CE IVD

# GA-map® COVID-19 Fecal Test

**Intended use**

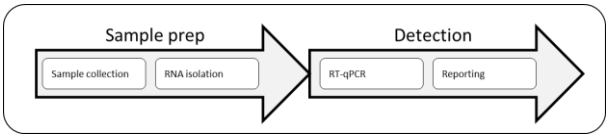
The GA-map® COVID-19 Fecal Test is intended to detect SARS-CoV-2 virus in fecal samples.

## Introduction

It has been shown that the human GI tract serve as an important reservoir for SARS-CoV-2 and that the virus can be detected in fecal samples for up to 40 days after infection (Xu et al. 2020, Wu et al. 2020). SARS-CoV-2 can infiltrate gastrointestinal (GI) cells and may cause GI infection (Xiao et al. 2020). Further, new results indicate that fecal-oral virus transmission is (can be) an important route for COVID-19 spread (Hindson et al. 2020). This means that patients can be SARS-CoV-2 positive and possibly infectious for several weeks despite negative nasopharyngeal results. Thus, there is a need for establishing follow-up regimes for COVID-19 patients that includes fecal SARS-CoV-2 testing.

## Test description

The CE-marked GA-map® COVID-19 Fecal Test (the Test) is designed to qualitatively detect SARS-CoV-2 in fecal samples. The Test constitute a full workflow from sample collection to result reporting.




### *Fecal sampling*

SARS-CoV-2 can be detected in fecal samples either collected and shipped without preservative, or preferably samples collected with the GA-map® COVID-19 fecal sampling kit provided by Genetic Analysis. The kit contains a sample collection device with a molecular medium specially designed to stabilize and preserve microbial and human nucleic acids (RNA/DNA) for prolonged time periods. Sampling should be performed as described in the GA-map® COVID-19 fecal sampling Instructions included in the kit. Sampling can be performed at any convenient place, including in the privacy of the donor's home.

### *Lab procedure*

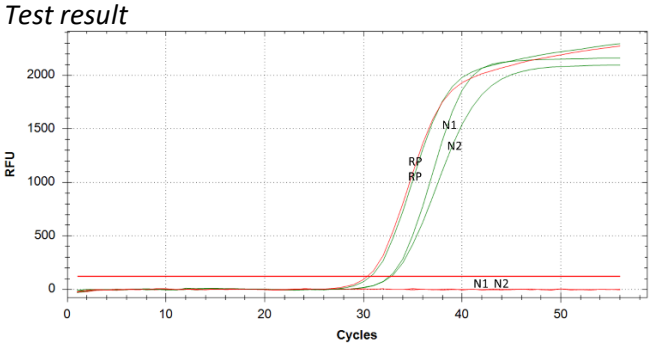
Viral ribonucleic acid (RNA) is isolated from human fecal samples followed by selective amplification of the target gene using specific primers for two sequences within the SARS-CoV-2 Nucleocapsid gene (N1 and N2). RNA detection probes labeled with a fluorescent dye act as a reporter. Each probe also has a second dye which acts as a quencher. When not bound to the target sequence, the fluorescent signals of the intact probes are suppressed by the quencher dye. The real-time data is recorded in a real-time PCR instrument and the results are reported as either positive or negative based on cycle threshold (Ct) recordings.

| Test specifications | |
|---|---|
| Specimen type | Human feces |
| Sample input volume | Sample dissolved in 140 µL buffer |
| Test duration | Results are available within 5 hours after initiating the RNA isolation step |
| Technology | Qualitative Real Time PCR |
| Probe Design | Single Stranded Linear Probe |
| Target Region | N-gene |
| Limit of Detection (LoD)[1] | 12 copies/µl |
| Specificity | 100% |
| Sensitivity (PPA)[2] | 2x LoD: 99.6% (87.1 – 99.6) |
| | 4x LoD: 100% (91.2 – 100) |
| Results Reporting | Detected / Not Detected |
| Internal Control (IC) | Human RNaseP (RP) gene amplified with dedicated primers for every sample |
| Controls | One negative and one positive control per run |

[1]LoD was determined by spiking negative samples with a titer of a plasmid containing the SARS-CoV-2 N-gene in the PCR reaction.

[2]The sensitivity of the GA-map® COVID-19 Fecal Test was evaluated using low positive and moderate positive samples prepared by spiking simulated clinical matrix with 2x LoD and 4x LoD of the positive assay control, respectively. The results are reported as Positive Percent Agreement (PPA) with two-sided 95% confidence intervals.

### *Test result*




Amplification curves for one COVID-19 positive (green) and one COVID-19 negative (red) sample. The positive sample show amplification curves for all three targets (N1, N2 and RP), whereas no amplification is observed for the COVID-19-specific N1 and N2 targets in the negative sample. Horizontal red line illustrates signal threshold limit.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