



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

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 29-12-2018

PRODUCT : Truenat™ Universal Control Kit
LOT. NO. : UC015
MFG. DATE : 2018- 05
EXP. DATE : 2019- 04
PACK SIZE : 08 T
STORAGE : 2°C to 40°C

A.R. NO. : B-UC-015

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

Lot no: UC014		Specification (Ct Value)		Observation (Ct Value)	
Sr. No.	Test	Positive control	Negative control	Positive control	Negative control
1	HBV	20-35	ND	26.86	ND
2	MTB	20-35	ND	31.33	ND
3	H1N1	20-35	ND	31.17	ND
4	Dengue/Chikungunya	20-35	ND	DEN:27;CHIK:29.63	ND
5	CT/NG	20-35	ND	CT:25.6;NG:28.5	ND
6	HCV	20-35	ND	30.17	ND
7	HIV	20-35	ND	25.44	ND
8	Trich	20-35	ND	29.29	ND
9	MTB Plus	20-35	ND	23.6	ND
10	Salmonella	20-35	ND	26.67	ND
11	Pv/Pf	20-35	ND	Pv;27.2;24.6	ND
12	Rabies	20-35	ND	30.29	ND
13	MTB RIF	20-35	ND	P1:66.24;P2:24.6	ND
14	HPV _{HR}	20-35	ND	HP16:31;HP18:28.8	ND

*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

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