



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date:11/03/2023

Doc ID:COA/TP/USPT250

|                   |   |
|-------------------|---|
| Product Name      | Trueprep® AUTO Universal Sample Pre-treatment Pack      |
| Generic Name      | Universal Sample pre-treatment pack for Non MTB samples |
| Lot No.           | USPT250   |
| Mfg. Date         | 2023-02   |
| Exp. Date         | 2025-01   |
| Pack Size         | 5T,20T,25T, 50T   |
| Storage condition | 2°C to 40°C   |

**PRECAUTION:** Refer Safety Data Sheet and follow instructions for use.

| Sr. No. | Components in each kit  | Specification                  | Observation |
|---------|---|--------------------------------|-------------|
| A       | Contents in the carton (Trueprep® AUTO Universal Sample Pre-treatment Pack) | (Present (P)/Not Present (NP)) |             |
| 1       | Lysis Buffer  | Present                        | Present     |
| 2       | Disposable Transfer Pipette (1 ml Graduated)                                | Present                        | Present     |
| 3       | Package Insert  | Present                        | Present     |

## Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



| Performance on Truelab® Real Time micro PCR Analyzers |                   |                                     |                            |                  |                      |       |
|---|-------------------|-------------------------------------|----------------------------|------------------|----------------------|-------|
| Sr. No.   | Control           |                                     | Specification (Ct Values)  |                  | Test Lot (Ct Values) |       |
|   | Specificity Tests | Test                                | IC                         | Test 1 (Average) | Test 2 (Average)     | IC    |
| <b>Negative Control</b>                               |                   |                                     |                            |                  |                      |       |
| 1   | Negative HBV      | ND                                  | Control should be detected | ND               | NA                   | 26.67 |
| 2   | Negative HBV      | ND                                  |                            | ND               | NA                   | 27.02 |
| 3   | Negative HBV      | ND                                  |                            | ND               | NA                   | 26.53 |
| 4   | Negative HCV      | ND                                  |                            | ND               | NA                   | 26.93 |
| 5   | Negative HCV      | ND                                  |                            | ND               | NA                   | 26.74 |
| 6   | Negative HCV      | ND                                  |                            | ND               | NA                   | 27.01 |
| 7   | Negative HIV      | ND                                  |                            | ND               | NA                   | 26.88 |
| 8   | Negative HIV      | ND                                  |                            | ND               | NA                   | 26.83 |
| 9   | Negative HIV      | ND                                  |                            | ND               | NA                   | 26.69 |
| <b>Positive Control</b>                               |                   |                                     |                            |                  |                      |       |
| 1   | Positive HCV      | Test and Control should be detected |                            | 29.62            | NA                   | 27.07 |
| 2   | Positive HCV      | Test and Control should be detected |                            | 29.47            | NA                   | 27.13 |
| 3   | Positive HCV      | Test and Control should be detected |                            | 29.73            | NA                   | 27.04 |

\*Ct-Cycle Threshold \*IC- Internal Control \*ND- Not Detected \*NA- Not Applicable

**Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.**

  
  
**Name:** Dr.Praveen Kumar MK  
**Department:** Quality Control  
**Designation:** QC Head

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