

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

Licence No.: MFG/IVD/2019/000018

Date: 29/07/2026

Document ID: COA/TN/I0002MY

|                   |                                                                |
|-------------------|----------------------------------------------------------------|
| Product Name      | Truenat <sup>®</sup> Mgen                                      |
| Generic Name      | Chip-based Real Time PCR Test for <i>Mycoplasma genitalium</i> |
| Lot No.           | I0002MY                                                        |
| Set No.           | NA                                                             |
| Mfg. Date         | 2026-06                                                        |
| Exp. Date         | 2028-05                                                        |
| Pack Size         | 5T, 20T, 25T                                                   |
| Storage condition | 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 DNase and RNase free filter barrier microtip | 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 |                              |              |
|--------------------------|------------------------------|--------------|
| Samples                  | Ct Values                    |              |
|                          | <i>Mycoplasma genitalium</i> | Control      |
| Non Template Control     | ND                           | ND           |
| Negative Sample          | ND                           | 27.42 ± 0.54 |
| Positive Sample 1        | 23.53 ± 0.96                 | 25.59 ± 0.57 |
| Positive Sample 2        | 27.43 ± 0.39                 | 25.50 ± 0.18 |
| Positive Sample 3        | 31.18 ± 0.72                 | 26.97 ± 0.30 |

ND – Not detected, Ct- Cycle threshold

Mfg- Manufacturing, Exp- Expiry

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

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

