

CERTIFICATE OF ANALYSIS



Product Name: RAID-CRC Symptomatic qPCR Kit
Number of reactions: 250 reactions
Catalogue Number: CRC-01-2250-01
Lot Number: 0000690821
Manufacturing Date: 2022/05
Exp. Date: 2023/05

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

GOODGUT S.L.U. manufactures this product for its specific intended use. See product label and directions for intended use statements. GOODGUT S.L.U. products are manufactured in accordance with the ISO13485:2016 Quality Management System and the current regulations on In Vitro Medical Devices.

Storage

The RAID-CRC Symptomatic 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 in accordance with GOODGUT, S.L.U QC and QA procedures. The product has met all GOODGUT S.L.U. quality requirements.

Date of signature:



20-may-2022.

Dr. Juan Vicente Gómez
Quality Assurance Manager



GOODGUT

Enhancing digestive health

GOODGUT S.L.U

CIF: B55206916

C/Pic de Peguera, 11- 17003 Girona

Catalonia, Spain

Tel. +34 972 18 32 20

e-mail: info@goodgut.eu

www.goodgut.eu