

**Department of Health - Centre for Health Protection, Public Health Laboratory Services Branch,
Microbiology Division**

衛生署，衛生防護中心，公共衛生化驗服務處，微生物科

ADDRESS : Public Health Laboratory Centre, 382 Nam Cheong Street, Shek Kip Mei, Kowloon,
地址 Hong Kong
香港九龍石硤尾，南昌街 382 號，公共衛生檢測中心

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| CLIENTELE 服務對象 | : Medical Testing | : Public and private hospitals and clinics |
| | 醫務化驗 | : 公營及私營醫院和診所 |
| | Proficiency Testing Providers | : National Influenza Centres |
| | 能力驗證提供者 | : 國家流感中心 |
| | | : Local laboratories |
| | | : 本地實驗所 |

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(i) Automated Serology Laboratory (ASE)
(ii) Bacteriology Laboratory (BAC)
(iii) Conventional Microbiology Laboratory (CMI)
(iv) Virology and Serology Laboratory (VSL)
(v) Molecular Laboratory (MOL)
(vi) Mycobacteriology Laboratory (TBL)

LABORATORY DIRECTOR : **Pathologist Director 病理學主管：**
化驗所主管 Dr Janice LO Yee-chi
羅懿之醫生
MBBS(HK), FRCPA, FHKCPath, FHKAM (Pathology)

PATHOLOGIST IN CHARGE OF THE ACCREDITED DISCIPLINE : Clinical Microbiology and Infection
臨床微生物學及傳染病
Dr Janice LO Yee-chi (Full-time 全職)
負責認可範疇的病理學專科醫生 羅懿之醫生

ACCREDITED TEST CATEGORY : **Medical Testing 醫務化驗**
Clinical Microbiology and Infection 臨床微生物學及傳染病
認可測試類別

Proficiency Testing Providers 能力驗證提供者

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| MEDICAL TESTING | | | |
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| DISCIPLINE 專科範疇 | TEST AREA OR SAMPLE TYPE 測試範圍或樣本種類 | SPECIFIC EXAMINATION OR PROPERTY MEASURED 特定測試或量度的特性 | METHOD OR TECHNIQUE USED 方法或應用技術 |
| This laboratory is accredited for performing the examinations and for providing clinical interpretation of the examinations listed in the scope below. | | | |
| Clinical Microbiology and Infection | Virology – Serology Serum | Hepatitis A virus antibody (IgG) by Immunoassay (chemiluminescent label) | Abbott Architect HAVAb-IgG |
| | | Hepatitis B virus antibody: - anti-HBc by Immunoassay (enzyme-based label) (polyvalent) | bioMérieux VIDAS anti-HBc Total II |
| | | - anti-HBcIgM by Immunoassay (chemiluminescent label) | Roche Cobas Anti-HBcIgM |
| | | - anti-HBe by Immunoassay (chemiluminescent label) | Roche Cobas anti-HBe |
| | | Hepatitis C virus antibody by Immunoassay (enzyme-based label) | DiaSorin Murex anti-HCV Version 4.0 Ortho HCV 3.0 Vidas anti-HCV |
| | | Hepatitis E virus antibody (IgG) by Immunoassay (enzyme-based label) | WanTai HEV IgG ELISA assay |
| | | Hepatitis E virus antibody (IgM) by Immunoassay (enzyme-based label) | WanTai HEV IgM ELISA assay |
| | | Hepatitis B virus antigen: - HBeAg by Immunoassay (chemiluminescent label) | Roche Cobas HBeAg |
| | | - HBsAg by Immunoassay (chemiluminescent label) | Roche Elecsys HBsAgII Roche Elecsys HBsAgII Confirmatory |
| | | Immunochromatographic test | Abbott Determine HBsAg 2 |
| | | Human immunodeficiency virus antigen and antibody by Immunoassay (chemiluminescent label) Immunoassay (enzyme-based label) Enzyme-linked Fluorescent Assay | Roche Elecsys HIV-DUO assay BioRad Genscreen Ultra HIV Ag-Ab bioMérieux VIDAS HIV DUO Ultra |

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| Clinical Microbiology and Infection (cont'd) | Virology – Serology (cont'd) Serum (cont'd) | Human immunodeficiency virus antibody by Western Blot | MP Diagnostics HIV Blot 2.2 MP Diagnostics HIV-2 Blot 1.2 BioRad Geenius HIV 1/2 confirmatory assay |
| | | Immunochromatographic assay | |
| | | Human T-cell lymphotropic virus I antibody by Enzyme immunoassay Western Blot | DiaSorin Murex HTLV I+II MP Diagnostics HTLV Blot 2.4 |
| | Urine | Rubella virus antibody by Enzyme-linked Fluorescent Assay (ELFA) (IgG) Immunoassay (enzyme-based label) (IgG) | bioMérieux VIDAS RUB IgG II Assay Roche Elecsys Rubella IgG |
| | | Human immunodeficiency virus I antibody by Western Blot | MP Diagnostics HIV Blot 2.2 |
| | Syphilis serology Serum | <i>Treponema pallidum</i> antibody by Immunoassay (chemiluminescent label) | Roche Elecsys Syphilis assay |

