

# GENOMERA<sup>®</sup> SARS-CoV-2 2.0 ASSAY KIT

## USABILITY AND SENSITIVITY TAKEN TO A NEW LEVEL



Fast and reliable detection of SARS-CoV-2 using RT-PCR, the golden standard for COVID-19 diagnostics. The easy-to-use GenomEra platform combines the simplicity of rapid testing and the superior sensitivity of PCR methods in one reliable system.

# CORRECT AND QUICK RESULTS TO BREAK THE CHAINS OF INFECTION

## What's new in GenomEra SARS-CoV-2 2.0 Assay Kit?

The GenomEra SARS-CoV-2 2.0 is a rapid and highly sensitive multiplex RT-qPCR test for the detection of SARS-CoV-2 from respiratory samples. Only a short and simple sample preparation is needed, after which the assay is fully automated and the result will be automatically interpreted with Ct values after 50 minutes. This enables rapid start of infection control to break the chains of infection.

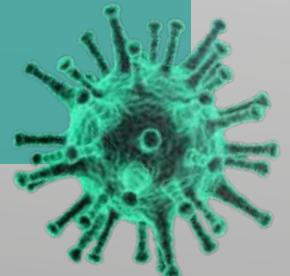
The assay is compatible with a wide range of commercial sample collection media available, including inactivating media. If the sample is collected to an inactivating media, it allows safe handling of the sample without the need for extensive biosafety measures and minimizes the hands-on time. Additionally, the new assay includes an integrated sample processing control targeting a specific human housekeeping gene mRNA.

## Basics of the test

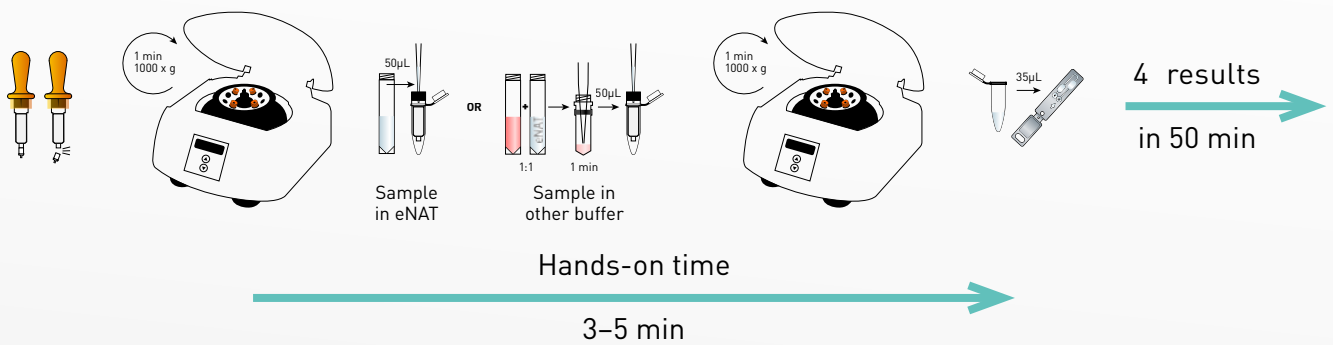
To achieve excellent reliability and ensure that the overall test performance is not affected by emerging of different variant strains, the GenomEra SARS-CoV-2 2.0 simultaneously detects two different targets in the SARS-CoV-2 virus genome – the RdRp and E genes. All reagents required for the RT-qPCR are readily contained in dry form inside the GenomEra Test Chips. No reagents need to be prepared by the end user, which removes the need for separate clean room facilities and enables testing in laboratories without prior PCR expertise.

The scalable capacity of the GenomEra CDX system enables simultaneous analysis of 1–4 samples per instrument. In multi-instrument settings, up to 32 samples can be simultaneously analysed.

- **Rapid PCR test with sensitivity and specificity at the level of conventional PCR**
- **Short hands-on-time of 3–5 minutes per 1–4 samples**
- **Assay run time only 50 minutes**
- **No extensive safety measures nor dedicated PCR facilities required**



## Preparation of samples for SARS-CoV-2 2.0 test



## Proven clinical performance

The GenomEra SARS-CoV-2 2.0 was evaluated in a multi-center study. In total, 915 samples were tested and compared to another RT-PCR method.

Positive Percent Agreement: 98.3%

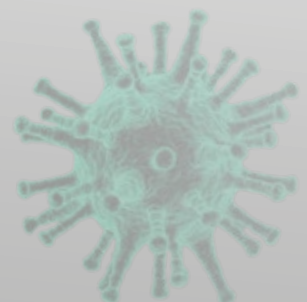
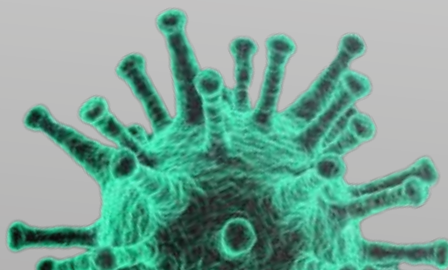
Negative Percent Agreement: 99.8%

Table 1. The GenomEra SARS-CoV-2 2.0 Assay Kit is highly sensitive and specific.

GenomEra SARS-CoV-2 2.0	Reference assay	
	Positive	Negative
Positive	350	1
Negative	6	558

*“Due to the high performance of the test and the fast assay time, we find it an excellent choice for COVID-19 testing.”*

*Fimlab Vaasa clinical laboratory, Finland*





## Contact your local distributor!

### GenomEra SARS-CoV-2 2.0 – high quality combined with reliable deliveries

- All required materials are provided within the kit or as accessories.
- Simple test chip design keeps the amount of waste to a minimum.
- Assay Kits are designed and manufactured in Finland under ISO 13485 certified Quality Management System.

#### Ordering information

GenomEra SARS-CoV-2 2.0 Assay Kit, 20 pcs	CDX-150-01-20
GenomEra SARS-CoV-2 2.0 Assay Kit, 100 pcs	CDX-150-01-100
GenomEra CDX system	CDX-10-020

#### Accessories

FastGene High Speed Mini Centrifuge	CDX-10-041
GenomEra Lysis Tubes	CDX-20-720
Cap Puncher	CDX-20-730
Copan Flexible Minitip Flocked Swab	CDX-503CS01-100
Copan eNAT 1mL supplied with GenomEra kits	CDX-608C-50

#### Manufacturer

Abacus Diagnostica Oy  
Tykistökatu 4 D  
FI-20520 Turku, Finland  
Tel: + 358 20 7188 380  
Info@abacusdiagnostica.com  
www.abacusdiagnostica.com

#### Distributor



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016203.

The test is CE marked in accordance with the IVD directive. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability. GenomEra is a registered trademark of Abacus Diagnostica Oy.