



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 12/09/2020

PRODUCT :Truenat™ Universal Control Kit
LOT. NO. : UC024
MFG. DATE : 2020-05
EXP. DATE : 2021-04
PACK SIZE : 08 T
STORAGE : 2°C to 40°C

A.R. No.: B-UC-024

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.	Truenat™ test name	Specification (Ct Value)		Observation (Ct Value)	
		Positive control	Negative control	Positive control	Negative control
1	MTB	27.8 ± 2	ND	27.8	ND
2	HBV	29.25 ± 2	ND	29.25	ND
3	Dengue/Chikungunya	28.13 ± 2; 31.33 ± 2	ND	DEN: 28.13 ; CHIK: 31.33	ND
4	CT	26.5 ± 2	ND	26.5	ND
5	HCV	28.58 ± 2	ND	28.58	ND
6	HIV-1	28.33 ± 2	ND	28.33	ND
7	Nipah	29.29 ± 2	ND	29.29	ND
8	NG	29.33 ± 2	ND	29.33	ND
9	Beta CoV	30.17 ± 2	ND	30.17	ND
10	H1N1	31.25 ± 2	ND	31.25	ND
11	Salmonella	31.5 ± 2	ND	31.5	ND
12	LTS	24.17 ± 2	ND	24.17	ND
13	HLA-B27	29.5 ± 2	ND	29.5	ND

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0



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Sr. No.	Truenat™ test name	Specification (Ct Value)		Observation (Ct Value)	
		Positive control	Negative control	Positive control	Negative control
14	HAV	27.14 ± 2	ND	27.14	ND
15	HEV	30.5 ± 2	ND	30.5	ND
16	Influenza A/B	29 ± 2; 29.33 ± 2	ND	INF A: 29; INF B: 29.33	ND
17	Malaria Pv/Pf	29.22 ± 2; 28.14 ± 2	ND	Pv: 29.22 ; Pf: 28.14	ND
18	HPV _{HR}	30.13 ± 2; 28.67 ± 2	ND	HP16/31: 30.13; HP18/45: 28.67	ND
19	MTB-RIF Dx	RIF resistance not detected	Indeterminate	RIF resistance not detected	Indeterminate
20	SARS CoV-2	30.5 ± 2	ND	30.5	ND
21	COVID-19	30.2 ± 2; 30.17 ± 2	ND	E gene: 30.2 Orf1: 30.17	ND
22	Trich	29.29 ± 2	ND	29.29	ND
23	GBS	29 ± 2	ND	29	ND
24	MTB Plus	25.4 ± 2	ND	25.4	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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