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LABORATORY LOCATION: (PERMANENT LABORATORY) 	Jabatan Patologi, Hospital Tengku Ampuan Afzan Jalan Tanah Putih, 25100 Kuantan, Pahang , 25100, PAHANG MALAYSIA
ACCREDITED SINCE :	25 AUGUST 2011
FIELD(S) OF MEDICAL TESTING :	CYTOPATHOLOGY HISTOPATHOLOGY HAEMATOLOGY MEDICAL MICROBIOLOGY 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 Communiqué, November 2021)

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CENTRAL LOCATION	Jabatan Patologi, Hospital Tengku Ampuan Afzan Jalan Tanah Putih, 25100 Kuantan, Pahang, 25100, Pahang
FIELD(S) OF MEDICAL TESTING :	CYTOPATHOLOGY, HISTOPATHOLOGYHAEMATOLOGYMEDICAL MICROBIOLOGYMEDICAL MICROBIOLOGY (VIROLOGY)

SCOPE OF MEDICAL TESTING : CYTOPATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Non-gynaecological Specimens	Non-Gynaecological Cytology Examination	Specimen Preparation (Manual) and Routine Staining (Automated): Method as documented in HTAA-PAT-CY-AK-01, HTAA-PAT-CY-AK-02, HTAA-PAT-CY-AK-03 and HTAA-PAT-CY-AK-07 Leica autostainer XL - Papanicolaou Stain - Diff Quick Rapid Stain - Diff Quick Rapid Stain (commercial reagent)
Fine Needle Aspirate	FNA Cytology Examination	Specimen Preparation (Manual) and Routine Staining (Automated): Method as documented in HTAA-PAT-CY-AK-04, HTAA-PAT-CY-AK-07 and HTAA-PAT-CY-AK-08 Leica Autostainer XL
Gynaecological Specimens	Gynaecological Cytology Examination	Specimen Preparation (Manual) and Routine Staining (Automated): Method as documented in HTAA-PAT-CY-AK-05 HTAA-PAT-CY-AK-011 HTAA-PAT-CY-AK-016 and - Conventional smear and Pap Staining - Manual Screening

SCOPE OF MEDICAL TESTING : HISTOPATHOLOGY

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Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Diagnostic Histopathology	Histology Examination	Specimen Preparation and routine Staining (Automated) - Haematoxylin and Eosin Method as documented in HTAA/PAT/HP/AK01-01 to HTAA/PAT/HP/ AK01-05, HTAA/PAT/HP/AK01-09 to HTAA/PAT/HP/AK01-11 HTAA/PAT/HP/AK01-23 (Sakura Tissue-Tek Prisma Plus) Special staining Method (Manual) as documented in HTAA/PAT/HP/AK01-07 Special staining Method (Automated) as documented in HTAA/PAT/HP/AK01-19 (Dako Artisan Automated Special Staining Sytem) (addition) Immunostaining (Automated) Method as documented in HTAA/PAT/HP/AK01-18 (Dako Autostainer Plus) and HTAA/PAT/HP/AK01-21 (Ventana BenchMark Ultra)
Intraoperative Frozen Sections	Histology Examination	Specimen Preparation and routine Staining (Manual Method) Method as documented in HTAA/PAT/HP/AK01-08 - Haematoxylin and Eosin

SCOPE OF MEDICAL TESTING : HAEMATOLOGY

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

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Whole Blood	RBCs count	Blood Cell Count: Direct Current Detection with Hydro Dynamic Focusing Method as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000
	WBCs count	Blood Cell Count: Flowcytometry with Semi Conductor Laser Method as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000
	Haemoglobin	Blood Cell Count: SLS hemoglobin Cyanide Free Method as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000
	Haematocrit	Blood Cell Count: Direct Current Detection with Hydro Dynamic Focusing Method as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000
	Mean Cell Volume (MCV)	Blood Cell Count: Calculated Method as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000
	Mean Cell Haemoglobin (MCH)	n (MCH) Blood Cell Count: Calculated Method as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000
	Mean Cell Haemoglobin Concentration (MCHC)	Blood Cell Count: Calculated Method as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000
	Platelet count	Blood Cell Count: Direct Current Detection with Hydro Dynamic Focusing Method as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000
	Reticulocyte count	Blood Cell Count: Flowcytometry with Semi Conductor Laser Method as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000