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| Clinical Microbiology and Infection | Bacteriology – Culture and sensitivity tests and/or microscopy Blood | Culture and antimicrobial susceptibility test for pathogens by Aerobic and anaerobic broth culture | Culture: Method as documented in MIC-MTH-BAC-B01 using BD BACTEC FX40 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Blood and bone marrow | Culture for acid-fast bacilli (AFB) by Aerobic broth culture | Method as documented in MIC-MTH-BAC-B01 using BD BACTEC FX40 |
| | CSF | Microscopy for Cell count by Counting chamber Cell morphology by Giemsa stain Bacteria by Gram stain Encapsulated yeast by India ink stain Culture and antimicrobial susceptibility test for pathogens by Aerobic, CO ₂ and anaerobic culture | Method as documented in MIC-MTH-BAC-B02 Culture: Method as documented in MIC-MTH-BAC-B02 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | CSF (Postmortem) | Culture for pathogens by Aerobic and anaerobic broth culture | Culture: Method as documented in MIC-MTH-BAC-B02 using BD BACTEC FX40 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 |
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| Clinical Microbiology and Infection (cont'd) | Bacteriology – Culture and sensitivity tests and/or microscopy (cont'd) Genital samples | Microscopy for cell morphology and bacteria by Gram stain Culture and antimicrobial susceptibility test for genital pathogens (except <i>Chlamydia trachomatis</i>) by Aerobic and CO ₂ culture | Method as documented in MIC-MTH-BAC-GEN Culture: Method as documented in MIC-MTH-BAC-GEN Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Intrauterine contraceptive device | Culture for Actinomycetes by Anaerobic culture | Method as documented in MIC-MTH-BAC-GEN |
| | Swabs, inoculated Modified Thayer-Martin Medium | Culture and antimicrobial susceptibility test for <i>Neisseria gonorrhoeae</i> by CO ₂ culture | Culture and identification: Method as documented in MIC-MTH-BAC-GC1 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Miscellaneous sample (including pus, body fluid, tissue, swabs, etc.) | Microscopy for Bacteria by Gram stain Cell count by counting chamber and Gram stain Cell morphology by Giemsa stain | Method as documented in MIC-MTH-BAC-M01 to M06 |
| | Superficial wound | Culture and antimicrobial susceptibility test for pathogens by Aerobic and CO ₂ culture | Culture: Method as documented in MIC-MTH-BAC-M01 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |

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| Clinical Microbiology and Infection (cont'd) | Bacteriology – Culture and sensitivity tests and/or microscopy (cont'd) Deep wound and tissue | Culture and antimicrobial susceptibility test for pathogens by Aerobic, CO ₂ and anaerobic culture | Culture: Method as documented in MIC-MTH-BAC-M02 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Sterile body fluid | Culture and antimicrobial susceptibility test for pathogens by Aerobic, CO ₂ and anaerobic culture | Culture: Method as documented in MIC-MTH-BAC-M03 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Dialysis fluid | Culture and antimicrobial susceptibility test for pathogens by Aerobic, CO ₂ and anaerobic culture | Culture: Method as documented in MIC-MTH-BAC-M04 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Eye samples (swab) | Culture and antimicrobial susceptibility test for pathogens by Aerobic and CO ₂ culture | Culture: Method as documented in MIC-MTH-BAC-M05 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |

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| Clinical Microbiology and Infection (cont'd) | Bacteriology – Culture and sensitivity tests and/or microscopy (cont'd) Eye samples (pus/aspirate, tissue/biopsies, intraocular fluid, other sterile specimens, e.g. optisol) | Culture and antimicrobial susceptibility test for pathogens by Aerobic, CO ₂ and anaerobic culture | Culture: Method as documented in MIC-MTH-BAC-M05 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Ear sample (swab) | Culture and antimicrobial susceptibility test for pathogens by Aerobic and CO ₂ culture | Culture: Method as documented in MIC-MTH-BAC-M06 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Ear sample (pus and discharge) | Culture and antimicrobial susceptibility test for pathogens by Aerobic, CO ₂ and anaerobic culture | Culture: Method as documented in MIC-MTH-BAC-M06 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Upper respiratory tract samples (including throat swab, oral swab, nasal swab/pus/discharges, etc.) | Culture and antimicrobial susceptibility test for upper respiratory tract pathogens by Aerobic, CO ₂ and anaerobic culture | Culture: Method as documented in MIC-MTH-BAC-R01 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |

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| Clinical Microbiology and Infection (cont'd) | Bacteriology – Culture and sensitivity tests and/or microscopy (cont'd) | | |
| | Nasal swab | Culture and antimicrobial susceptibility test for specific pathogens or those with clinical indications by Aerobic culture ▪ <i>Staphylococcus aureus</i> ▪ Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) | Culture: Method as documented in MIC-MTH-BAC-R01 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 |
| | Nasopharyngeal/pernasal swab | Culture and antimicrobial susceptibility test for specific pathogens or those with clinical indications by Aerobic culture ▪ <i>Bordetella pertussis</i> | Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Lower respiratory tract samples (including sputum, bronchial aspirate, tracheal aspirate, etc.) | Microscopy for Cell morphology by Gram stain Culture and antimicrobial susceptibility test for lower respiratory tract pathogens by Aerobic and CO ₂ culture Culture for specific pathogens or those with clinical indications by Aerobic culture ▪ <i>Legionella</i> species ▪ <i>Nocardia</i> species Anaerobic culture ▪ <i>Actinomyces</i> species | Culture and microscopy: Method as documented in MIC-MTH-BAC-R01 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST Culture: Method as documented in MIC-MTH-BAC-R01 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 |

