



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

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

Date: 29-11-2019

PRODUCT : Truenat™ Universal Control Kit  
LOT. NO. : UC019  
MFG. DATE : 2019-10  
EXP. DATE : 2020-09  
PACK SIZE : 08 T  
STORAGE : 2°C to 40°C

A.R. No. : B-UC-019

**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.	Test	Positive control	Negative control	Positive control	Negative control
1	HBV	30.5 ± 2	ND	30.5	ND
2	MTB	30.4 ± 2	ND	30.4	ND
3	H1N1	26.67 ± 2	ND	26.67	ND
4	Dengue/Chikungunya	27.33 ± 2; 30.5 ± 2	ND	DEN: 27.33; CHIK: 30.5	ND
5	CT/NG	27.2 ± 2; 26.75 ± 2	ND	CT: 27.2; NG: 26.75	ND
6	HCV	29.73 ± 2	ND	29.73	ND
7	HIV	25.2 ± 2	ND	25.2	ND
8	Nipah	32.29 ± 2	ND	32.29	ND
9	MTB Plus	28.8 ± 2	ND	28.8	ND
10	Influenza A/B	27.2 ± 2; 28.33 ± 2	ND	INF A: 27.2; INF B: 28.33	ND
11	Pv/Pf	29.25 ± 2; 31.0 ± 2	ND	Pv: 29.25; Pf: 31.0	ND
12	Rabies	28.2 ± 2	ND	28.2	ND
14	HPV <sub>-HR</sub>	31.67 ± 2; 29.1 ± 2	ND	HP16/31: 31.67 HP18/45: 29.1	ND
15	HLA-B27	28.43 ± 2	ND	28.43	ND
16	MTB RIF Dx	Rif resistance not detected	Indeterminate	Rif resistance not detected	Indeterminate

\*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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