



Valid from 19 June 2023  
to 17 January 2025  
Issued on 19 June 2023

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



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, 11 <sup>th</sup> Ed. 2018 M02, 13th ed. 2018  Interpretation by CLSI M100 31 <sup>st</sup> Ed. 2021 M45 3 <sup>rd</sup> Ed. 2016		
7		Aerobic culture identification and antimicrobial susceptibility testing Throat swab			Pathogens present / pathogens absent / no growth
8		Aerobic culture identification and antimicrobial susceptibility testing Sputum			Positive / Negative
9		Aerobic culture identification and antimicrobial susceptibility testing Urine			Significant result /(<10 <sup>3</sup> ) Insignificant result/ No growth
10		Aerobic culture identification and antimicrobial susceptibility testing CVP catheter tip			No growth / Insignificant growth / significant growth
11		Aerobic culture identification and antimicrobial susceptibility testing Eye swab	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

SI	Field of Testing	Test	Test Method	Test Instrument	Reference range /Detection Limit
			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	MCIM *CLSI		Present / absent
21	Serology	Bacterial Antigen detection	Particle agglutination	Microscope	Positive / Negative
22		<i>Mycoplasma</i> antibody detection			Negative Equivocal Significant
23		<i>Leptospira</i> Antibody detection	Microscopic Agglutination Test (MAT)		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		mecA gene detection in <i>S. aureus</i>			mecA 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. paraptensis</i>	Molecular assay Method 1 Method 2	Rotor Gene Q Series Realtime PCR Multiplex	<i>B.pertussis</i> 0.74 genome copies, <i>B.paraptensis</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			