



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date: 28/08/2020

PRODUCT : Truenat™ Universal Control Kit
LOT. NO. : UC023
MFG. DATE : 2020-05
EXP. DATE : 2021-04
PACK SIZE : 08 T
STORAGE : 2°C to 40°C

A.R. No.: B-UC-023

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Negative control	Present	Present
2	Positive control (08- strip tubes containing dried down positive control)	Present	Present
3	Package insert	Present	Present

Specification (Ct Value)				Observation (Ct Value)	
Sr. No.	Truenat™ test name	Positive control	Negative control	Positive control	Negative control
1	MTB	28.2 ± 2	ND	28.2	ND
2	HBV	28.18 ± 2	ND	28.18	ND
3	GBS	28.14 ± 2		28.14	ND
4	Dengue/Chikungunya	29 ± 2; 28.2 ± 2	ND	DEN: 29 ; CHIK: 28.2	ND
5	CT	27.4 ± 2	ND	27.4	ND
6	HCV	28.25 ± 2	ND	28.25	ND
7	HIV-1	27.4 ± 2	ND	28.2	ND
8	Nipah	29.29 ± 2	ND	29.29	ND
9	MTB Plus	27.5 ± 2	ND	27.5	ND
10	Beta CoV	32.13 ± 2	ND	32.13	ND
11	Trich	30.4 ± 2	ND	30.4	ND
12	NG	27 ± 2	ND	27	ND

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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Specification (Ct Value)				Observation (Ct Value)	
Sr. No.	Truenat™ test name	Positive control	Negative control	Positive control	Negative control
13	Salmonella	30.2 ± 2	ND	30.2	ND
14	LTS	27 ± 2	ND	27	ND
15	HLA-B27	28.67 ± 2	ND	28.67	ND
16	HAV	31.8 ± 2	ND	31.8	ND
17	HEV	25.5 ± 2	ND	25.5	ND
18	Influenza A/B	29.33 ± 2; 30.14 ± 2	ND	INF A: 29.33; INF B: 30.14	ND
19	Malaria Pv/Pf	28.4 ± 2; 26.71 ± 2	ND	Pv: 28.4; Pf: 26.71	ND
20	HPV ^{-HR}	30 ± 2; 28.17 ± 2	ND	HP16/31: 30 HP18/45: 28.17	ND
21	MTB-RIF Dx	RIF resistance not detected	Indeterminate	RIF resistance not detected	Indeterminate
22	SARS CoV-2	29.5 ± 2	ND	29.5	ND
23	COVID-19	29 ± 2; 30.6 ± 2	ND	E gene: 29 Orf1: 30.6	ND

*ND- Not detected, Ct- Cycle threshold

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE



QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC HEAD

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