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| Clinical Microbiology and Infection (cont'd) | Bacteriology – Culture and sensitivity tests and/or microscopy (cont'd) Lower respiratory tract samples (including abscess, biopsy, transtracheal / transbronchial / transthoracic needle aspirates) | Microscopy for Cell morphology and bacteria by Gram stain Culture and antimicrobial susceptibility test for lower respiratory tract pathogens by Aerobic, CO ₂ and anaerobic culture | Culture and microscopy: Method as documented in MIC-MTH-BAC-R01 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Urine | Culture and antimicrobial sensitivity test for urinary pathogens by Standard loop method and aerobic culture | Culture: Method as documented in MIC-MTH-BAC-U01 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | Suprapubic urine | Culture and antimicrobial sensitivity test for specific urinary pathogens or those with clinical indications by Aerobic and anaerobic culture | Culture: Method as documented in MIC-MTH-BAC-U01 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |

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| Clinical Microbiology and Infection (cont'd) | Bacteriology – Culture and sensitivity tests and/or microscopy (cont'd) Clinical isolates | Identification of clinical isolates by <ul style="list-style-type: none"> Conventional biochemical tests Nucleic Acid Amplification and DNA Sequencing (Target region: 16S rRNA) MALDI-TOF Mass Spectrometry Antimicrobial susceptibility test for clinical isolates by Gradient MIC strip Antimicrobial susceptibility test for clinical isolates by broth micro-dilution MIC determination | Method as documented in MIC-MTH-BAC-ID3, MIC-MTH-MOL-PCR-NVP and MIC-MTH-MOL-PCR-NVP-OTH-RC2 - DNA sequencing using ABI 3730 or 3130xl Genetic Analyser Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST-DIL |
| | Bacteriology – Serology Urine | <i>Legionella pneumophila</i> serogroup 1 Antigen by Immunochromatographic assay | Binax NOW® Legionella Urinary Antigen Test |

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| Clinical Microbiology and Infection (cont'd) | Urinalysis and/or urine microscopy Urine | Urine formed elements by Microscopic examination with fixed volume in microtitre plate well | Method as documented in MIC-MTH-BAC-U01 |

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| Clinical Microbiology and Infection | Bacteriology – Serology <i>Salmonella</i> isolates | Serotyping of <i>Salmonella</i> species by - Slide agglutination test - Microsphere-based molecular serotyping assay Target region: genes involved in the expression of serotype-specific antigens | Method as documented in MIC-MTH-CMI-SE1 xMAP® <i>Salmonella</i> Serotyping Assay Kit as documented in MIC-MTH-SPI-SAL |
| | <i>Streptococcus pneumoniae</i> isolates | Serotyping of <i>Streptococcus pneumoniae</i> by - Capsular reaction test - Multiplex real-time polymerase chain reaction Target region: genes of capsule locus | Method as documented in MIC-MTH-CMI-SE2 Nucleic acid extraction by in-house method as documented in MIC-MTH-MOL-EXT Amplification and detection by ABI 7500 Fast/QS7 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-NVP and MIC-MTH-MOL-PCR-NVP-GPB-RC1 |
| | Mycology – Culture, ID and Serology Dermatological samples (including skin, nail, hair specimens, etc.) | Culture for dermatophytes and pathogenic mould and yeast by Aerobic culture | Method as documented in MIC-MTH-CMI-MY1 |
| | Respiratory samples | Culture for fungi by Aerobic culture | Method as documented in MIC-MTH-CMI-MY2 |
| | Tissue and body fluid | Culture for fungi by Aerobic culture | Method as documented in MIC-MTH-CMI-MY2 |
| | Fungal isolates | Identification of dermatophytes, pathogenic mould and yeast by conventional identification tests, test kits for fungi and molecular testing using rRNA gene sequencing | Identification of dermatophytes and moulds: Method as documented in MIC-MTH-CMI-MY4 Identification of yeasts: Method as documented in MIC-MTH-CMI-MY5 |

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| Clinical Microbiology and Infection (cont'd) | Mycology – Microscopy Dermatological samples (including skin, nail, hair specimens, etc.) | Microscopy for fungal elements and yeast by KOH with Chlorazol Black smear | Method as documented in MIC-MTH-CMI-MY1 |
| | Respiratory samples | Microscopy for fungal elements and yeast by KOH with Chlorazol Black smear | Method as documented in MIC-MTH-CMI-MY2 |
| | Tissue and body fluid | Microscopy for - fungal elements and yeast by KOH with Chlorazol Black smear - <i>Cryptococcus neoformans</i> (only for CSF) by India ink smear | Method as documented in MIC-MTH-CMI-MY2 |
| | Bacteriology – Culture and sensitivity tests Enteric samples (stool and rectal swab) | Culture and antimicrobial susceptibility test for enteric pathogens by Aerobic and microaerophilic culture | Culture: Method as documented in MIC-MTH-CMI-EC1 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST |
| | | Culture and antimicrobial susceptibility test for specific pathogens or those with clinical indications by Aerobic culture ▪ <i>Escherichia coli</i> O157 ▪ <i>Yersinia</i> species ▪ <i>Listeria monocytogenes</i> ▪ <i>Staphylococcus aureus</i> ▪ <i>Bacillus cereus</i> ▪ <i>Vancomycin Resistant Enterococcus</i> ▪ <i>Carbapenem Resistant Enterobacteriaceae</i> <i>Clostridium perfringens</i> spore count by Anaerobic culture | Culture: Method as documented in MIC-MTH-CMI-EC1 Identification of isolates: Method as documented in MIC-MTH-BAC-ID3 Antimicrobial susceptibility tests: Method as documented in MIC-MTH-BAC-AST Method as documented in MIC-MTH-CMI-EC1 |

