTO/PK-11 (Pengendalian Spesimen Biopsi Renal) 3. HM/JP/HISTO/PK-12 (Pengendalian Spesimen Skin Biopsy) 4. HM/JP/HISTO/AK-01 (Pengrosan Tisu) 5. HM/JP/HISTO/AK-03 (Pemotongan Tisu) 6. HM/JP/HISTO/AK-06 (Label spesimen) 8. HM/JP/HISTO/AK-06 (Label spesimen) 8. HM/JP/HISTO/AK-09 (Pencelupan Histokimia)  Automated tissue processing as documented in - HM/JP/HISTO/AK-02 (Pemprosesan Tisu): 1. Sakura Tissue Tek VIP6 2. Leica ASP6025  Automated H& E staining using Sakura Tissue Tek & Leica Autostainer XL as documented in HM/JP/HISTO/AK-04 (Pencelupan H&E)  Automated Immunohistochemistry staining as documented in HM/JP/HISTO/AK-16 (Pengendalian Ujian Imunohistokimia) HM/JP/HISTO/AK-26 (Ventana Benchmark Ultra)

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Intra-operative Fresh Tissue	Frozen section	Manual method as documented in: 1. HM/JP/HISTO/PK-10 (Pengendalian Kes Frozen Section) 2. HM/JP/HISTO/AK-07 (Irisan Beku)
Fresh Tissue Specimens And Biopsies	Immunofluorescence Examination	Manual method as documented in:  1. HM/JP/HISTO/PK-11 (Pengendalian Spesimen Biopsi Renal) 2. HM/JP/HISTO/PK-12 (Pengendalian Spesimen Skin Biopsy) 3. HM/JP/HISTO/AK-11 (Ujian Imunofloresens) 4. HM/JP/HISTO/AK-22 (Disinfection of cryostat) 5. HM/JP/ HISTO/TPM-118 (C3c complement) 6. HM/JP/ HISTO/TPM-119 (C4c complement) 7. HM/JP/ HISTO/TPM-120 (IgG) 8. HM/JP/ HISTO/TPM-121 (IgA) 9. HM/JP/ HISTO/TPM-122 (IgM) 10. HM/JP/ HISTO/TPM-123 (Fibrinogen) 11. HM/JP/ HISTO/TPM-124 (C1q)

#### SCOPE OF MEDICAL TESTING: CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum	Alpha Feto Protein (AFP)	Atellica IM / 2-'site sandwich immunoassay as Documented in HM/JP/PATK/TPM-004
	Cortisol	Atellica IM/ Competitive immunoassay using direct chemiluminescent as Documented in HM/JP/PATK/TPM-018
	Ferritin	Atellica IM/ 2-site sandwich immunoassay as Documented in HM/JP/PATK/TPM-022

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FSH	Atellica IM/ 2-site sandwich
	immunoassay as Documented in HM/JP/PATK/TPM-023
HCG	Atellica IM / 2-site sandwich
	immunoassay using direct
	chemiluminometric as
	Documented in
	HM/JP/PATK/TPM-008
LH	Atellica IM / 2-site sandwich
	immunoassay as Documented in
	HM/JP/PATK/TPM-031
TIBC	Atellica CH / Sequential process
	monitored spectrophotometrically
	as Documented in
	HM/JP/PATK/TPM-052
Progesterone	Atellica IM / competitive
	immunoassay as Documented in
Declaration	HM/JP/PATK/TPM-042
Prolactin	Atellica IM / 2-site sandwich
	immunoassay as Documented in
Drostate Chapitic Antigon (DCA)	HM/JP/PATK/TPM-041 Atellica IM / 2-site sandwich
Prostate Specific Antigen (PSA)	
	immunoassay as Documented in HM/JP/PATK/TPM-049
Testosterone	Atellica IM / competitive
	immunoassay using direct
	chemiluminescent technology as
	Documented in
	HM/JP/PATK/TPM-045
Free T4	Atellica IM / competitive
	immunoassay using direct
	chemiluminescent technology as
	Documented in HM/JP/PATK/TPM-024
TSH	Atellica IM/ 3rd generation
1311	immunoassay using direct
	chemiluminescent technology as
	Documented in
	HM/JP/PATK/TPM-051
Vitamin B12	Atellica IM/ competitive
	immunoassay using direct
	chemiluminescent technology as
	Documented in
	HM/JP/PATK/TPM-063
Folate	Atellica IM / competitive
	immunoassay using direct
	chemiluminescent technology as
	Documented in
	HM/JP/PATK/TPM-064

