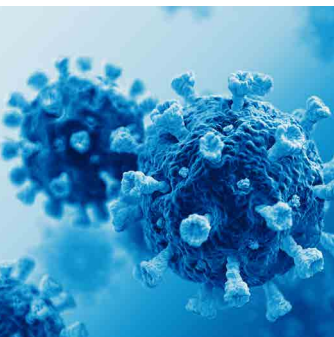
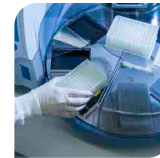
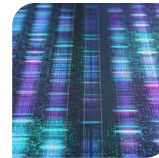




GSD NovaPrime® SARS-CoV-2 Mplex FLA (Sanger)

As the spread of COVID-19 (SARS-CoV-2) continues to accelerate worldwide, diagnostic laboratories face an unprecedented demand for mainly qRT-PCR testing capacities.

The new GSD NovaPrime® SARS-CoV-2 Mplex FLA (Sanger) kit utilizes the well-established Fragment Length Analysis principle on widely used Sanger sequencing instruments to further boost high throughput capacities beyond established qRT-PCR set-ups.

This unique assay enables each single ABI 3730xl sequencer to process more than 2,000 samples per day. Importantly, the new approach also provides the essential fastest time to results and cost-effectiveness, similar to qRT-PCR testing.



SARS-CoV-2 Detection Fragment Length Analysis

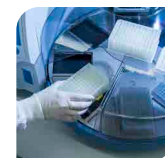
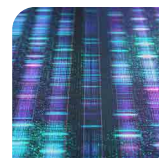
The innovative Fragment Length Analysis (FLA) assay enables sensitive, fast and cost-efficient high throughput SARS-CoV-2 testing on Sanger sequencing equipment.



Key Benefits

- Sensitivity (5 copies per reaction)
- Fast time-to-result: overnight / 24h
- Enables to increase COVID-19 testing capacities with no need of qRT-PCR equipment
- Cost per sample / reaction are below most qRT-PCR
- CE-IVD mark will be available soon

GSD NovaPrime® SARS-CoV-2 Mplex FLA (Sanger)



The GSD NovaPrime® SARS-CoV-2 Mplex FLA (Sanger) assay was developed to enable the specific detection of the SARS-CoV-2 virus in RNA extracted from human specimen samples (e.g. nasal wash/swab, nasopharyngeal wash/swab, oropharyngeal swab) via Fragment Length Analysis (FLA).

The assay detects two highly specific N gene fragments of the SARS-CoV-2 viral genome with highest sensitivity. Its limit of detection (5 copies/reaction) is matching the performance of the best available qRT-PCR assays. The kit's multiplex reactions also cover an intrinsic human housekeeping gene which serves as convenient internal control for the successful entire sampling, extraction, amplification and detection process.

Two step approach

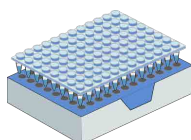
1. RT-PCR

→ detection of N1 /N2 of the N-gene (nucleocapsid)

→ detection of a human housekeeping transcript (PPIA) as internal control

2. Fragment Length analysis (FLA)

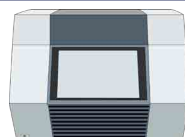
1.



Prepare RT-PCR:

- Purified template RNA
- Enzyme mastermix
- Primer mix

2.



Perform thermal cycling

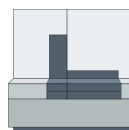
3.



Preparation of electrophoresis:

- Dilution of PCR products
- Addition of size standard

4.



Electrophoresis

5.



Analyse data with GeneMapper software

Validated equipments:

- 96-well GeneAmp® PCR System 9700 (Applied Biosystems) for RT-PCR
- ABI PRISM 3730XL Genetic Analyzer (Life Technologies) for FLA.

Validated RNA Extraction kit

- GSD NovaPrime® IVD RNA Extraction AE1 kit

Product Name (Research Use Only)	Cat. No.
GSD NovaPrime® SARS-CoV-2 Mplex FLA (Sanger; RUO; 1x)	5728411001
GSD NovaPrime® SARS-CoV-2 Mplex FLA (Sanger; RUO; 12x)	5728411015

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Technologies