

As an accredited laboratory, this laboratory is entitled to use the following accreditation symbol.



Valid from 18 January 2022
to 17 January 2025
Issued on 25 January 2022



ISO 15189
ML 037-01

Schedule of Accreditation

Accreditation Scheme for Medical/Clinical Laboratories
Sri Lanka Accreditation Board for Conformity Assessment
Accreditation Number: ML 037-01

**Clinical Bacteriology Laboratory, Medical Research Institute,
Colombo 08**

Scope of Accreditation: Performing Medical/Clinical testing under the fields of Molecular Biology, Microbiology and Serology

The laboratory is accredited for the following tests.

| Sl | Field of Testing | Test | Test Method | Test Instrument | Reference range /Detection Limit |
|----|------------------|---|---|---------------------|--|
| 1 | Bacteriology | Gram stain | Microscopic Gram staining method | Microscope | Presence/ absence of pus cells, epithelial cells and organisms |
| 2 | | Aerobic culture identification Blood | By Fluorometry on BACTEC | BD BACTEC FX 200 | Positive / Negative |
| 3 | | Aerobic culture identification and antimicrobial susceptibility testing Sterile fluids | Identification by conventional method; differential and selective culture media, Biochemical/ Morphological/ Microscopical Identification | Incubator Manual | |
| 4 | | Aerobic culture identification and antimicrobial susceptibility testing CSF | | BD Phoenix® 100 | |

| Sl | Field of Testing | Test | Test Method | Test Instrument | Reference range /Detection Limit | | |
|----|------------------|---|---|--|---|--|--|
| 5 | Bacteriology | Aerobic culture identification and antimicrobial susceptibility Testing Wound swab / pus / discharge /tissue | Identification by conventional method; differential and selective culture media, Biochemical/ Morphological/ Microscopical Identification | Incubator Manual BD Phoenix® 100 | Positive / Negative | | |
| 6 | | Aerobic culture identification and antimicrobial susceptibility testing Bronchoalveolar lavage | *Antimicrobial Susceptibility Testing (AST) by CLSI guidelines: Method by CLSI M07, 11 th Ed. 2018 M02, 13 th ed. 2018 Interpretation by CLSI M100 31 st Ed. 2021 M45 3 rd Ed. 2016 | | | | |
| 7 | | Aerobic culture identification and antimicrobial susceptibility testing Throat swab | | | Identification by; Automated Fluorometry | Pathogens present / pathogens absent / no growth | |
| 8 | | Aerobic culture identification and antimicrobial susceptibility testing Sputum | | | Manual | Positive / Negative | |
| 9 | | Aerobic culture identification and antimicrobial susceptibility testing Urine | | | BD Phoenix® 100 | Significant result /(<10 ³) Insignificant result/ No growth | |
| 10 | | Aerobic culture identification and antimicrobial susceptibility testing CVP catheter tip | | | Manual | No growth / Insignificant growth / significant growth | |
| 11 | | Aerobic culture identification and antimicrobial susceptibility testing Eye swab | | | Manual | No growth / Growth present | |
| 12 | | Aerobic culture Identification from clinical isolates and other sources | | | Identification by conventional method; differential and selective culture media, Biochemical/ Morphological/ Microscopical Identification | Manual | Positive / Negative |
| 13 | | Aerobic culture Identification from clinical isolates and other sources | | | Identification by; Automated fluorogenic and chromogenic | BD Phoenix® 100 | Identified / Not identified |
| 14 | | <i>S. aureus</i> screening swabs | | | Identification by conventional method; differential and selective culture | Manual | <i>S. aureus</i> / MRSA isolated, <i>S. aureus</i> not |

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|----|--|---|--|--|--|
| | | | media, Biochemical/ Morphological/ Microscopical Identification | | isolated or No growth |
| 15 | Bacteriology | <i>Leptospira</i> culture | Conventional by semisolid and broth media | Manual | <i>Growth present</i> / <i>No growth</i> |
| 16 | | Bacterial culture Antimicrobial Susceptibility Test (AST) | Disk diffusion method *CLSI | | Susceptible / Intermediate / Resistant |
| 17 | | Bacterial culture Antimicrobial Susceptibility Test (AST) MIC | E test method *CLSI | | Susceptible / Intermediate / Resistant / Nonsusceptible |
| 18 | | Bacterial culture Antimicrobial Susceptibility Test (AST) MIC | Automated MIC *CLSI | BD Phoenix® 100 | Susceptible / Intermediate / Resistant / Nonsusceptible |
| 19 | | Bacterial culture Antimicrobial Susceptibility Test (AST) MIC | Broth dilution method *CLSI | Manual | Susceptible / Intermediate / Resistant / Nonsusceptible |
| 20 | | Bacterial culture Cabapenemases detection | Modified Hodge test *CLSI | | Present / absent |
| 21 | Serology | Bacterial Antigen detection | Particle agglutination | | Positive / Negative |
| 22 | | <i>Mycoplasma</i> antibody detection | | | Negative Equivocal Significant |
| 23 | | <i>Leptospira</i> Antibody detection | Microscopic Agglutination Test (MAT) | Microscope | Negative Insignificant Equivocal Significant |
| 24 | Molecular Biology in Infectious Diseases | Aerobic culture Identification from clinical isolates and other sources | Identification by; Gene detection | Rotor Gene Q Series Realtime PCR | Detected / Not detected |
| 25 | | ESBL resistance gene detection | Molecular assay | | Clinical sensitivity & specificity 99.9% & 99.5% |
| 26 | | Carbapenem resistance gene detection | | | |

| SI | Field of Testing | Test | Test Method | Test Instrument | Reference range /Detection Limit |
|----|--|--|---|--|---|
| 27 | Molecular Biology in Infectious Diseases | AmpC resistance gene detection | Molecular assay | | |
| 28 | | <i>mecA</i> gene detection in <i>S. aureus</i> | | | <i>mecA</i> gene 40 gene copies |
| 29 | | <i>S. aureus</i> gene detection | | Rotor Gene Q Series Realtime PCR | <i>S. aureus</i> ≥100 gene copies |
| 30 | | PVL gene detection in <i>S. aureus</i> | | | Species: 100 genome copies, PVL gene 20 genome copies |
| 31 | | <i>Brucella</i> gene detection | | 500 genome copies/mL | |
| 32 | | **Pathogenic <i>Leptospira</i> gene detection | Molecular assay In-house, validated | Rotor Gene Q Series Realtime PCR, In house | Blood 5 genome copies /mL Urine 8 genome copies /mL |
| 33 | | Detection of DNA <i>Bordetella pertussis</i> , <i>B. parapertussis</i> | Molecular assay Method 1 Method 2 | Rotor Gene Q Series Realtime PCR Multiplex | <i>B.pertussis</i> 0.74 genome copies, <i>B.parapertussis</i> 0.60 genome copies ≥ 10 DNA copies / reaction |
| 34 | | <i>Streptococcus pneumoniae</i> DNA detection | Molecular assay | Rotor Gene Q series Realtime PCR | ≥10 DNA copies per reaction |
| 35 | | <i>Neisseria meningitidis</i> DNA detection | | | |
| 36 | | <i>H. influenzae</i> DNA detection | | | |