

CERTIFICATE OF ANALYSIS



Product Name: **TestUrGut qPCR Kit**

Number of reactions: **24**

Catalogue Number: **TUG-01-1024**

Lot Number: **0000975930**

Manufacturing Date: **07/05/2026**

Expiration Date: **03/05/2028**

| Test parameter | Test description | Acceptance criteria | Result |
|---|-------------------|--|---------------|
| Accuracy TestUrGut qPCR Kit | Real-Time PCR | The Ct values obtained for the kit's positive controls fall within $\pm 10\%$ of the average value (as specified in the Technical Specifications). | Passed |
| Sensitivity and specificity of megamixes | Real-Time PCR | An adequate amplification curve is observed when certified external specific PCR products (C+) and DNA samples are analysed. No amplification is detected in the non-template control (NTC), or amplification appears beyond the limit Ct value (as stated in the Technical Specifications). | Passed |
| Sensitivity and specificity of positive controls (C+) | Real-Time PCR | An adequate amplification curve is observed when the C+ is analysed using an external megamix. No amplification is detected in the NTC, or amplification appears beyond the limit Ct value (as defined in the Technical Specifications). | Passed |
| Efficiency of Multiplex qPCR Master Mix | Real-Time PCR | The qPCR efficiency for the Eubacteria marker is between 90% and 110%. No amplification is detected in the NTC, or amplification appears beyond the limit Ct value (as specified in the Technical Specifications). | Passed |
| Visual inspection control | Visual inspection | Packaging, kit components and labels are in accordance with the specifications. | Passed |

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GOODGUT, S.L.U. manufactures this product for its specifically intended use. Please refer to the product label and accompanying documentation for detailed intended use statements. All GOODGUT S.L.U. products are manufactured in accordance with the the ISO13485:2016 Quality Management System and applicable regulations for *in vitro* medical devices.

Storage

The TestUrGut qPCR Kit must be stored immediately upon receipt at -15 to -30°C in a temperature-controlled freezer.

Certification Statement:

This certifies that the product has been manufactured and tested in accordance with GOODGUT S.L.U. Quality Control (QC) and Quality Assurance (QA) procedures, and has met all applicable GOODGUT, S.L.U. quality requirements.

Date of signature:

19, May 2026

Dr. Juan Vicente Gómez

Quality Assurance Manager



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