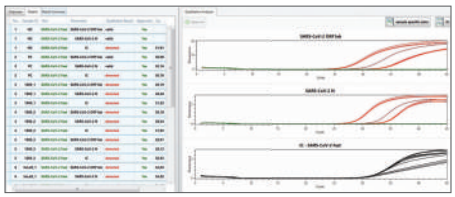
# EURORealTime SARS-CoV-2 Fast



- **Particularly fast PCR test for specific detection of SARS-CoV-2, including relevant variants***
- **Sensitive detection of two SARS-CoV-2 target sequences in separate fluorescence channels**
- **Reverse transcription of the viral RNA and real-time PCR in one step**
- **Only one reaction per sample**

* Alpha (B.1.1.7 lineage), Beta (B.1.351 lineage), Gamma (P.1 lineage), Delta (B.1.617.2 lineage), Lambda (C.37 lineage), Mu (B.1.621 lineage) and Omicron (B.1.1.529 lineage)

## Technical data

| | |
|---|---|
| **Test principle** | Reverse transcription of the SARS-CoV-2 genome followed by PCR amplification and real-time detection using specific primers and probes |
| **Test procedure** | Reverse transcription and real-time PCR in one test (approx. 45 min), software-supported evaluation |
| **Sample material** | RNA from nasopharyngeal swab |
| **Reagents** | Ready for use |
| **Controls** | Internal inhibition and extraction control (RNA), SARS-CoV-2 Fast positive control (RNA), negative control |
| **CE-IVD mark** | Test system validated for the automated nucleic acid extraction and PCR setup with the PreNat II system (PerkinElmer and for the automated nucleic acid extraction with the chemagic 360 (PerkinElmer chemagen) instrument, test system validated for the following real-time PCR cyclers: Eonis Q96 (PerkinElmer), LightCycler 480 II (Roche), 7500 Fast Real-Time PCR Instrument (Applied Biosystems), CFX96 Touch (Bio-Rad), qTower3 (Analytik Jena); other instruments need to be validated individually by the user. |
| **Test kit format** | 100, 200 or 1000 reactions |
| **Order number** | **MP 2606-0100-8, -0200-8, -1000-8** |

## Clinical significance

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, previously called 2019-nCoV) belongs to the family of coronaviruses and, like SARS-CoV, is classified in the genus *Betacoronavirus*. At the end of 2019, SARS-CoV-2 was identified as the causative pathogen in a cluster of pneumonia cases of unclear origin. The virus caused an infection wave that has spread rapidly over the world and was declared a pandemic by the WHO at the beginning of 2020.

SARS-CoV-2 is mainly transmitted via aerosols during coughing or sneezing or through close contact with an infected person. Human-pathogenic coronaviruses originate from the animal kingdom, however, the reservoir of SARS-CoV-2 is unknown. The incubation time is three to seven, maximally 14 days. The symptoms of SARS-CoV-2 infection are fever, cough, breathing difficulties, fatigue and loss of smell or taste as well as gastrointestinal complaints. In most patients the infection manifests with symptoms of a mild febrile illness with irregular lung infiltrates. Some patients, especially elderly or chronically ill patients, develop acute respiratory distress syndrome (ARDS). In February 2020, the disease caused by SARS-CoV-2 was named COVID-19 by the WHO. By the end of 2021, over 281 million COVID-19 cases with more than 5.4 million deaths had been registered worldwide. In the course of the pandemic several virus variants emerged that carry mutations that can affect immune response, infectivity and disease progression (variants of concern, VOC).

Suitable methods for the diagnosis of SARS-CoV-2 infections include, in particular, the detection of viral RNA by RT-PCR (reverse transcription polymerase chain reaction) or of virus protein by means of ELISA or rapid test, primarily in sample material from the upper respiratory tract (nasopharyngeal or oropharyngeal swab, anterior nasal swab). The viral load is highest in the first week of the illness. Virus RNA can be detected for up to 14 to 17 days after the onset of symptoms. The detection of viral antigens is less sensitive than RT-PCR testing.



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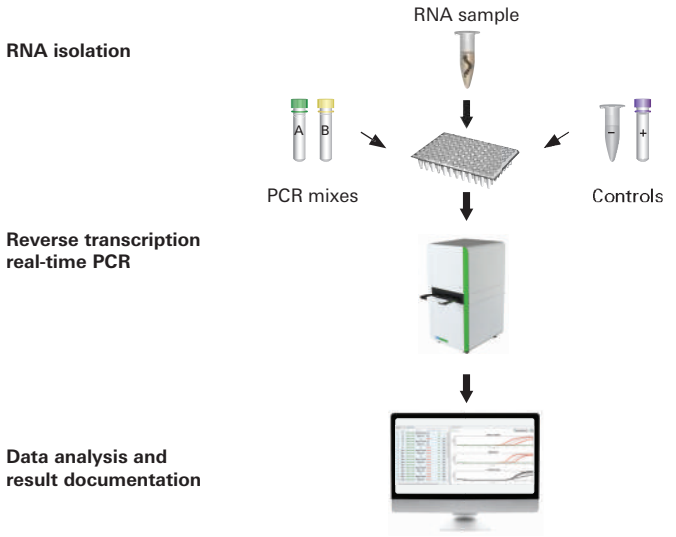
## Test principle