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Differential count (Neutrophil, Lymphocyte, Monocyte, Eosinophil and Basophil)	Flowcytometry with Semi Conductor Laser Method as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000 Slide Preparation and Routine Staining (Automated) as documented in HTAA/PAT/HEMA/AK01-01 and Hematology Slide Stainer Cytocentrifuge User's Manual
Full Blood Picture: a) Blood cell count and Reticulocyte count	Flowcytometry / DC Detection / SLS Hemoglobin Methods as documented in HTAA/PAT/HEMA/AK01-01 Sysmex XN 3000
b) Differential count (Manual) & Morphology	Slide Preparation and Routine Staining (Automated) as documented in HTAA/PAT/HEMA/AK01-01 and Hematology Slide Stainer Cytocentrifuge User's Manual
Haemoglobin Analysis: a) Blood cell count	Flowcytometry / DC Detection / SLS Hemoglobin Methods as documented in HTAA/PAT/HEMA/AK03-01 Sysmex XN 3000
b) Haemoglobin Electrophoresis	Electrophoresis Method as documented in HTAA/PAT/HEMA/AK02-03 and User's Manual Sebia Hydrasys Electrophoresis System
c) Hb A2 and Hb F Quantitation	High Performance Liquid Chromatography (HPLC) Method as documented in HTAA/PAT/HEMA/AK02-02 and User's Manual Variant Biorad II
d) Hb H Inclusion Bodies	Specimen Preparation and Special Staining (Manual Method) as documented in HTAA/PAT/HEMA/AK02-04
e) Morphology	Specimen Preparation and Routine Staining (Automated) as documented in HTAA/PAT/HEMA/AK01-01 and Hematology Slide Stainer Cytocentrifuge User's Manual

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	f) Capillary Electrophoresis	Electrophoresis method using Electro-Osmotic Flow (EOF) as documented in HTAA/PAT/HEMA/AK02-01 Capillary 2 Sebia Flex Piercing
Dried Blood (on Filter Paper)	Glucose-6-Phosphate Dehydrogenase (G6PD) Screening	Beutler and Mitchell Method as documented in HTAA/PAT/HEMA/AK01-03
Bone Marrow	Bone Marrow Aspiration	Specimen Preparation and Special Staining (Manual Method): Method as documented in HTAA/PAT/HEMA/AK01-02: May Grunwald-Giemsa Stain Perl's Prussian Blue (Iron Stain) Peroxidase Stain Periodic Acid-SCHIFF Stain Alpha-Naphthyl Esterase Stain

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Mycology Cerebrospinal Fluid (csf)	Culture	As documented in HTAA/PAT/MYCO/AK08-01 and HTAA/PAT/MYCO/AK08-02
Mycology Sputum/bronchial Washing And Throat Swab And Urine	Culture	As documented in HTAA/PAT/MYCO/AK08-01 and HTAA/PAT/MYCO/AK08-02
Mycology Tissue Biopsies, Blood, Bone Marrow, Body Fluid	Culture	As documented in HTAA/PAT/MYCO/AK08-01 and HTAA/PAT/MYCO/AK08-02
Mycology Skin Scraping/nail Clipping/ Hair	Culture	As documented in HTAA/PAT/MYCO/AK08-01 and HTAA/PAT/MYCO/AK08-02
Bacteriology Blood	Culture	Using BACTEC System consists of Aerob, Peds Plus, Anaerob & MYCO/F Method as documented in HTAA/PAT/MIK/ AK03-02
	Microscopy	Gram Stain for positive culture, as documented in HTAA/PAT/MIK/ AK04-08
Bacteriology Stool	Culture	Method as documented in HTAA/PAT/MIK/ AK03-21
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01

