



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:09/02/2022
DOCID:COA/TN/AB009

BRAND NAME	Truenat®Influenza A/B
GENERIC NAME	Chip based Real Time Duplex PCR Test For Influenza A and Influenza B
LOT No.	AB009
MFG. DATE	2021-12
EXP. DATE	2023-11
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-AB-009	

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	30.0
Positive Control (INF A)	27.29	ND	29
Positive Control (INF B)	ND	28.0	28.6
Positive Control (INF A/B)	27.13	26.25	28.4
	26.33	26.6	28.33
Standard deviation	± 0.56	±0.24	± 0.04

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

*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 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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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO