# **CERTIFICATE OF ANALYSIS**



Product Name: RAID-CRC Screen qPCR Kit Number of reactions: 250 reactions Catalogue Number: CRC-01-1250-01 Lot Number: 0000868157 Manufacturing Date: 2024/08/01 Expiration Date: 2025/12/05

| Test parameter   | Test description | Acceptance criteria   | Result |
|--|------------------|---|--------|
| Accuracy RAID-CRC Screen   | Real-Time PCR    | PCR accuracy and Cq values of the positive controls SCR_A, SCR_B, and SCR_C are within the specified range  | Passed |
| Specificity  |                  |   |        |
| Positive control SCR_A<br>Positive control SCR_B<br>Positive control SCR_C                               | Real-Time PCR    | Specific PCR products are present   | Passed |
| Efficiency QuantiNova<br>Multiplex PCR MM  | Real-Time PCR    | PCR efficiency and Cq values are within the specified range   | Passed |
| Absence of Endonucleases<br>QuantiNova DNA Polymerase  | Enzymatic Assay  | Endonuclease activity is below the specified limit  | Passed |
| Absence of Ribonucleases<br>QuantiNova DNA Polymerase<br>RNAse-free Water                                | Enzymatic Assay  | Ribonuclease activity is below the specified limit  | Passed |
| Concentration QuantiNova<br>DNA Polymerase   | Activity Assay   | Within specified range  | Passed |
| Sensitivity QuantiNova DNA<br>Polymerase   | Endpoint PCR     | Specific PCR products are present,<br>and the yield is above the specified<br>limit                         | Passed |
| Density of Hot Start<br>QuantiNova DNA Polymerase  | Density Assay    | Cq values and melting peaks are<br>within the specified range No non-<br>specific melting peaks are visible | Passed |
| Dye concentration QuantiNova<br>Multiplex PCR MM Yellow<br>Template Dilution buffer ROX<br>Reference Dye | OD measurement   | Within specified range  | Passed |

## **CERTIFICATE OF ANALYSIS**



GOODGUT, S.L.U. manufactures this product for its specific intended use. See the product label and directions for intended use statements. GOODGUT, S.L.U. products are manufactured under the ISO13485:2016 Quality Management System and the current regulations on *in vitro* medical devices.

### Storage

The RAID-CRC SCREEN qPCR Kit should be stored immediately upon receipt at -15 to -30 °C in a constant temperature freezer.

#### **Certification Statement:**

This certifies that the product was manufactured and tested according to GOODGUT, S.L.U. QC and QA procedures and has met all GOODGUT, S.L.U. quality requirements.

### Date of signature:

November 28, 2025



**Dr. Juan Vicente Gómez** Quality Assurance Manager



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