

Valid from 23 October 2018 to 22 October 2021 Issued on 26 February 2019



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, Histocompatibility Testing 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, Capillary Gel Electrophoresis	PCR machine and genetic analyzer	≥ 10 ng of genomic DNA
		Establishment of identity by DNA typing			≥ 100 ng of genomic DNA
		Maternity testing (Mother and Child) By DNA typing			≥ 100 ng of genomic DNA
		Paternity testing (Mother, Child and Putative father) by DNA typing			≥ 100 ng of genomic DNA
02	Cancer Markers	Philadelphia chromosome (bcr-abl translocation) Detection by PCR	RT-PCR, Nested PCR, AGE	PCR machine and Gel electrophoresis unit	10 copies per I ng of nRNA

	Infectious Diseases	Chikungunya viral genome detection by RT-PCR	RT-PCR, AGE	PCR machine and Gel electrophoresis unit	≥ 1000 copies
		Dengue genome detection by RT-PCR			≥ 1000 copies
		Hepatitis C genome by RT-PCR			≥ 1000 copies
03		Hepatitis B genome detection by PCR	PCR, AGE		≥ 100 copies
		Human Papilloma viral genome detection by PCR			≥ 100 copies
		Mycobacterium tuberculosis genome detection by PCR			≥ 100 CFU
		Plasmodium vivax, Plasmodium falciparum genome detection by PCR			≥ 10 copies

Sample Collection Centers

No	Sample Collection Centre	Contact person and Number	Address	Matrix of the sample
1	Lanka Hospitals Ltd.	011-5437016-19 Padma Thyagaraj	578, Elvitigala Mawatha, Narahenpita, Colombo 05.	Whole blood clotted blood
2	Hemas Hospital – Wattala	011- 7888725 Hasanthi Theodor	389, Negombo Road, Wattala.	swabs sputum
3	Hemas Hospital, Thalawathugoda.			stool urine
4	Hemas Laboratory and Channeling Service, Ragama.	011-7205888 Arun Nishanth	37F, Hospital Junction, Thalgolla Road, Ragama.	CSF Bone marrow BAL Aspirates

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