



GSD NovaPrime® SARS-CoV-2 (COVID-19) Multiplex Real-Time PCR

Real-Time PCR test intended for the qualitative determination of SARS-CoV-2 genomic RNA in respiratory samples to aid in the diagnosis of COVID-19

MAIN FEATURES

- Dual target assay (N-gene)
- Multiplex PCR - one reaction
- Results in 2 hours
- No cross reactivity with common human coronavirus strains
- Extraction/inhibition control included
- Positive control included
- CE-IVD marked

GSD NovaPrime® SARS-CoV-2 (COVID-19) Multiplex Real-Time PCR kit



RT-PCR testing

Molecular detection is established as the primary and more accurate method for direct detection of SARS-CoV-2 in the early stages of infection. The real-time reverse transcriptase polymerase chain reaction (RT-PCR) is highly sensitive and specific, and can deliver a reliable result quickly.

Performance Data

The PCR assay demonstrates excellent performance with a 100 % Negative and Positive Percent Agreement (NPA, PPA) for all tested samples and no cross-reactivity with other common widely spread coronaviruses. The analytic sensitivity shows a limit of detection of 3.75 copies/reaction.

Validation

- **Extraction system:** NUCLISENS® easyMAG® or EMAG® from bioMérieux
- **Real-Time PCR cyler:** ABI Prism® 7500 SDS/Fast SDS (Applied Biosystems™ ThermoFisher Scientific)*.

*Further validation in progress.

Molecular Assays Product List

Product	Order No.	Format
GSD NovaPrime® SARS-CoV-2 (COVID-19)	PCOV6033	96 tests

Related SARS-CoV-2 products

Product	Order No.	Format
NovaLisa® SARS-CoV-2 (COVID-19) IgG	COVG0940	96 tests
NovaLisa® SARS-CoV-2 (COVID-19) IgA	COVA0940	96 tests
NovaLisa® SARS-CoV-2 (COVID-19) IgM	COVM0940	96 tests



The **Gold Standard Diagnostics Group** including Gold Standard Diagnostics Inc, NovaTec Immundiagnostica GmbH, and Virotech Diagnostics GmbH, is a group of specialized diagnostic technologies companies known as well-established providers of innovative solutions in infectious disease testing, immunology, and automation.

The combined market experience, devoted workforce, and scientific excellence of these companies resulted in the fast development of multiple immunoassays and qualitative pathogen RT-PCR kits to support health authorities in their fight against COVID-19. www.goldstandarddiagnostics.com

R05052020



NOVATEC IMMUNDIAGNOSTICA GmbH

Waldstrasse 23 A6, 63128 Dietzenbach, Germany (10)(2e)

(10)(2e) info@novatec-id.com www.novatec-id.com