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Plasma / Serum	Albumin	Atellica CH / BCG Dye Binding as
lasila / Coldin	, <b>.</b>	Documented in
		HM/JP/PATK/TPM-001
	Alkaline Phosphatase (ALP)	Atellica CH / IFCC as
		Documented in
		HM/JP/PATK/TPM-003
	Bilirubin (Direct)	Atellica CH / Vanadate Oxidation
		as Documented in
		HM/JP/PATK/TPM-009
	Bilirubin (Total)	Atellica CH / Vanadate Oxidation
		as Documented in
		HM/JP/PATK/TPM-010
	C-Reactive Protein (CRP)	Atellica CH / Latex Enhanced
		Immunoturbidimetric as
		Documented in
		HM/JP/PATK/TPM-021
	Creatine Kinase (CK)	Atellica CH / Enzymatic as
		Documented in
		HM/JP/PATK/TPM-019
	Cancer Antigen 125	Atellica IM / 2-site sandwich
		immunoassay as Documented in
		HM/JP/PATK/TPM-011
	Carcinoembryonic Antigen (CEA)	Atellica IM / 2-site sandwich
		immunoassay as Documented in
	OL L (T )	HM/JP/PATK/TPM-016
	Cholesterol (Total)	Atellica CH/ Colorimetric as
		Documented in
	HDL-Cholesterol	HM/JP/PATK/TPM-016
	HDL-Cholesterol	Atellica CH / Elimination and
		Catalase as Documented in
	Iron	HM/JP/PATK/TPM-027 Atellica CH / Ferrozine as
	IIOII	Documented in
		HM/JP/PATK/TPM-028
	LDH	Atellica CH / Lactate to Pyruvate
	LDII	as Documented in
		HM/JP/PATK/TPM-030
	Magnesium	Atellica CH / Xylidyl Blue as
	Magnooidiii	Documented in
		HM/JP/PATK/TPM-032
	Protein (Total)	Atellica CH / Biuret as
		Documented in
		HM/JP/PATK/TPM-048
	SGOT (AST)	Atellica CH / Modified IFCC as
		Documented in
		HM/JP/PATK/TPM-007
	SGPT (ALT)	Atellica CH / Modified IFCC as
	, ,	Documented in
		HM/JP/PATK/TPM-002

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	Triglycerides	Atellica CH / GPO as
	3,1111	Documented in
		HM/JP/PATK/TPM-050
Plasma / Serum / Urine	Amylase	Atellica CH / Ethylidene Blocked-
	,	pNPG7 as Documented in
		HM/JP/PATK/TPM-006
	Calcium	Atellica CH / Arsenazo -
		Colorimetric as Documented in
		HM/JP/PATK/TPM-012
	Chloride	Atellica CH / Indirect Integrated
	S.ms.nus	Multisensor Technology (IMT) as
		Documented in
		HM/JP/PATK/TPM-15
	Creatinine	Atellica CH / Jaffe as
	Oreas, m. e	Documented in
		HM/JP/PATK/TPM-020
	Inorganic Phosphorus	Atellica CH / Phosphomolybdate
	morgamo i nosprioras	as Documented in
		HM/JP/PATK/TPM-036
	Osmolality	Advance Micro-Osmometer 3320/
	Osmolality	Freezing Point as Documented in
		HM/JP/PATK/TPM-60
	Potassium	Atellica CH / Indirect Integrated
	1 Otassium	Multisensor Technology (IMT) as
		Documented in
		HM/JP/PATK/TPM-037
	Urea	Atellica CH / Urease with GLDH
	Orca	as Documented in
		HM/JP/PATK/TPM-056
	Uric Acid	Atellica CH / Uricase/Peroxidase
	One Acid	as Documented in
		HM/JP/PATK/TPM-057
	Sodium	Atellica CH/ Indirect Integrated
	Codiditi	Multisensor Technology (IMT) as
		Documented in
		HM/JP/PATK/TPM-044
Whole Blood	HbA1c	1. Variant II Turbo/ High
		Performance Liquid
		Chromatography (HPLC) as
		Documented in
		HM/JP/PATK/TPM-026
		2. Pengendalian Peralatan
		Variant TM II Turbo as
		documented in
		HM/JP/PatK/AK-028
Urine	Microalbumin	Atellica CH / PEG-enhanced
		Immunoturbidimetric as
		Documented in
		HM/JP/PATK/TPM-058

