

**MOLBIO DIAGNOSTICS LIMITED**

EN ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

License No.: MFG/IVD/2019/000003

Date: 27/02/2025

Doc ID: COA/TP/ALR004/50T

|                          |                                                 |
|--------------------------|-------------------------------------------------|
| <b>Product Name</b>      | Trueprep <sup>®</sup> AUTO Liquefaction Reagent |
| <b>Generic Name</b>      | Reagent Pack for Liquefaction of samples        |
| <b>Lot No.</b>           | ALR004                                          |
| <b>Mfg. Date</b>         | 2025-02                                         |
| <b>Exp. Date</b>         | 2027-01                                         |
| <b>Pack Size</b>         | 50T                                             |
| <b>Storage condition</b> | 2°C to 40°C                                     |

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

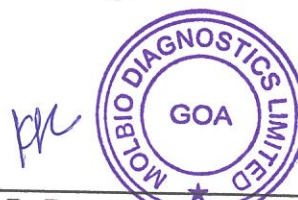
| Sr. No.  | Components in each kit                                                                | Specification                         | Observation |
|----------|---------------------------------------------------------------------------------------|---------------------------------------|-------------|
| <b>A</b> | <b>Contents in the carton (Trueprep<sup>®</sup> AUTO Sputum Liquefaction Reagent)</b> | <b>(Present (P)/Not Present (NP))</b> |             |
| 1        | Liquefaction Reagent                                                                  | Present                               | Present     |

| Performance on Truelab <sup>®</sup> Real Time micro PCR Analyzer |                   |      |                            |                |                      |
|------------------------------------------------------------------|-------------------|------|----------------------------|----------------|----------------------|
| Sr. No.                                                          | Control           |      | Specification (Ct Values)  |                | Test lot (Ct Values) |
|                                                                  | Specificity Tests | Test | Control                    | Test (Average) | Control (Average)    |
| <b>Samples</b>                                                   |                   |      |                            |                |                      |
| 1                                                                | Sputum            | ND   | Control should be detected | ND             | 26.84                |
| 2                                                                | Sputum            | ND   |                            | ND             | 26.55                |
| 3                                                                | Sputum            | ND   |                            | ND             | 27.02                |

|                             |        |                                           |  |    |       |
|-----------------------------|--------|-------------------------------------------|--|----|-------|
| 3                           | Sputum | ND                                        |  | ND | 27.02 |
| <b>Non Template Control</b> |        |                                           |  |    |       |
| 1                           | NTC    | Test 1 and Control should not be detected |  | ND | ND    |

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

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



**Name:** Dr.Praveen Kumar MK  
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**Designation:** QC Head