COVID-19 PCR DIATHEVA
Detection Kit
Molecular test for the qualitative detection of SARS-CoV-2 RNA
in upper and lower respiratory samples

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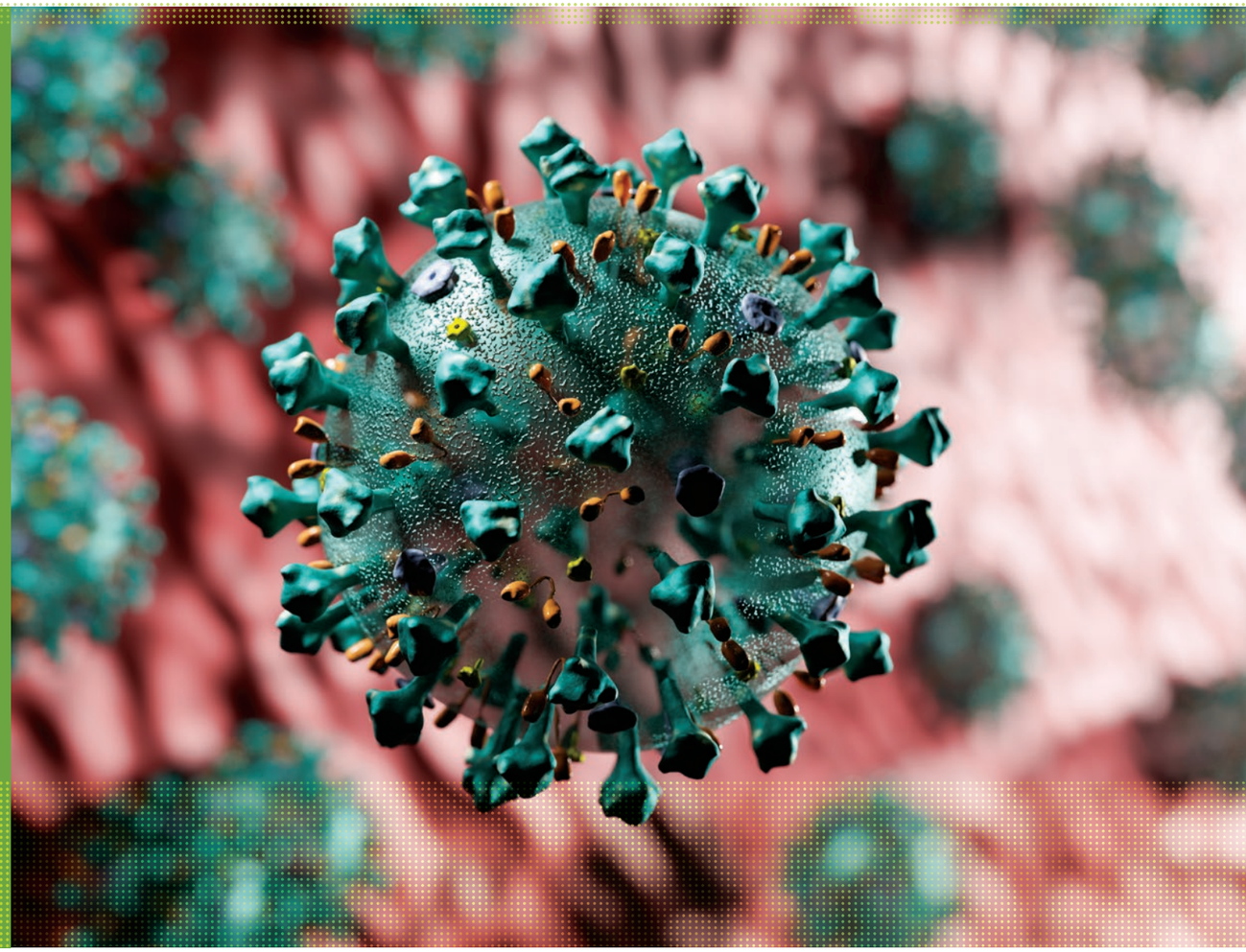

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Coronaviruses are a large family of viruses that are common in people and many different species of animals.
In December 2019, a cluster of patients with a novel coronavirus was identified in Wuhan, China. The virus named SARS-CoV-2 can cause the disease named coronavirus disease 2019

COVID-19 PCR DIATHEVA Detection Kit

COVID-19 is an infectious disease triggered by the SARS-CoV-2 virus.
The incubation period of this virus, i.e. the time that elapses from when you come into contact with the virus to when the symptoms of the disease occur, varies from 1 to 14 days, most commonly it is about 5 days.

The most common symptoms are: fever, tiredness and dry cough. These symptoms are generally mild to moderate in intensity and gradually manifest themselves. Some infected people do not develop any symptoms (asymptomatic). About 1 in 6 infected, on the other hand, becomes seriously ill and has difficulty breathing [World Health Organization: https://www.who.int/news-room/q-a-detail/q-a-coronaviruses].

COVID-19 PCR DIATHEVA Detection kit allows the qualitative detection of SARS-CoV-2 RNA in upper and lower respiratory samples during the acute phase of infection.
Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.
Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological observations.
Testing with the kit is intended for use by laboratory trained personnel in the technique of real-time PCR and in vitro diagnostic procedures.

Principle of the assay

The COVID-19 PCR DIATHEVA Detection kit is a One-step real-time reverse transcription (RT-PCR) multiplex assay based on fluorescent-labelled probe used to confirm the presence of SARS-CoV-2 RNA by amplification of RdRp and E target genes recommended by Charité, [Corman et al., 2020, Berlin protocol].

The assay includes also RNAse P gene as internal positive control to evaluate the RNA extraction and identify the presence of PCR inhibitors.
The kit provides all the reagents required for the analysis. PCR positive and negative controls are also included.

Diatheva offers also an optimized version of the kit (D-MBK0094) intended for the use with automated extraction systems.

Workflow

1. Sample collection

Upper and lower respiratory samples

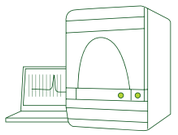
2. RNA extraction

RNA isolation and purification

3. RT-PCR set-up

add RNA sample and controls to PCR tubes containing amplification reagents

4. Real-time RT-PCR



RT-PCR amplification

5. Results analysis

Benefits

- **Ease of use: minimal hands-on time**
- **Results: less than 2 hours after extraction**
- **Reaction set-up at room temperature**
- **Compatibility: highly consistent results on various real-time instruments**
- **Reliability: the amplification of the internal control RNAse P allows to evaluate the quality of the RNA extraction and identify the presence of PCR inhibitors**

Ordering information

Code	Product	Size
D-MBK0091	COVID-19 PCR DIATHEVA Detection kit	96 tests
D-MBK0094	COVID-19 Automatic PCR DIATHEVA Detection Kit	96 tests