



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

CERTIFICATE OF ANALYSIS

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

Date: 20-06-2019

PRODUCT : Truenat™ Universal Control Kit
LOT. NO. : UC017
MFG. DATE : 2019-02
EXP. DATE : 2020-01
PACK SIZE : 08 T
STORAGE : 2°C to 40°C

A.R. NO. : B-UC-017

PRECAUTION: The product is offered without warranty for any other specific use than that specified in the 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	20-35	ND	26.5	ND
2	MTB	20-35	ND	28	ND
3	H1N1	20-35	ND	29	ND
4	Dengue/Chikungunya	20-35	ND	DEN: 24; CHIK: 27.14	ND
5	CT/NG	20-35	ND	CT: 30.2; NG: 24.4	ND
6	HCV	20-35	ND	29.55	ND
7	HIV	20-35	ND	28.0	ND
8	Trich	20-35	ND	29.17	ND
9	MTB Plus	20-35	ND	23.71	ND
10	Salmonella	20-35	ND	25.6	ND
11	Pv/Pf	20-35	ND	Pv: 25.83; Pf: 23.5	ND
12	Rabies	20-35	ND	28.0	ND
14	HPV _{HR}	20-35	ND	HP16/31: 30.43 HP18/45: 27.67	ND
15	HLA-B27	20-35	ND	24.0	ND
16	MTB RIF Dx	Rif resistance not detected	Indeterminate	Rif resistance not detected	Indeterminate

*ND- Not detected

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

1

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