

Molbio Diagnostics Limited

(Formerly Molbio Diagnostics Private Limited) Plot No. L-46, Phase II D, Verna Industrial Estate Verna, Goa - 403722, India S+918326724888 www.molbiodiagnostics.com

MOLBIO DIAGNOSTICS LIMITED EN ISO 13485:2016 certified company **CERTIFICATE OF ANALYSIS**

Licence No.: MFG/IVD/2019/000018

Date: 04/02/2025

Document ID:COA/TN/SL024/25T

| Truenat® Salmonella | |
|--|--|
| Chip-based Real Time PCR Test for Salmonella Spp | |
| SL024 | |
| NA | |
| 2025-01 | |
| 2026-12 | |
| 25T | |
| 2°C to 30°C | |
| | |

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

| Sr. No. | Components in each kit | Specification | Observation |
|---------|--|--|----------------------------|
| 01 | Number of pouches as per pack size | Should be present | Present |
| 02 | Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip | Should be present | Present |
| 03 | Colour of desiccant pouch | Should be present and Orange in Colour | Present / Orange Colour |
| 04 | Package Insert | Should be present | Present |
| 05 | Seal integrity test | Should pass | Pass |

| Performance testing data | | | | |
|--|---------------------|---------------------|--|--|
| | Ct Values | | | |
| Samples | Salmonella | Control | | |
| Non Template Control | ND | ND | | |
| Negative Sample | ND | 27.37 ± 0.35 | | |
| Positive sample 1 | 21.66 ± 0.58 | 24.98 <u>+</u> 0.32 | | |
| Positive sample 2 | 24.91 <u>+</u> 0.51 | 26.85 ± 0.23 | | |
| Positive Sample 3 | 29.91 ± 0.89 | 28.25 ± 0.78 | | |
| ND - Not detected, Ct- Cycle threshold | | | | |

*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC Standards and is approved.

Name : Dr. Praveen Kumar **Department: Quality Control**

Designation: QC Head

FM/QT/219-03