



Valid from 25 April 2022
to 24 April 2025
Issued on 24 May 2022

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



ISO 15189
ML 007-01

Schedule of Accreditation

Accreditation Scheme for Medical/Clinical Laboratories
Sri Lanka Accreditation Board for Conformity Assessment

Accreditation Number: ML 007-01

Genetech Molecular Diagnostics
No. 54, Kitulwatta Road,
Colombo 08

Scope of Accreditation: Performing Medical tests on Molecular Biology (Infectious Disease Diagnostics, Cancer markers and DNA typing)

The laboratory is accredited for the following tests.

Sl	Field of Testing	Test	Test Method	Test Instrument	Reference range / Detection Limit
01	DNA Typing	Forensic DNA Typing	PCR, Genetic Analyzer	Vortex, Centrifuge, Dry bath, PCR machine, Electrophoretic Unit, Automated Genetic Analyzer	1 ng of genomic DNA
		Establishment of identity by DNA typing			
		Maternity testing (Mother and Child) by DNA typing			
		Paternity testing (Mother, Child and Putative father) by DNA typing			
02	Cancer Markers	Philadelphia chromosome (bcr-abl translocation) detection by PCR	RT-nested PCR, Agarose Gel Electrophoresis		One ph+ cell in a background of million normal cells

SI	Field of Testing	Test	Test Method	Test Instrument	Reference range / Detection Limit
03	Infectious Diseases	<i>Chikungunya</i> viral genome detection	RT- nested PCR, Agarose Gel Electrophoresis	Vortex, Centrifuge, Dry bath, PCR machine, Electrophoretic Unit, Automated Genetic Analyzer	≥ 1000 copies
		Dengue Viral genome detection	RT- PCR, Agarose Gel Electrophoresis		
		Hepatitis C viral genome detection	RT- PCR, Agarose Gel Electrophoresis		
		Hepatitis B viral genome detection	PCR, Agarose Gel Electrophoresis		≥ 100 copies
		<i>Human Papilloma</i> viral genome detection			
		<i>Mycobacterium tuberculosis</i> genome detection			
		<i>Plasmodium vivax</i> , <i>Plasmodium falciparum</i> genome detection			

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

Approved List of Sample Collection Centers

Genetech Molecular Diagnostics

No.	Location	Address	Matrix of the sample
01	Lanka Hospitals Ltd.	578, Elvitigala Mawatha, Narahenpita, Colombo 05.	Whole blood clotted blood swabs sputum stool urine CSF Bone marrow BAL Aspirates
02	Hemas Hospital – Wattala	389, Negombo Road, Wattala.	
03	Hemas Hospital, Thalawathugoda.	647/2a, Pannipitiya Road, Thalawathugoda.	
04	Nawaloka Hospital	23, Deshamanya, H K Dharmadasa Mawatha, 00200	

Director/CEO

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