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| Clinical Microbiology and Infection (cont'd) | Microbiology – Miscellaneous tests Autoclave biological indicator | Processing of autoclave biological indicator | Method as documented in MIC-MTH-CMI-SPO |
| | Parasitology Stool | Microscopy for enteric parasites by - Direct wet smear - Smear after concentration | Method as documented in MIC-MTH-CMI-EP1 |
| | | Microscopy for <i>Cryptosporidium</i> , <i>Isospora</i> and <i>Cyclospora</i> oocytes by Modified Ziehl Neelsen with iron haematoxylin staining | Method as documented in MIC-MTH-CMI-EP1 |
| | | Identification of intestinal protozoa parasites by Modified Ziehl Neelsen with iron haematoxylin staining | Method as documented in MIC-MTH-CMI-EP1 |
| | Urine and sputum | Microscopy for parasites by Smear after concentration | Method as documented in MIC-MTH-CMI-EP2 |
| | Skin and hair | Microscopy for parasites by Direct smear | Method as documented in MIC-MTH-CMI-EP2 |
| | Blood | Microscopy for Malaria Parasites by - thin smear and Giemsa stain at pH7.2 - thick smear and Giemsa stain at pH7.2 | Method as documented in MIC-MTH-CMI-MA1 |

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| Clinical Microbiology and Infection | Syphilis serology Serum | <i>Treponema pallidum</i> antibody by - Fluorescent treponemal antibody- absorption test (FTA-ABS) - <i>Treponema pallidum</i> Passive Particle Agglutination test (TPPA) | Immuno Diagnostics AccuDiag FTA-ABS (Syphilis) IFA Method as documented in MIC-MTH-ASE-SYP-TPA |
| | Serum and CSF | Reagin antibodies in response to <i>Treponema</i> infection by Venereal Disease Research Laboratory test (VDRL) | Method as documented in MIC-MTH-ASE-SYP-VDR |
| | Virology – Serology Serum | Adenovirus antibody by Complement fixation test | Method as documented in MIC-MTH-CSE-CFT |
| | | Coxsackie B virus antibody by Neutralisation test | Method as documented in MIC-MTH-CSE-ENT |
| | | Cytomegalovirus antibody by Complement fixation test | Method as documented in MIC-MTH-CSE-CFT |
| | | Dengue virus antibody by Haemagglutination inhibition test Immunoassay (enzyme-based label) (IgM) | Method as documented in MIC-MTH-CSE-DJE-HAI InBios DENV Detect IgM Capture ELISA Abbott Bioline Dengue IgM Capture ELISA |
| | | Dengue virus antigen by Immunoassay (NS1 Ag) | BIORAD PLATELIA Dengue NS1 Ag |
| | | Epstein-Barr virus antibody by Indirect immunofluorescence test (anti-EBV Viral Capsid Antigen (VCA) IgG) | Method as documented in MIC-MTH-CSE-EBV using in-house prepared EBV VCA smears |
| | | Indirect immunofluorescence test (anti-EBV Viral Capsid Antigen (VCA) IgA) | Method as documented in MIC-MTH-CSE-EBV using in-house prepared EBV VCA smears |
| | | Indirect immunofluorescence test (anti-EBV Viral Capsid Antigen (VCA) IgM) | Method as documented in MIC-MTH-CSE-EBV using in-house prepared EBV VCA smears |

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| Clinical Microbiology and Infection (cont'd) | Virology – Serology (cont'd) Serum (cont'd) | Hantavirus antibody by Indirect immunofluorescence test (Polyvalent) Indirect immunofluorescence test (IgM) | Method as documented in MIC-MTH-CSE-HAN using in-house prepared Hantavirus infected Vero E6 cell smears |
| | | Herpes simplex virus antibody by Complement fixation test | Method as documented in MIC-MTH-CSE-CFT |
| | | Japanese encephalitis (JE) virus antibody by Haemagglutination inhibition test Immunoassay (enzyme-based label) (IgM) | Method as documented in MIC-MTH-CSE-DJE-HAI InBios JE Detect IgM Capture ELISA |
| | | Measles virus antibody by Complement fixation test Enzyme-linked Fluorescent Assay (ELFA) (IgG) Immunoassay (enzyme-based label) (IgM) | Method as documented in MIC-MTH-CSE-CFT bioMérieux VIDAS Measles IgG assay Microimmune Measles IgM Kit |
| | | Mumps virus antibody by Complement Fixation Test Enzyme-linked Fluorescent Assay (ELFA) (IgG) Immunoassay (enzyme-based label) (IgM) | Method as documented in MIC-MTH-CSE-CFT bioMérieux VIDAS Mumps IgG assay Microimmune Mumps IgM Kit |
| | | Polio virus antibody by Neutralisation test | Method as documented in MIC-MTH-CSE-ENT |
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| Clinical Microbiology and Infection (cont'd) | Virology – Serology (cont'd) Serum (cont'd) | Rabies virus antibody by Immunoassay (enzyme-based label) (IgG) Rubella virus antibody by Haemagglutination inhibition test (IgG) Enzyme-linked Fluorescent Assay (ELFA) (IgM) Immunoassay (enzyme-based label) (IgM) Varicella zoster virus antibody by Complement fixation test Enzyme-linked Fluorescent Assay (ELFA) (IgG) | Platelia Rabies II Kit Method as documented in MIC-MTH-CSE-RUH bioMérieux VIDAS RUB IgM Assay Microimmune Rubella IgM capture EIA Method as documented in MIC-MTH-CSE-CFT bioMérieux VIDAS Varicella-zoster IgG Assay |