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	Protein	Atallias CH / Dva hinding as
	Protein	Atellica CH / Dye binding as
		Documented in
		HM/JP/PATK/TPM-054
	Biochemistry	1. Cobas U601/ Dry method as
	• pH	Documented in HM/JP/PATK/WI
	Specific Gravity	041
	<ul> <li>Leucocyte (pus Cell)</li> </ul>	
	Nitrite	2. Cobas U411/ Dry Method as
	Protein	Documented in
	Glucose	HM/JP/PATK/WI-030
	<ul> <li>Ketone</li> </ul>	
	<ul> <li>Urobilinogen</li> </ul>	3. Urine Biochemistry as
	Bilirubin	documented in
	Red Blood Cells (RBC)	HM/JP/PatK/TPM-053
	Pregnancy Test	Urine Pregnancy Test/
		Immunochromatography test as
		Documented in
		HM/JP/PATK/TPM-078
Blood Gases	Blood Gases	1. pH/ Reflectance Photometry as
	• pH	Documented in
	• pO2	HM/JP/PATK/TPM-039
	• pCO2	2. pO2/ Electrical potential as
	1 pooz	Documented in
		HM/JP/PATK/TPM-043
		3. pCO2/ pH alteration as
		Documented in
		HM/JP/PATK/TPM-040
		4. Blood Gassed Testing by Gem
		Premier 3500 Analyser as
		Documented in
	- 10 "BI	HM/JP/PATK/WI-040
Faecal	Faecal Occult Blood	Faecal Occult Blood/
		Immunoassay as Documented in
		HM/JP/PATK/TPM-079
Plasma	Ammonia	Atellica CH / Enzymatic as
		Documented in
		HM/JP/PAT/TPM-005
	Glucose	Atellica CH/ Hexokinase as
		Documented in
		HM/JP/PATK/TPM-025
	Lactate	Atellica CH / Lactate to Pyruvate
		as Documented in
		HM/JP/PAT/TPM-029

**SCOPE OF MEDICAL TESTING: HAEMATOLOGY** 

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

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	CD4/CD8	Flow Cytometry Method/ Beckman Coulter Aquious  As documented in CD4/CD8: HM/JP/HAEM/TPM-021 and HM/JP/HAEM/WI 028.
Bone Marrow	Bone marrow aspiration Cytochemistry stain: 1. Perl's stain 2. Periodic acid Schiff (PAS) 3. Myeloperoxidase (MPO)	Specimen Preparation & Manual Staining as documented in Cytochemistry: HM/JP/HAEM/WI-006  Pengendalian Specimen Sum-Sum Tulang: HM/JP/HAEM/QP-002 MGG: HM/JP/HAEM/TPM-007 Perl's: HM/JP/HAEMTPM-008 PAS:
		HM/JP/HAEM/TPM-011 MPO: HM/JP/HAEM/TPM-012
Plasma	Coagulation: i. Prothrombin Time (PT) ii. Activated Partial Thromboplastin Time (APTT) iii. Fibrinogen iv. Factor VIII & FIX	Clotting method / Sysmex CS 2500 as documented in PT: HM/JP/HAEM/WI-13 APTT: HM/JP/HAEM/TPM-14 Fibrinogen: HM/JP/HAEM/TPM-15 Factor VIII & Fix: HM/JP/HAEM/TPM-16
	APTT Mixing Test	Clotting method / Sysmex CS 2500 as documented in APTT Mixing HM/JP/HAEM/TPM-17
	D-Dimer	Clotting method / Sysmex CS 2500 D-Dimer: HM/JP/HAEM/TPM-18
	Lupus Anticoagulant	Clotting method / Sysmex CS 2500 Lupus anticoagulant: HM/JP/HAEM/TPM-33
	FVIII and FIX Inhibitor	Clotting method / Sysmex CS 2500 FVIII & FIX: HM/JP/HAEM/TPM-34

