

Valid from 18 January 2025 to 17 January 2029 Issued on 22 September 2025



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	Linearity range
1	Bacteriology/ Serology	Gram stain Sterile fluids, CSF/ wound swab/ pus/ discharge/ tissue/ lower respiratory specimens/ throat swab/ urine/ eye and ear discharge/ isolates/ bone marrow	Microscopic Gram staining method	Microscope	Presence or absence of pus cells/ epithelial cells/ organisms
2		Aerobic culture isolation Blood, bone marrow, sterile fluid	By Fluorometry on BACTEC	BD BACTEC FX 200	Positive/ Negative
3		Aerobic culture isolation, identification and antimicrobial susceptibility testing Sterile fluids/ CSF/ wound swab/ pus/ discharge/ tissue/ lower respiratory specimens/ throat swab/ urine/ eye and ear discharge	Conventional method; differential and selective culture media, Biochemical/ Morphological/ Microscopical Identification	Manual Incubator	Positive/ Negative
			Automated fluorometry *Antimicrobial Susceptibility Testing (AST) by CLSI	BD Phoenix® 100	Susceptible/ Intermediate/ Resistant/ Non- susceptible
4		Aerobic culture isolation, identification and antimicrobial susceptibility testing - CVP catheter tip	Manual	Manual Incubator	No growth Insignificant growth/ significant growth
5		Aerobic culture Identification from clinical isolates and other sources	Identification by; Automated fluorogenic and chromogenic	BD Phoenix® 100	Confirmed/ Not identified

Sl	Field of Testing	Test	Test Method	Test Instrument	Linearity range
6	Bacteriology/ Serology	S. aureus screening swabs Nasal, perineum, throat, axillae, wound swab/s	Conventional method; differential and selective culture media, Biochemical/ Morphology/ Microscopic identification	Manual Incubator	S. aureus/ MRSA isolated S. aureus not isolated No growth
7		Bacterial culture Cabapenemas es detection	mCIM by CLSI	Manual Incubator	Present / absent
8		Leptospira Culture Blood	Conventional by semisolid and broth media	Manual Incubator	Growth present / No growth
9		Antimicrobial Susceptibility Test (AST) Isolate blood	Disk diffusion method CLSI	Manual Incubator	Susceptible/ Intermediate/ Resistant/Non- susceptible
10		Antimicrobial Susceptibility Test (AST) MIC Isolate	E test method CLSI	Manual Incubator	Susceptible/ Intermediate/ Resistant / Non- susceptible
11		Antimicrobial Susceptibility Test (AST) MIC Isolate	Automated MIC CLSI	BD Phoenix® 100	Susceptible/ Intermediate/ Resistant / Non- susceptible
12		Antimicrobial Susceptibility Test	Agar dilution	Manual Incubator	\leq 0.25 to \geq 128 µg/mL
		(AST) Minimum Inhibitory Concentration Isolate	Broth dilution	Manual Incubator	≤ 0.001 to ≥64 μg/mL
13		Mycoplasma antibody detection Blood/ serum	Particle agglutination		Negative/ Equivocal/ Significant
14		Leptospira Antibody detection Blood/ serum	Microscopic Agglutination Test (MAT)		Negative Insignificant Equivocal/ Significant

Sl	Field of testing	Test	Test Method	Test Instrument	Linearity range
01	Molecular Biology	Detection of DNA Bordetella pertussis, B. parapertusis Blood/ serum/ Isolate	Molecular assay Method 1	Realtime PCR Multiplex	B.pertusis 0.74 genome copies, B.parapertusis 0.60 genome copies
		Broom seram Isolate	Method 2		≥ 10 DNA copies / reaction
02		Streptococcus pneumoniae DNA detection Blood/ serum/ Isolate	Molecular assay	Realtime PCR	≥10 DNA copies per reaction
03		Neisseria meningitidis DNA detection Blood/ serum/ Isolate	Molecular assay	Realtime PCR	≥10 DNA copies per reaction
04		H. influenzae DNA detection Blood/ serum/ Isolate	Molecular assay	Realtime PCR	≥10 DNA copies per reaction

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