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| Clinical Microbiology and Infection (cont'd) | Bacteriology – Serology Serum | <i>Borrelia burgdorferi</i> antibody by Western Blot (IgG) Western Blot (IgM) <i>Leptospira</i> antibody by Immunoassay (enzyme-based label) (IgM) <i>Leptospira</i> antibody titre by Microscopic agglutination test Scrub typhus group antibody by Indirect immunofluorescence test Spotted fever group antibody by Indirect immunofluorescence test Typhus group antibody by Indirect immunofluorescence test | Euroimmun Anti-Borrelia EUROLINE-RN-AT (IgG) Euroimmun Anti-Borrelia EUROLINE-RN-AT (IgM) Abbott Panbio Leptospira IgM ELISA Method as documented in MIC-MTH-CSE-LAT Method as documented in MIC-MTH-CSE-RIO-IFA using Australian Rickettsial Reference Laboratory IFA slides for anti- <i>Orientia tsutsugamushi</i> Method as documented in MIC-MTH-CSE-RIO-IFA using Australian Rickettsial Reference Laboratory IFA slides for anti-Rickettsia species of spotted fever group Method as documented in MIC-MTH-CSE-RIO-IFA using Australian Rickettsial Reference Laboratory IFA slides for anti-Rickettsia species of Typhus group |
| | Mycology – Serology Serum | Cryptococcal antigen by - Qualitative latex agglutination test - Quantitative latex agglutination test | Meridian Bioscience Cryptococcal Antigen Latex Agglutination System (CALAS) |

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| Clinical Microbiology and Infection (cont'd) | Parasitology – Serology Serum | <i>Toxoplasma gondii</i> antibody by Enzyme-linked Fluorescent Assay (ELFA) (IgM) Enzyme-linked Fluorescent Assay (ELFA) (IgG) Immunoassay (enzyme-based label) (IgAGM) | bioMérieux VIDAS TOXO IgM Assay bioMérieux VIDAS TOXO IgG II Assay Euroimmun <i>Anti-Toxoplasma gondii</i> Screen ELISA (IgAGM) |

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| Clinical Microbiology and Infection (cont'd) | Viral culture and identification Miscellaneous specimens | Viruses – detection by culture for characteristic cytopathic effect using tube culture or shell vial culture in appropriate cell lines | Method as documented in MIC-MTH-VIR-CUL-IDV, MIC-MTH-VIR-CUL-FLU and MIC-MTH-VIR-CUL-CMV |

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| Clinical Microbiology and Infection | Molecular diagnosis Respiratory specimens | Detection of <i>Chlamydia pneumoniae</i> , <i>Chlamydia psittaci</i> and <i>Legionella pneumophila</i> Serogroup 1 by Multiplex real-time PCR Target region: CPN: MOMP gene Target region: CPS: 16S rRNA Target region: SG1: LPS gene | Multiplex real-time PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-NVP and MIC-MTH-MOL-PCR-ATP-RC1 |
| | | Detection of Picornavirus, Enterovirus type 71 and bovine viral diarrhoea virus (BVDV) by Respiratory Multiplex PCR F Target region: Picornavirus: 5'UTR Target region: EV71: VP1 Target region: BVDV: Npro | Multiplex one step real-time RT PCR using ABI QuantStudio 7 Flex - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-RVM-RC1 |
| | | Detection of Influenza A, B, C and Parainfluenza 1 by Respiratory Multiplex PCR A Target region: Influenza A: M gene Target region: Influenza B: HA gene Target region: Influenza C: NP gene Target region: Parainfluenza 1: HN gene | Multiplex one step real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-RVM-RC1 |
| | | Detection of Adenovirus, Influenza A H1pdm09 virus, Influenza A H3 and Parainfluenza 3 by Respiratory Multiplex PCR B Target region: Adenovirus: hexon gene Target region: Influenza A H1 pdm09: HA gene Target region: Influenza A H3: HA gene Target region: Parainfluenza 3: HN gene | Multiplex one step real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-RVM-RC1 |
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| Clinical Microbiology and Infection (cont'd) | Molecular diagnosis (cont'd) Respiratory specimens (cont'd) | Detection of Human metapneumovirus, Respiratory Syncytial virus, Parainfluenza 2 and Parainfluenza 4 by Respiratory Multiplex PCR C Target region: Human metapneumovirus: N gene Target region: RSV: N gene Target region: Parainfluenza 2: P gene Target region: Parainfluenza 4: NP gene | Multiplex one step real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-RVM-RC1 |
| | | Adenovirus type 1, 2 and 3 – Typing by Real-time polymerase chain reaction Target region: Hexon gene | Multiplex one step real-time PCR using Qiagen Rotor-Gene Q - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-ADN-RC1 |
| | | Adenovirus type 4, 5 and 7 – Typing by Real-time polymerase chain reaction Target region: Hexon gene | Multiplex one step real-time PCR using Qiagen Rotor-Gene Q - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-ADN-RC1 |
| | Serum | Rhinovirus – detection by Real-time reverse transcription polymerase chain reaction Target region: 5' UTR | Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-PIC-RC1 |
| | | Cytomegalovirus – detection by Real-time polymerase chain reaction Target region: MIE gene | PCR using Qiagen Rotor-Gene Q - <i>Primers, probe(s) and test conditions:</i> Watzinger F et al. Real-time Quantitative PCR Assays for Detection and Monitoring of Pathogenic Human Virus in Immuno-suppressed Paediatric Patients, Journal of Microbiology 2004; 42; 5189-5198. |