#### SCOPE OF MEDICAL TESTING: MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/	Test Methods, Specifications/
	<b>Properties Measured/</b>	<b>Equipment/Techniques Used</b>
Bacteriology	Culture & Sensitivity	Semi-automated Method as
Blood		documented in HM/JP/MI/WI-001
Bacteriology	Culture & Sensitivity Microscopy	Manual Method as documented
Csf		in HM/JP/MI/WI-005

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Bacteriology	Culture & Sensitivity	Manual as documented in
Hvs / Urethral Swab	Saltare a Constantly	HM/JP/MI/WI-004
Bacteriology	Culture & Sensitivity	Manual Method as documented
Nasal Swab	Canalis a Constituting	in HM/JP/MI/WI-008
Bacteriology	Culture & Sensitivity	Manual Method as documented
Pus	Canalis a Constituting	in HM/JP/MI/WI-002
Bacteriology	Culture & Sensitivity	Manual Method as documented
Body Fluids		in HM/JP/MI/WI-003
Bacteriology	Culture & Sensitivity Microscopy	Manual Method as documented
Sputum	, , , ,	in HM/JP/MI/WI-008
Bacteriology	Culture & Sensitivity	Manual Method as documented
Throat Swab	,	in HM/JP/MI/WI-008
Bacteriology	Culture & Sensitivity	Manual Method as documented
Bronchial / Tracheal Aspiration		in HM/JP/MI/WI-008
Bacteriology	Culture & Sensitivity Microscopy	Manual Method and Examination
Urine		of Uncentrifuge urine as
		documented in HM/JP/MI/WI-007
Bacteriology	Culture & Sensitivity	Manual Method as documented
Stool		in HM/JP/MI/WI-006
Bacteriology	Culture & Sensitivity	Manual Method as Documented
Ujian Berkaitan Kawalan Infeksi		In:
Nosokomial		1. HM/JP/MI/WI-027 (Processing
		of Biological Specimen Indicator)
		2. HM/JP/MI/WI-028 (Air
		Sampling)
		3. HM/JP/MI/WI-029 (Sterility
		Testing)
		4. HM/JP/MI/WI-030 (Processing
		of Environmental Swab
		Specimen)
Bacteriology	Antibiotic Sensitivity Testing	Manual, Disk Diffusion Kirby-
Bacterial Culture		Baur, E-test strip Method as
		documented in HM/JP/MI/WI-015
Bacteriology	Culture & Sensitivity	Manual Method as documented
Tissue		in HM/JP/MI/WI-012
Bacteriology	Antibodies to HIV 1/2	Qualitative Immunoassay (Rapid
Serum		Test) / Wondfo HIV1/2 as
		Documented in
	IgM Chapitia Antibadias ta	HM/JP/SE/TPM-02
	IgM Specific Antibodies to	Latex Agglutination (Rapid Test)/
	Leptospira	Leptorapide/ as documented in HM/JP/SE/TPM-03
	NS1 Antigen, IgG and IgM	Dengue Duo Combo Rapid Test
	Antibodies to Dengue Virus	
	Antibodies to Deligue Vilus	(SD Dengue NS1+Ab Combo) as documented in for
		HM/JP/SE/TPM-042
	Anti-Streptolysin O Antibody	Latex Agglutination/ VEDA LAB
	Anti-otreptoryalit o Antibody	as documented in
		HM/JP/SE/TPM-05