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Bacteriology Urine	Culture	Semi quantitative using dip strips Method as documented in HTAA/PAT/MIK/ AK03-23 Examination of uncentrifuged urine using IRIS analyser Method as documented in HTAA/PAT/MIK/ AK05-08
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
Bacteriology Urogenital Specimen	Culture	Direct culture from swab sent in transport media HTAA/PAT/MIK/ AK03-24
	Microscopy (when requested for gonococcus infection)	Gram Stain as documented in HTAA/PAT/MIK/ AK04-08
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
Bacteriology Ear, Eye, Nasal & Throat (ent)	Culture	Direct culture from swab sent in transport media. Methods as documented in: HTAA/PAT/MIK/ AK03-09 (Ear) HTAA/PAT/MIK/ AK03-11 (Eye) HTAA/PAT/MIK/ AK003-16 (Nasal) HTAA/PAT/MIK/ AK03-22 (Throat)
	Microscopy (only for eye)	Gram Stain as documented in HTAA/PAT/MIK/ AK04-08
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
Bacteriology Body Fluid	Culture	Method as documented in HTAA/PAT/MIK/ AK03-03 (Body fluid) and HTAA/PAT/MIK/ AK03-06 (CAPD)
	Microscopy	Gram Stain of centrifuged specimen as documented in HTAA/PAT/MIK/ AK04-08
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
Bacteriology Cerebral Spinal Fluid	Culture Latex Agglutination Test Microscopy	Method as documented in HTAA/PAT/MIK/ AK03-07 HTAA/PAT/MIK/ AK04-08 (Gram Stain) HTAA/PAT/MIK/ AK04-09 (India Ink)
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01

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	Culture	Method as documented in HTAA/PAT/MIK/ AK03-04 (Bone, Tissue & Pus aspirated)
	Microscopy	Gram stain as documented in HTAA/PAT/MIK/ AK04-08
Bacteriology Lower Respiratory Specimen	Culture	Method as documented in HTAA/PAT/MIK/ AK03-12
	Microscopy	Gram stain as documented in HTAA/PAT/MIK/ AK04-08
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
Mycobacteriology Sputum	Microscopy	AFB stain as documented in HTAA/PAT/MIK/ AK03-14
	Culture for Mycobacterium	MGIT system & Conventional Method as documented in HTAA/PAT/MIK/ AK03-13 & HTAA/PAT/MIK/ AK05-01 (addition)
Parasitology Whole Blood	Blood film malaria Parasite	Thick & thin film, permanent stain (Giemsa) Manual microscopy Method as documented in HTAA/PAT/PARA/ AK01-02
	Anti Streptolysin-O-Titre	Manual method - Latex agglutination method as documented in HTAA/PAT/SERO/ AK01-01
	Rheumatoid Factor	Manual method - Latex agglutination method as documented in HTAA/PAT/SERO/ AK01-02
	Mycoplasma pneumoniae	Manual method – Particle Agglutination method as documented in HTAA/PAT/SERO/ AK01-12
	Dengue IgM	ELISA method - method as documented in HTAA/PAT/SERO/ AK01-13 (Dengue IgM/IgG), HTAA/PAT/SERO/ AK01-15 (Personal Lab)
	Dengue IgG	ELISA method - method as documented in HTAA/PAT/SERO/ AK01-13 (Dengue IgM/IgG), HTAA/PAT/SERO/ AK01-15 (Personal Lab)
	Leptospira IgM	Latex agglutination method - method as documented in HTAA/PAT/SERO/ AK01-05