The test system uses a one-tube reaction based on reverse transcription (RT) for conversion of viral RNA into complementary DNA (cDNA), followed by PCR amplification and fluorescence-based real-time detection of two defined sections in the ORF1ab and the N gene of the SARS-CoV-2 genome. The detection of the target sequences is carried out in two separate fluorescence channels. Reverse transcription, amplification and detection of the SARS-CoV-2 cDNA are performed by means of specific primers and probes. The test contains an internal amplification control, which serves as an inhibition control and can additionally be used as an extraction control. A SARS-CoV-2 Fast positive control provided with the test kit is analysed as an external control in every test run. The real-time PCR is completed in approx. 45 minutes (depending on the type of instrument used). The EURORealTime Analysis software supports the user with analysing and evaluating the measurements from different PCR cyclers, including all controls. Furthermore, the software provides full guidance through the individual work steps, thus ensuring a simple and error-free test procedure.




## Analytical sensitivity

The primers and probes used in the EURORealTime SARS-CoV-2 Fast were developed based on the following sequence for SARS-CoV-2: NC_045512.2 (National Center for Biotechnology Information (NCBI)). The limit of detection (LoD) relative to the RNA sample was determined using quantified SARS-CoV-2-specific RNA (in vitro transcripts (IVT)) for the two detection regions. The LoD was confirmed in three independent investigations using three independent lots with 21 replicates each in the presence of 200 ng of human nucleic acid in ≥ 95 % of the reactions. The LoD is the minimum detection limit and amounts to 3 cp/µl and 6 cp/µl nucleic acid eluate for the SARS-CoV-2 ORF1ab (IVT) and SARS-CoV-2 N (IVT), respectively. However, the test system usually also detects fewer copies (cp) of RNA.

## Analytical specificity

The analytical specificity of the test system is ensured by the primer and probe design and the PCR conditions given in the instructions for use. All primers and probes used in the test system were checked for potential homologies by means of sequence comparison analyses in order to exclude potential cross reactivity. All available sequences in the "nr" database of the NCBI (status 20 April 2022) were taken into account (https://www.ncbi.nlm.nih.gov/tools/primer-blast/).

Additionally, nucleic acid of pathogens that are found in the respiratory tract or are closely related to SARS-CoV-2 were investigated using the EURORealTime SARS-CoV-2 Fast. No cross reactions (CR) were detected (see table). To exclude cross reactivity with human genomic DNA or RNA, 100 ng of each was used per reaction. No cross reactions were detected.

| Pathogen nucleic acid (1 ng nucleic acid/reaction) | CR |
|---|---|
| *Bordetella pertussis* | 0 % |
| *Chlamydia pneumoniae* | 0 % |
| Coronavirus MERS | 0 % |
| Coronavirus NL63 | 0 % |
| Coronavirus OC43 | 0 % |
| Coronavirus SARS HKU39849 | 0 % |
| Coronavirus 229E | 0 % |
| Enterovirus 71 | 0 % |
| *Haemophilus influenzae* | 0 % |
| Influenza virus A | 0 % |
| Influenza virus B | 0 % |
| *Legionella pneumophila* | 0 % |
| *Mycoplasma pneumoniae* | 0 % |
| Parainfluenza virus 1, 2 and 4 | 0 % |
| Respiratory syncytial virus A | 0 % |
| Respiratory syncytial virus B | 0 % |
| Rhinovirus | 0 % |
| *Pneumocystis jirovecii* | 0 % |
| *Streptococcus pneumoniae* | 0 % |
| *Streptococcus pyogenes* | 0 % |

| Pathogen nucleic acid (< 1 ng nucleic acid/reaction) | CR |
|---|---|
| Adenovirus 5 | 0 % |
| Coronavirus HKU1 | 0 % |
| Parainfluenza virus 3 | 0 % |

| Pathogen nucleic acid (50,000 cp/reaction) | CR |
|---|---|
| *Mycobacterium tuberculosis* | 0 % |

## Evaluation

A clinical sample panel (nasopharyngeal swabs) was analysed with the EURORealTime SARS-CoV-2 Fast to evaluate its clinical performance. The results were compared to those obtained with reference tests. The precharacterisations for all samples determined in two independent analyses were in agreement:

**Positive agreement:** 100 %
**Negative agreement:** 100 %

| 201 samples (nasopharyngeal swabs) | | Precharacterisation using SARS-CoV-2 real-time PCR reference tests* | |
|---|---|---|---|
| | | positive | negative |
| Results of EURORealTime-SARS-CoV-2 Fast | positive | 102 | 0 |
| | negative | 0 | 99 |

* Determination 1: ViroQ Rapid SARS-CoV-2 (BAG Diagnostics), determination 2: EURORealTime SARS-CoV-2 (EUROIMMUN)



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MP_2606_D_UK_C01, 06/2022