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| Clinical Microbiology and Infection (cont'd) | Molecular diagnosis (cont'd) Serum, faecal specimens, respiratory specimens, CSF | Enterovirus Type 71 (EV71) – detection by One-step real-time reverse transcription polymerase chain reaction Target region: VP1 gene | One-step real-time RT PCR using ABI QuantStudio 7 Flex and Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-PIC-RC1 |

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| Clinical Microbiology and Infection (cont'd) | Molecular diagnosis (cont'd) Respiratory specimens | <p>Influenza A virus – detection by Real-time reverse transcription polymerase chain reaction Target region: M gene</p> <p>Influenza A virus subtype H5 – detection by Real-time reverse transcription polymerase chain reaction Target region: H5 gene</p> <p>Influenza A virus subtype H1/H3 – detection by Multiplex real-time one-step RT-PCR Target region: H1 and H3 genes</p> <p>Influenza A virus subtype H7 and N9 – detection by Real-time reverse transcription polymerase chain reaction Target region: H7 and N9 genes</p> <p>Influenza A virus subtype H9 – detection by Real-time reverse transcription polymerase chain reaction Target region: H9 gene</p> | <p>Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> WHO information for Molecular diagnosis of influenza-update</p> <p>Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-FLU-RC1</p> <p>Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-FLU-RC1</p> <p>Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-FLU-RC1</p> |
| | Faecal specimens | <p>Norovirus/rotavirus – detection by Real-time reverse transcription polymerase chain reaction Target region: 5' of the VP1 capsid region</p> | <p>Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-VGE-RC1</p> |

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| Clinical Microbiology and Infection (cont'd) | Molecular diagnosis (cont'd) | | |
| | Serum, plasma and urine | Zika virus – detection and confirmation by Real-time reverse transcription polymerase chain reaction Target region: Envelope protein gene (detection) NS3 and 2K (confirmation) | Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-ARB-RC1 |
| | Serum | Parvovirus B19 – detection by Real-time polymerase chain reaction Target region: VP2 gene | Real-time RT PCR using Qiagen Rotor-Gene Q - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-MIS-RC1 |
| | | Rickettsia – detection by Polymerase chain reaction Target region: Rickettsial 16S ribosomal RNA | PCR - <i>Primer and test conditions:</i> Breitschwerdt EB et al. Efficacy of Doxycycline, Azithromycin, or Trovaflaxacin for treatment of experimental Rocky Mountain Spotted Fever in dogs. Antimicrobial Agents and Chemotherapy 1999; 43: 813-821. |
| | Respiratory specimens | Middle East Respiratory Syndrome - Coronavirus – detection by Real-time reverse transcription polymerase chain reaction Target region: ORF-1b / upE | Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-COR-RC1 |
| | | Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) - detection by Real-time reverse transcription polymerase chain reaction Target region: RdRp | Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-COR-RC1 |

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| Clinical Microbiology and Infection (cont'd) | Molecular diagnosis (cont'd) Respiratory specimens (cont'd) | Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) - detection by Urbani-aaa + NCOV2 Real-time reverse transcription polymerase chain reaction Target region: RdRp | Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-COR-RC1 |
| | | Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) - detection by NCOV10 Real-time reverse transcription polymerase chain reaction Target region: RdRp | Real-time RT PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-COR-RC1 |

