



MOLBIO DIAGNOSTICS PVT. LTD.
An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

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

Date: 30/05/2020

PRODUCT :Truenat™ Universal Control Kit
LOT. NO. : UC021
MFG. DATE : 2020-05
EXP. DATE : 2021-04
PACK SIZE : 08 T
STORAGE : 2°C to 40°C

A.R. No.: B-UC-021

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.	Test	Specification (Ct Value)		Observation (Ct Value)	
		Positive control	Negative control	Positive control	Negative control
1	MTB	28.14 ± 2	ND	28.14	ND
2	HBV	25.75 ± 2	ND	25.75	ND
3	H1N1	24.33 ± 2	ND	24.33	ND
4	Dengue/Chikungunya	26.67 ± 2; 25.6 ± 2	ND	DEN: 26.67; CHIK: 25.6	ND
5	CT/NG	28.4 ± 2; 31 ± 2	ND	CT: 28.4; NG: 31	ND
6	HCV	30.5 ± 2	ND	30.5	ND
7	HIV-1	27.4 ± 2	ND	27.4	ND
8	Nipah	30.33 ± 2	ND	30.33	ND
9	MTB Plus	30.4 ± 2	ND	30.4	ND
10	Beta CoV	30.71 ± 2	ND	30.71	ND

Page 1 of 2

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-2783267 E mail: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



MOLBIO DIAGNOSTICS PVT. LTD.
An ISO 9001 & ISO 13485 certified company
CERTIFICATE OF ANALYSIS

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

Date: 30/05/2020

PRODUCT : Truenat™ Universal Control Kit
LOT. NO. : UC021
MFG. DATE : 2020-05
EXP. DATE : 2021-04
PACK SIZE : 08 T
STORAGE : 2°C to 40°C

A.R. No.: B-UC-021

Specification (Ct Value)				Observation (Ct Value)	
Sr. No.	Test	Positive control	Negative control	Positive control	Negative control
11	Trich	31.11 ± 2	ND	31.11	ND
12	Salmonella	28.83 ± 2	ND	28.83	ND
13	LTS	26.29 ± 2	ND	26.29	ND
14	HLA-B27	24.33 ± 2	ND	24.33	ND
15	HAV	25.8 ± 2	ND	25.8	ND
16	HEV	31.33 ± 2	ND	31.33	ND
17	Influenza A/B	29 ± 2; ND	ND	INF A: 29; INF B: ND	ND
18	Malaria Pv/Pf	25.2 ± 2; 28.33 ± 2	ND	Pv: 25.2; Pf: 28.33	ND
19	HPV _{HR}	30.5 ± 2; 30 ± 2	ND	HP16/31: 30.5 HP18/45: 30	ND
20	MTB-RIF Dx	RIF resistance not detected	Indeterminate	RIF resistance not detected	Indeterminate
21	SARS CoV-2	28.8 ± 2	ND	28.8	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

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-2783267 E mail: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO