



## 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	Linearity Range
01	DNA Typing	Forensic DNA Typing Establishment of identity by DNA typing Maternity testing (Mother and Child) by DNA typing Paternity testing (Mother, Child and Putative father) by DNA typing	PCR, Automated Fragment Analysis	PCR Machine, Genetic Analyzer	≥10 ng of genomic DNA

Sl	Field of Testing	Test	Test Method	Test Instrument	Linearity Range
02	Cancer Markers	Philadelphia chromosome (bcr-abl translocation) detection by RT-PCR	RT-nested PCR, Agarose Gel Electrophoresis	PCR Machine, Gel Electrophoresis Apparatus	One ph+ cell in a background of million normal cells
		Janus Kinase 2 gene, 1849G>T Point Mutation detection by PCR (p. V617F)	PCR, Agarose Gel Electrophoresis		2% in background of normal chromosomes
03	Infectious Diseases Diagnostics	Chikungunya viral genome detection by RT-PCR	RT- nested PCR, Agarose Gel Electrophoresis		≥ 1000 copies
		Hepatitis C viral genome detection by RT-PCR	RT- PCR, Agarose Gel Electrophoresis		
		Hepatitis B viral genome detection by PCR Human Papilloma viral genome detection by PCR Mycobacterium tuberculosis genome detection by PCR	PCR, Agarose Gel Electrophoresis		≥ 100 copies
		Plasmodium vivax, Plasmodium falciparum genome detection by PCR			≥ 10 copies
		Neisseria gonorrhoeae genome detection by PCR Chlamydia trachomatis genome detection by PCR			≥ 100 copies

## **Approved List of Sample Collection Centers**

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

Acting Director/CEO Sri Lanka Accreditation Board for Conformity Assessment