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| Clinical Microbiology and Infection (cont'd) | Molecular diagnosis (cont'd) | | |
| | Stool | Shiga toxin gene – detection by Real-time polymerase chain reaction Target region: <i>stx1</i> and <i>stx2</i> | Real-time PCR using ABI 7500 Fast / QuantStudio 7 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-NVP and MIC-MTH-MOL-PCR-NVP-GN1-RC1 |
| | Nasopharyngeal/pernasal swab | <i>Bordetella pertussis</i> – detection by Real-time polymerase chain reaction Target region: <i>IS481</i> and <i>ptp</i> | Real-time PCR using ABI 7500 Fast / QuantStudio 7 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-NVP and MIC-MTH-MOL-PCR-NVP-GN2-RC1 |
| | Bacterial isolates | Community-associated methicillin resistant <i>Staphylococcus aureus</i> – detection by Real-time polymerase chain reaction Target region: <i>mecA</i> and <i>pvl</i> | Nucleic acid extraction by in-house method as documented in MIC-MTH-MOL-EXT Amplification and detection by ABI 7500 Fast/QS7 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-NVP and MIC-MTH-MOL-PCR-NVP-GPB-RC1 |
| | Genital, vesicular and skin specimens | Detection of Monkeypox virus by Real-time polymerase chain reaction Target region: B7R gene | PCR using Roche LightCycler 480 - <i>Primers, probe(s) and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-SPZ |

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| Clinical Microbiology and Infection (cont'd) | Molecular diagnosis (cont'd) | | |
| | Male urethral swab | <i>Chlamydia trachomatis</i> – detection by Nucleic acid amplification and hybridization, qualitative Target region: 23S rRNA | Nucleic acid extraction, amplification and detection by PANTHER using APTIMA Combo 2 Assay |
| | | <i>Neisseria gonorrhoeae</i> – detection by Nucleic acid amplification and hybridization, qualitative Target region: 16S rRNA | Nucleic acid extraction, amplification and detection by PANTHER using APTIMA Combo 2 Assay |
| | Urine and genital specimens | <i>Chlamydia trachomatis</i> / <i>Neisseria gonorrhoeae</i> detection by Real-time polymerase chain reaction, qualitative Target region: cryptic plasmid and ompA gene for <i>Chlamydia trachomatis</i> and DR-9 region for <i>Neisseria gonorrhoeae</i> | Nucleic acid extraction, amplification and detection by COBAS 6800 using cobas CT/NG assay |
| | Respiratory specimens | Adenovirus typing by Polymerase chain reaction followed by DNA sequencing Target region: Hexon gene | PCR and sequencing of PCR product - <i>Primer and test conditions</i> : Crawford-Miksz L K et al. Strain variation in Adenovirus serotypes 4 and 7a causing acute respiratory disease. Journal of Clinical Microbiology 1999; 37: 1107-1112. - DNA sequencing using ABI 3730 or 3130xl Genetic Analyser |

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| Clinical Microbiology and Infection (cont'd) | Molecular diagnosis (cont'd) Serum, faecal specimens, respiratory specimens, CSF | Enterovirus typing by Reverse transcription polymerase chain reaction and DNA sequencing Target region: VP1 gene | RT PCR and sequencing of PCR product - <i>Primer and test conditions:</i> Oberste, M.S., K. Maher, D.R. Kilpatrick, M.R. Flemister, B.A. Brown, and M.A.Pallansch. Typing of human enteroviruses by partial sequencing of VP1. J Clin. Microbiol. 1999; 37:1288-1293. - DNA sequencing using ABI 3730 or 3130xl Genetic Analyser |
| | Serum and plasma | Hepatitis C virus – detection and genotyping by Reverse Transcription Nested Polymerase Chain Reaction and sequencing of PCR Product Target region: 5' UTR (untranslated region) | Nested RT PCR and sequencing - <i>Primer and test conditions:</i> Mellor J, et al. Analysis of a new hepatitis C virus type and its phylogenetic relationship to existing variants. Journal of General Virology 1992;73: 1131-1141. - DNA sequencing using ABI 3730 or 3130xl Genetic Analyser |
| | | Target region: NS5B gene | Conventional RT-PCR and sequencing - <i>Primer and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-HEP-RC1 - DNA sequencing using ABI 3730 Genetic Analyser |

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| Clinical Microbiology and Infection (cont'd) | Molecular diagnosis (cont'd) | | |
| | Plasma | Human immunodeficiency virus - antiviral resistance testing by DNA sequencing Target region: pol region of HIV-1 genome | RT PCR: - <i>Primer and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-VLS and MIC-MTH-MOL-PCR-HIV-RC1 - DNA sequencing using ABI 3730 or 3130xl Genetic Analyser |
| | Plasma and serum | Hepatitis B virus viral load - quantitative determination of DNA by Real-time polymerase chain reaction Target region: pre-core and core gene Hepatitis C virus viral load - quantitative determination of RNA by Real-time reverse transcription polymerase chain reaction Target region: 5'NTR | Nucleic acid extraction, amplification and detection by COBAS 6800 using cobas® HBV Nucleic acid extraction, amplification and detection by COBAS 6800 using cobas® HCV |
| | Plasma | Human immunodeficiency virus viral load - quantitative determination of RNA by Real-time reverse transcription polymerase chain reaction Target region: gag and LTR regions of HIV-1 | Nucleic acid extraction, amplification and detection by COBAS 6800 using cobas® HIV-1 |

