



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**  
ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

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

Date: 19/09/2020

PRODUCT : Truenat™ Universal Control Kit  
LOT. NO. : UC025  
MFG. DATE : 2020-05  
EXP. DATE : 2021-04  
PACK SIZE : 08 T  
STORAGE : 2°C to 40°C

A.R. No.: B-UC-025

**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

Sr. No.	Specification (Ct Value)			Observation (Ct Value)	
	Truenat™ test name	Positive control	Negative control	Positive control	Negative control
1	MTB	30.75 ± 2	ND	30.75	ND
2	HBV	28.88 ± 2	ND	28.88	ND
3	Dengue/Chikungunya	28.0 ± 2; 30.25 ± 2	ND	DEN: 28.0 ; CHIK: 30.25	ND
4	CT	25.8 ± 2	ND	25.80	ND
5	HCV	32.14 ± 2	ND	32.14	ND
6	HIV-1	27.6 ± 2	ND	27.6	ND
7	Nipah	28.83 ± 2	ND	28.83	ND
8	NG	29.50 ± 2	ND	29.50	ND
9	Beta CoV	29.33 ± 2	ND	29.33	ND
10	H1N1	29.67 ± 2	ND	29.67	ND
11	Salmonella	31.0 ± 2	ND	31.0	ND
12	LTS	24.5 ± 2	ND	24.5	ND
13	HLA-B27	31.4 ± 2	ND	31.4	ND

Page 1 of 2

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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
14	HAV	32.14 ± 2	ND	32.14	ND
15	HEV	30.6 ± 2	ND	30.6	ND
16	Influenza A/B	32.8 ± 2; 28.6 ± 2	ND	INF A: 32.8; INF B: 28.6	ND
17	Malaria Pv/Pf	29.11 ± 2; 31 ± 2	ND	Pv: 29.11 ; Pf: 31	ND
18	HPV <sup>-HR</sup>	29.14 ± 2; 30.40 ± 2	ND	HP16/31: 29.14; HP18/45: 30.40	ND
19	MTB-RIF Dx	RIF resistance not detected	Indeterminate	RIF resistance not detected	Indeterminate
20	SARS CoV-2	31 ± 2	ND	31	ND
21	COVID-19	28.17 ± 2; 26.57 ± 2	ND	E gene: 28.17 Orf1: 26.57	ND
22	Trich	29.86 ± 2	ND	29.86	ND
23	GBS	28.25 ± 2	ND	28.25	ND
24	MTB Plus	30.67 ± 2	ND	30.67	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

Page 2 of 2

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