



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : MFG/IVD/2019/000018

Date:18/10/2021  
DOCID:COA/TN/AB008

BRAND NAME	Truenat®Influenza A/B
GENERIC NAME	Chip based Real Time Duplex PCR Test For Influenza A and Influenza B
LOT No.	AB008
MFG. DATE	2021-10
EXP. DATE	2023-09
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C

A.R. No. : B-AB-008

PRECAUTION: Refer Safety Data Sheet and 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 no, 20 no, 50 no.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE			
CONTROLS	Test Lot (Ct Values)		
	INF A	INF B	Control
Specificity Tests			
Negative Control	ND	ND	31.57
Positive Control (INF A)	30	ND	30
Positive Control (INF B)	ND	31.17	31
Positive Control (INF A/B)	28	30.2	31.5
	27.5	29.82	31.75
Standard deviation	± 0.35	± 0.26	± 0.17

\*ND- Not detected, Ct- Cycle threshold, INF A-Influenza A, INF B- Influenza B

\*A deviation of  $\leq 1.5$  is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS QC APPROVED FOR SALE

  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head  
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**Molbio Diagnostics Private Limited**

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