



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 27/10/2021
Doc ID: COA/TN/SL014

BRAND NAME	Truenat [®] Salmonella
GENERIC NAME	Chip-based Real Time PCR Test for Salmonella spp.
LOT No.	SL014
MFG. DATE	2021-09
EXP. DATE	2023-08
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-SL-014	

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, 50no	Pass
2	Colour of dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	SAL	Control
Negative Control	ND	30.5
Positive Control	28.8	28.4
	28.11	30.22
	28.33	29.8
	29.33	30.33
Standard deviation	± 0.54	± 0.88

*ND- Not detected, Ct- Cycle threshold, SAL- Salmonella

*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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Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO