



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:18/10/2022
Doc ID: COA/TN/AB012a

BRAND NAME	Truenat® Influenza A/B		
GENERIC NAME	Chip- based Real Time Duplex PCR Test For Influenza A and Influenza B		
LOT No.	AB012	CHIP LOT NO.	HDLW483
MFG. DATE	2022-10	EXP. DATE	2024-09
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No. : B-AB-012a

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 dessicant pouch and 1 filter barrier tip	5 no, 20 no, 25no, 50no.	Pass
2	Colour of dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE			
CONTROLS	Test Lot (Ct Values)		
Specificity Tests	INF A	INF B	Control
Negative Control	ND	ND	31.75
Positive Control (INF A)	28.13	ND	29
Positive Control (INF B)	ND	28.78	29.17
Positive Control (INF A/B)	27.6	29.78	29.29
	27.8	29.75	29.8
Average	27.7	29.77	29.55
Standard deviation	± 0.14	±0.02	± 0.36

*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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