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	Toxoplasma IgM	Electrochemiluminescence Immunoassay ECLIA - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	Anti Nuclear Antibody Factor (ANA)	Manual method – Immuno Florescence method as documented in HTAA/PAT/SERO/AK01-23
	Ds DNA	Manual method – Immuno Florescence method as documented in HTAA/PAT/SERO/AK01-23
	HIV-Particle Agglutination	Manual method – Particle Agglutination method as documented in HTAA/PAT/SERO/AK01-08
	Rubella IgM	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	HSV 1/2 IgM	ELISA method - method as documented in HTAA/PAT/SERO/AK01-15 (Personal Lab), HTAA/PAT/SERO/AK01-22
	CMV IgM	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	HIV Ag-Ab	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	Anti- HCV	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
Serum / Csf	Cryptococcus antigen	Manual method – Lateral Flow (dipstick) method as documented in HTAA/PAT/SERO/AK01-03

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY (VIROLOGY)

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Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Mycology Cerebrospinal Fluid (csf)	Culture	As documented in HTAA/PAT/MYCO/AK08-01 and HTAA/PAT/MYCO/AK08-02
Mycology Sputum/bronchial Washing And Throat Swab And Urine	Culture	As documented in HTAA/PAT/MYCO/AK08-01 and HTAA/PAT/MYCO/AK08-02
Mycology Tissue Biopsies, Blood, Bone Marrow, Body Fluid	Culture	As documented in HTAA/PAT/MYCO/AK08-01 and HTAA/PAT/MYCO/AK08-02
Mycology Skin Scraping/nail Clipping/ Hair	Culture	As documented in HTAA/PAT/MYCO/AK08-01 and HTAA/PAT/MYCO/AK08-02
Bacteriology Blood	Culture	Using BACTEC System consists of Aerob, Peds Plus, Anaerob & MYCO/F Method as documented in HTAA/PAT/MIK/ AK03-02
	Microscopy	Gram Stain for positive culture, as documented in HTAA/PAT/MIK/ AK04-08
Bacteriology Stool	Culture	Method as documented in HTAA/PAT/MIK/ AK03-21
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
Bacteriology Urine	Culture	Semi quantitative using dip strips Method as documented in HTAA/PAT/MIK/ AK03-23
		Examination of uncentrifuged urine using IRIS analyser Method as documented in HTAA/PAT/MIK/ AK05-08
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
Bacteriology Urogenital Specimen	Culture	Direct culture from swab sent in transport media HTAA/PAT/MIK/ AK03-24
	Microscopy (when requested for gonococcus infection)	Gram Stain as documented in HTAA/PAT/MIK/ AK04-08
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01

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Bacteriology Ear, Eye, Nasal & Throat (ent)	Culture	Direct culture from swab sent in transport media. Methods as documented in: HTAA/PAT/MIK/ AK03-09 (Ear) HTAA/PAT/MIK/ AK03-11 (Eye) HTAA/PAT/MIK/ AK003-16 (Nasal) HTAA/PAT/MIK/ AK03-22 (Throat)
	Microscopy (only for eye)	Gram Stain as documented in HTAA/PAT/MIK/ AK04-08
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
Bacteriology Body Fluid	Culture	Method as documented in HTAA/PAT/MIK/ AK03-03 (Body fluid) and HTAA/PAT/MIK/ AK03-06 (CAPD)
	Microscopy	Gram Stain of centrifuged specimen as documented in HTAA/PAT/MIK/ AK04-08
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
Bacteriology Cerebral Spinal Fluid	Culture Latex Agglutination Test	Method as documented in HTAA/PAT/MIK/ AK03-07
	Microscopy	HTAA/PAT/MIK/ AK04-08 (Gram Stain) HTAA/PAT/MIK/ AK04-09 (India Ink)
	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
	Culture	Method as documented in HTAA/PAT/MIK/ AK03-04 (Bone, Tissue & Pus aspirated)
Bacteriology Lower Respiratory Specimen	Microscopy	Gram stain as documented in HTAA/PAT/MIK/ AK04-08
	Culture	Method as documented in HTAA/PAT/MIK/ AK03-12
	Microscopy	Gram stain as documented in HTAA/PAT/MIK/ AK04-08
Bacteriology Lower Respiratory Specimen	Antimicrobial sensitivity testing	Method as documented in HTAA/PAT/MIK/ AK04-01
Mycobacteriology Sputum	Microscopy	AFB stain as documented in HTAA/PAT/MIK/ AK03-14
	Culture for Mycobacterium	MGIT system & Conventional Method as documented in HTAA/PAT/MIK/ AK03-13 & HTAA/PAT/MIK/ AK05-01 (addition)

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Parasitology Whole Blood	Blood film malaria Parasite	Thick & thin film, permanent stain (Giemsa) Manual microscopy Method as documented in HTAA/PAT/PARA/AK01-02
	Anti Streptolysin-O-Titre	Manual method - Latex agglutination method as documented in HTAA/PAT/SERO/AK01-01
	Rheumatoid Factor	Manual method - Latex agglutination method as documented in HTAA/PAT/SERO/AK01-02
	Mycoplasma pneumoniae	Manual method – Particle Agglutination method as documented in HTAA/PAT/SERO/AK01-12
	Dengue IgM	ELISA method - method as documented in HTAA/PAT/SERO/AK01-13 (Dengue IgM/IgG), HTAA/PAT/SERO/AK01-15 (Personal Lab)
	Dengue IgG	ELISA method - method as documented in HTAA/PAT/SERO/AK01-13 (Dengue IgM/IgG), HTAA/PAT/SERO/AK01-15 (Personal Lab)
	Leptospira IgM	Latex agglutination method - method as documented in HTAA/PAT/SERO/AK01-05
	Toxoplasma IgM	Electrochemiluminescence Immunoassay ECLIA - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	Anti Nuclear Antibody Factor (ANA)	Manual method – Immuno Florescence method as documented in HTAA/PAT/SERO/AK01-23
	Ds DNA	Manual method – Immuno Florescence method as documented in HTAA/PAT/SERO/AK01-23
	HIV-Particle Agglutination	Manual method – Particle Agglutination method as documented in HTAA/PAT/SERO/AK01-08

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	Rubella IgM	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	HSV 1/2 IgM	ELISA method - method as documented in HTAA/PAT/SERO/AK01-15 (Personal Lab), HTAA/PAT/SERO/AK01-22
	CMV IgM	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	HIV Ag-Ab	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	Anti- HCV	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
Serum / Csf	Cryptococcus antigen	Manual method – Lateral Flow (dipstick) method as documented in HTAA/PAT/SERO/AK01-03

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serology / Immunology Serum	Hepatitis B surface Antigen	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	Anti - Hepatitis B	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	Anti - Hepatitis B core Total	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)

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	RPR	Immunoassay Method - method as documented in HTAA/PAT/SERO/AK01-20
	TPPA	Manual method – Particle Agglutination method as documented in HTAA/PAT/SERO/AK01-11
Molecular Throat Swab In Vtm	Influenzae virus	Real time PCR (RT-PCR) as documented in HTAA/PAT/MOL/AK01-01

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY (VIROLOGY)

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serology / Immunology Serum	Hepatitis B surface Antigen	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	Anti - Hepatitis B	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	Anti - Hepatitis B core Total	Electrochemiluminescence Immunoassay (ECLIA) - method as documented in HTAA/PAT/SERO/AK01-20 (Cobas e601)
	RPR	Immunoassay Method - method as documented in HTAA/PAT/SERO/AK01-20
	TPPA	Manual method – Particle Agglutination method as documented in HTAA/PAT/SERO/AK01-11
Molecular Throat Swab In Vtm	Influenzae virus	Real time PCR (RT-PCR) as documented in HTAA/PAT/MOL/AK01-01

NOTE :