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

Valid from 06 March 2024
to 17 January 2025
Issued on 06 March 2024

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 BD Phoenix® 100	
4		Aerobic culture identification and antimicrobial susceptibility testing CSF			

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

Sl	Field of Testing	Test	Test Method	Test Instrument	Reference range /Detection Limit
			media, Biochemical/ Morphological/ Microscopical Identification		isolated or No growth
15	Bacteriology	*Leptospira* culture	Conventional by semisolid and broth media	Manual	*Growth present / No growth*
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	MCIM *CLSI		Present / absent
21	Serology	*Mycoplasma* antibody detection	Particle agglutination		Negative Equivocal Significant
22					
23		*Leptospira* 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			
27	Molecular Biology in	AmpC resistance gene detection	Molecular assay		

Sl	Field of Testing	Test	Test Method	Test Instrument	Reference range /Detection Limit
28	Infectious Diseases	mecA gene detection in *S. aureus*			mecA gene 40 gene copies
29		*S. aureus* gene detection		Rotor Gene Q Series Realtime PCR	*S. aureus* ≥100 gene copies
30		PVL gene detection in *S. aureus*			Species: 100 genome copies, PVL gene 20 genome copies
31		*Brucella* gene detection			500 genome copies/mL
32		**Pathogenic *Leptospira* 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 *Bordetella pertussis, B. parapertusis*	Molecular assay Method 1 Method 2	Rotor Gene Q Series Realtime PCR Multiplex	*B.pertusis* 0.74 genome copies, *B.parapertusis* 0.60 genome copies ≥ 10 DNA copies / reaction
34		*Streptococcus pneumoniae* DNA detection	Molecular assay	Rotor Gene Q series Realtime PCR	≥10 DNA copies per reaction
35		*Neisseria meningitidis* DNA detection			
36		*H. influenzae* DNA detection			

Director/CEO
Sri Lanka Accreditation Board for Conformity Assessment
Colombo, Sri Lanka