



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 21/11/2018

PRODUCT : Truenat™ Influenza A/B
LOT. NO. : AB002
MFG. DATE : 2018- 09
EXP. DATE : 2020- 08
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. NO. : B-AB-002a

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	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 nos, 20 nos.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01no.	Pass

Performance			
CONTROLS	Test Lot (Ct Values)		
	INF A	INF B	IC
Specificity Tests			
Negative Control	ND	ND	29.4
Positive Control	28	ND	26.75
	ND	28.11	29
	28.75	25.5	28.8
	29.75	26.4	29.33
Standard deviation	± 0.70	± 0.63	± 0.37

*ND- Not detected

*A deviation of ≤ 1.5 is acceptable for Ct values

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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