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| Clinical Microbiology and Infection | Mycobacteriology – Microscopy Respiratory and miscellaneous specimens | Microscopy for acid-fast bacilli (AFB) by - Auramine O fluorescent stain - Ziehl-Neelsen stain | Method as documented in MIC-MTH-TBL-AFS |
| | Mycobacteriology – Culture Respiratory specimens and urine | Culture for acid-fast bacilli (AFB) by Aerobic broth culture | Method as documented in MIC-MTH-TBL-CUL using BACTEC MGIT 960 |
| | Miscellaneous specimens | Culture for acid-fast bacilli (AFB) by Aerobic broth culture | Method as documented in MIC-MTH-TBL-CUL using BACTEC MGIT 960 |
| | Stool | Culture for acid-fast bacilli (AFB) by Aerobic broth culture | Method as documented in MIC-MTH-TBL-CUL using BACTEC MGIT 960 |

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| Clinical Microbiology and Infection (cont'd) | Mycobacteriology – Identification and/or sensitivity test <i>Mycobacterium</i> isolates | <p>Identification of <i>Mycobacterium</i> species in positive cultures by</p> <p>Conventional identification method</p> <p>Immunochromatographic method</p> <p>MALDI-TOF Mass Spectrometry</p> <p>Molecular method</p> <p>- Polymerase chain reaction (PCR) and real-time polymerase chain reaction for differentiation of <i>Mycobacterium tuberculosis</i> complex</p> <p>Target region: region of difference [RD]</p> <p>- Real-time polymerase chain reaction</p> <p>Target region: 16S rDNA and HSP</p> | <p>Method as documented in MIC-MTH-TBL-MID</p> <p>Abbott BIOLINE TB Ag MPT 64 Rapid kit</p> <p>Method as documented in MIC-MTH-BAC-BBT</p> <p>Nucleic acid extraction by in-house method as documented in MIC-MTH-TBL-MID</p> <p>Amplification and detection by QS7</p> <p>- <i>Primer and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-NVP and MIC-MTH-MOL-PCR-NVP-OTH-RC1</p> <p>Nucleic acid extraction by in-house method as documented in MIC-MTH-TBL-MID</p> <p>Amplification and detection by ABI 7500 Fast System/ QS7</p> <p>- <i>Primer, probe and test conditions:</i> In-house method as documented in MIC-MTH-MOL-PCR-NVP and MIC-MTH-MOL-PCR-NVP-OTH-RC1</p> |

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| Clinical Microbiology and Infection (cont'd) | Mycobacteriology – Identification and/or sensitivity test (cont'd) <i>M. tuberculosis</i> complex isolates | Antimicrobial susceptibility test by - MGIT method | Methods as documented in MIC-MTH-TBL-TST |
| | <i>M. kansasii</i> / <i>M. marinum</i> Isolates / Mycobacterium Rapid growers / <i>M. avium</i> complex isolates / aerobic actinomycetes | Antimicrobial susceptibility test by SENSITITRE - Rapidly growing nontuberculous Mycobacteria MIC plate SENSITITRE - Slowly growing nontuberculous Mycobacteria MIC plate | Methods as documented in MIC-MTH-TBL-NST |

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| PROVISION OF PROFICIENCY TESTING SCHEMES 提供能力驗證 | | |
|---|---|--|
| PROFICIENCY TESTING SCHEME AND ITEM 能力驗證計劃及項目 | MEASURAND OR CHARACTERISTIC MEASURED 測試參數或特質 | PROFICIENCY TESTING SCHEME PROCEDURE# 能力驗證計劃程序 |
| Proficiency Testing Scheme for Medical Testing: | | |
| WHO Influenza viruses / SARS-CoV-2 <ul style="list-style-type: none"> Dried RNA (Influenza viruses only) Inactivated viruses | Detection of Influenza viruses or SARS-CoV-2 by Polymerase chain reaction | As documented in MIC-PTP-MOL-WHO-COM and MIC-PTP-MOL-WHO-PRE |
| Acid Fast Bacillus Microscopy (AFB) <ul style="list-style-type: none"> Fixed sputum smear | Detection of acid fast bacillus by Acid fast staining and microscopic examination | As documented in MIC-PTP-TBL-AFB-PRE |
| Bacteriology (BAC) <ul style="list-style-type: none"> Simulated clinical specimens (lyophilized cultures) | Identification of potential pathogens and antimicrobial susceptibility testing | As documented in MIC-PTP-BAC-BAC-PRE |
| Blood-borne Parasite Detection (BPD) <ul style="list-style-type: none"> Fixed blood smears or blood specimens | Detection of blood-borne parasite and reporting of parasite density by Microscopic examination | As documented in MIC-PTP-CMI-BPD-PRE |
| Microbial Serology (MS) <ul style="list-style-type: none"> Simulated plasma or serum specimens <ol style="list-style-type: none"> Syphilis Serology (SSY) Human immunodeficiency virus (HIV) Serology (SHV) Hepatitis B virus (HBV) Serology (SHB) Hepatitis C virus (HCV) Serology (SHC) | <i>Treponema pallidum</i> total antibody by Enzyme immunoassay HIV antibody, qualitative HBsAg, qualitative HCV antibody, qualitative | As documented in MIC-PTP-ASE-MIS-PRE |
| Viral Nucleic Acid Testing (VNAT) <ul style="list-style-type: none"> Simulated plasma specimens Hepatitis B Virus DNA Quantification (HBQ) | HBV DNA quantification by Real-time polymerase chain reaction | As documented in MIC-PTP-SPI-NAT-PRE |

INCLUDING PROCEDURES FOR DETERMINING ASSIGNED VALUES AND THE UNCERTAINTY