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Rheumatoid Factor	Agglutination Test as
	documented in HM/JP/SE/TPM-06
Treponema Pallidum Antibody	Particle Agglutination Test/
,	SERODIA-TPPA as documented
	in HM/JP/SE/TPM-08
Mycoplasma pneumoniae	Particle Agglutination Test/
Antibody	SERODIA- MYCO II as
	documented in
	HM/JP/SE/TPM-12
HIV- 1 and HIV -2 Antibodies	Particle Agglutination Test/
	SERODIO HIV ½ MIX as
	documented in
	HM/JP/SE/TPM-14
Screening Test for Syphilis	Flocculation Test/ IMMUTREP
	RPR as documented in
	HM/JP/SE/TPM-15
Anti-nuclear antibody (ANA)	Indirect fluorescent Antibody
	Test/ Immunoconcepts/ UV
	Microscope as documented in
Land Austila adia a ta Dananca Vince	HM/JP/SE/TPM-16
IgM Antibodies to Dengue Virus	Dengue IgM Capture ELISA / Panbio as documented in
	HM/JP/SE/TPM-20
IgG Antibodies to Dengue Virus	Dengue IgG Capture ELISA /
igo Antibodies to Derigue virus	Panbio as documented in
	HM/JP/SE/TPM-21
HIV Ag/Ab Combo	Chemiluminescent Microparticle
	Immunoassay Test/ Abbott as
	documented in
	HM/JP/SE/TPM-27
Detection of HCV Antibody	Chemiluminescent Microparticle
·	Immunoassay Test/ Abbott as
	documented in
	HM/JP/SE/TPM-28
Detection of HBe Antigen	Chemiluminescent Microparticle
	Immunoassay Test/ Abbott as
	documented in
	HM/JP/SE/TPM-29
Detection of HBe Antibody	Chemiluminescent Microparticle
	Immunoassay Test/ Abbott as
	documented in
Detection of LD- Austine	HM/JP/SE/TPM-30
Detection of HBs Antigen	Chemiluminescent Microparticle
	Immunoassay Test/ Abbott as
	documented in
Dotaction of UPs Antibody	HM/JP/SE/TPM-31
Detection of HBs Antibody	Chemiluminescent Microparticle
	Immunoassay Test/ Abbott as documented in
	HM/JP/SE/TPM-32
	11 11VI/JE/OE/TEIVI-32

**Serology** Serum

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	Detection of HBcore Total Antibody	Chemiluminescent Microparticle Immunoassay Test/ Abbott as documented in HM/JP/SE/TPM-33
	Detection of Toxo IgM Antibody	Chemiluminescent Microparticle Immunoassay Test/ Abbott as documented in HM/JP/SE/TPM-34
	Detection of Toxo IgG Antibody	Chemiluminescent Microparticle Immunoassay Test/ Abbott as documented in HM/JP/SE/TPM-35
	Detection of Rubella IgM Antibody	Chemiluminescent Microparticle Immunoassay Test/ Abbott as documented in HM/JP/SE/TPM-36
	Detection of Rubella IgG Antibody	Chemiluminescent Microparticle Immunoassay Test/ Abbott as documented in HM/JP/SE/TPM-37
	Detection of CMV IgM Antibody	Chemiluminescent Microparticle Immunoassay Test/ Abbott as documented in HM/JP/SE/TPM-38
	Detection of CMV IgG Antibody	Chemiluminescent Microparticle Immunoassay Test/ Abbott as documented in HM/JP/SE/TPM-39
Serology Cerebrospinal Fluid (csf), Serum - Nasopharyngeal Aspirate - Nasopharyngeal Washes - Nasopharyngeal Swab	Cryptococcous neoformans	Lateral Flow Assay as documented in HM/JP/SE/TPM-07
	Screening and Identification Respiratory Viruses	Indirect Immunofluorescent Antibody test / D3 Ultra DFA Respiratory Virus Screening & ID Kit as documented in HM/JP/SE/TPM-40

### NOTE: