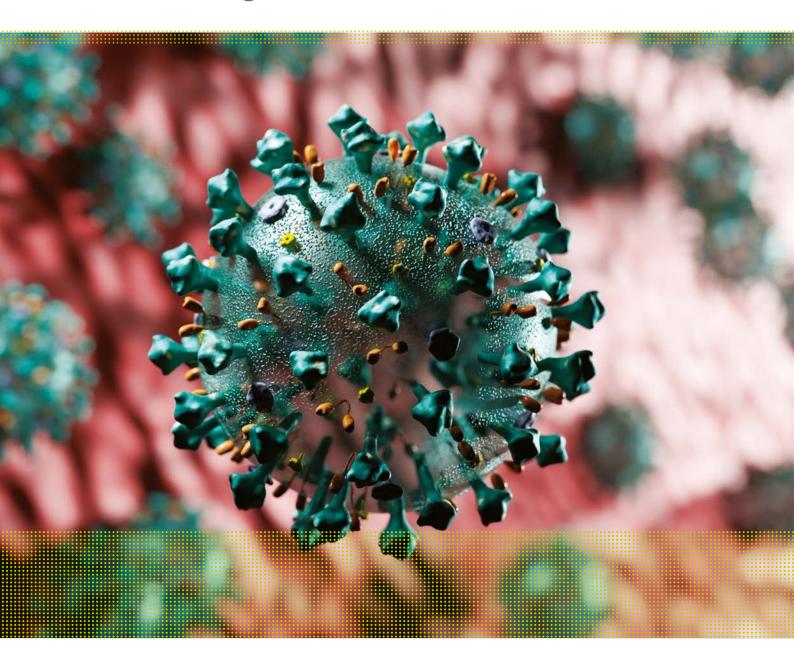


COVID-19 Portfolio

The complete range of Diatheva products for SARS-CoV-2 virus infection diagnosis





Coronaviruses are a large family of viruses that are widespread in humans and many species of animals. In December 2019, a group of patients with a new type of coronavirus was identified in Wuhan, China. The virus called SARS-CoV-2 can cause the infectious disease called coronavirus 2019 or COVID-19. The incubation period of the infection, that is the time between exposure to the virus and symptom onset, varies from 1 to 14 days. Generally it is around 5 days. The most common symptoms are fever, fatigue and dry cough. The intensity of these symptoms varies from mild to moderate and occur gradually. Some people despite being infected do not have any symptom (asymptomatic). About 1 in 6 infected becomes seriously ill with breathing difficulties.

Here are Diatheva's solutions to enable accurate diagnosis across a range complete with products. Diatheva offers high quality and easy to use kits for molecular analysis and detection of SARS-CoV-2 RNA from nasopharyngeal and oropharyngeal samples.

DIATHEVA COVID-19 PCR Kit CEIVD

Diatheva COVID-19 PCR Kit is a One-step real-time reverse transcription (RT-PCR) multiplex assay with fluorescent probes, which allows the detection of SARS-CoV-2 RNA by amplification of the ORF1b and N genes. The test is based on the guidelines issued by the WHO.

New generation kit:

- Two specific SARS-CoV-2 targets: ORF1b and N
- Higher reproducibility performance of results from low viral load samples
- Maximum stability of the endogenous internal control
- Correct COVID-19 diagnosis also in patients infected with the English, Brazilian and South African virus variants

COVID-FLU-RSV All-in-One RT PCR CEIVE

With the arrival of the flu season, incidence of respiratory infections such as influenza increase in the colder months, creating a challenge for medical systems and diagnostics alike.

Although these infections may have similar symptoms, treatments for SARS-CoV-2 infection, flu, and other infections are different, making it important to distinguish between SARS-CoV-2 infection and other respiratory conditions. Running multiple tests on each patient is a difficult and costly endeavor, but tests are now available that can distinguish between SARS-CoV-2 and common respiratory viruses in one effort.

Diatheva offers the COVID-FLU-RSV All-in-One RT PCR.

The kit is CE IVD marked, a one-step multiplex real-time RT-PCR test. The method allows the simultaneous detection of specific viral genes of ORF1b/N, M1/NS2 and M for SARS-CoV-2, Flu A/B, RSV A/B from the same respiratory sample.

Workflow

1. Sample collection



Upper and lower respiratory samples

2. RNA extraction



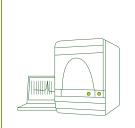
RNA purification and isolation

3. RT-PCR set-up



Samples and controls addition to the PCR wells containing the amplification reagents

4. Real-time RT-PCR



RT-PCR amplification

5. Results analysis



Benefits

- · Ease of use: minimum working times and preparation of the analysis at room temperature
- Open system: the kits are compatible and can be used on different extraction systems, including automated ones and on the most popular real-time PCR platforms
- Reliability: the amplification of the endogenous internal control (RNAse P) allows to evaluate the quality of the starting sample, of the RNA extraction and identify the presence of PCR inhibitors

Ordering Information

Product Code	Product	Description	Size
D-MBK0100	Diatheva COVID-19 PCR Kit	Real-time PCR	96 test
D-MBK0096	COVID-FLU-RSV RT PCR Detection kit	Real-time PCR kit	96 test
D-MBK0097	COVID-FLU-RSV All-in-One RT PCR	Real-time PCR Kit	96 test



Diatheva offers a range of quick solutions, POINT OF CARE, aimed at antigen research and at the serological analysis of antibodies.

COVID-19 IgG/IgM Rapid test

During a viral infection, our immune system produces specific antibodies.

IgM antibodies are the first defense against the viruses and their detection indicates a recent infection. IgG are produced later instead. IgG lasts longer and their detection indicates a previous infection.

The IgG / IgM rapid test marketed by Diatheva and certified CE IVD is a rapid immunochromatographic test used for detection of IgG and IgM antibodies directed to SARS-CoV-2 from human whole blood, serum or plasma samples.

The product is able to provide the result in just 15 minutes with the use of a simple lancet device.

Workflow

- 1. Sample collection Blood sampling using lancet device
- 2. Sample transfer Add the sample into the well
- Starting of the reaction Add the buffer to the well
- Results analysis Reading of the results at 15 minutes

Coronavirus Antigen Rapid test

The Coronavirus Antigen rapid test marketed by Diatheva is an immunochromatographic test. The product allows detection of the nucleocapsid antigenic protein from SARS-CoV-2 and therefore to identify the infection in progress.

The test is performed starting with nasopharyngeal swabs from individuals suspected of COVID-19. The test is performed by a health-care provider within the first ten days from the onset of SARS-CoV-2 symptoms.

Workflow

- 1. Sample collection Nasopharyngeal swab sampling
- 2. Preparation of the extraction buffer Add 10 drops of the extraction buffer in the test tube
- 3. Lysis Rotate the swab into the tube containing the extraction buffer
- 4. Sample Transfer Add 4 drops of sample solution in the sample well of the cassette test
- 5. Results analysis Reading of the results at 15 minutes

For both tests, the result for the final diagnosis must be evaluated by the medical staff together with the patient's clinics manifestations and results from other laboratory methods.

Benefits

- Easy to use
- CE-IVD certification
- Results in 15 minutes
 Point of care (POCT)
- High specificity and sensitivity

Ordering Information

Product Code	Product	Description	Size
COVID40	COVID19 IgG/IgM Rapid Test	Rapid immunochromatographic test	40 test
COVID-ANT	Coronavirus Ag Rapid Test Cassette-Swab	Rapid immunochromatographic test	20 test



Diatheva has developed a range of ELISA-based assays for semi-quantitative detection of IgG and IgM immunoglobulins specific for SARS-CoV-2. Both kits use the virus nucleocapsid protein as a diagnostic marker.

Protein N is the most expressed protein of the coronavirus and thanks to its high reactivity with antibodies, it represents an optimal diagnostic marker. Two types of antibodies are produced and secreted by our immune system: IgM and IgG. The presence of anti SARS-CoV-2 IgM in the serum of the patient indicates the acute phase of the infection while the presence of anti SARS-CoV-2 IgG indicates the lasting response and immunity against the virus.

COVID-19 ELISA IgG DIATHEVA kit CEIVE

is an enzyme-linked immunosorbent assay (ELISA) for the determination of IgG antibodies against the COVID-19 Coronavirus antigen Nucleocapsid (N) from plasma and serum.

Clinical Validation

Diagnostic Sensitivity	98.8%	
Diagnostic Sensitivity	98.0%	

COVID-19 ELISA IgM DIATHEVA kit CEIVE

is an enzyme-linked immunosorbent assay (ELISA) for the determination of IgM antibodies against the COVID-19 Coronavirus Nucleocapsid antigen (N) from plasma and serum.

Validazione Clinica

Diagnostic Sensitivity	97.52%
Diagnostic Sensitivity	99.60%

Workflow



Serum or plasma collection





20 minutes

Performance of

the ELISA analysis

(in automatic or manual mode)

Total analysis time: less than 2 hours and 30 minutes

Reading of results on a microplate

2 hours and 30 minutes

Benefits

- High specificity and sensitivity
- Analysis speed with an overall analysis time of less than 2 hours and 30 minutes
- · Convenience: all reagents are ready to use providing continuity, stability and a long shelf life

Ordering Information

Product Code	Product	Description	Size
D-AKE0021	COVID-19 ELISA IgG DIATHEVA kit	ELISA Kit	96 test/ 1 plate
D-AKE0022	COVID-19 ELISA IgM DIATHEVA kit	ELISA Kit	96 test/ 1 plate



COVID-19 Antibodies and proteins

Diatheva provides antibodies and proteins to be used for research on the SARS-CoV-2 virus.

Our aim is to provide high quality reagents supported by excellent technical assistance in order to help you achieve your goals. In order to satisfy any need, Diatheva can provide all materials marked with: customer choice fluorophores, biotin and HRP for different applications.

For reagents not in the catalog **Diatheva offers research services**, **customized development and production**.

Please contact info@diatheva.com.

The SARS-CoV-2 nucleocapsid (N) protein is an antigen of particular importance for the coronavirus. The nucleocapsid protein encloses the genome of the positive stranded viral RNA in a helix ribonucleocapsid (RNP) and plays a vital role during the assembly of the virion through interactions with the viral genome and the membrane protein M. The COVID-19 anti-Nucleocapsid polyclonal antibody was designed for nucleocapsid protein detection.

Ordering Information

Product Code	Product	Description	Size	Form
ANT0090	SARS-CoV-2 Nucleocapsid Polyclonal Antibody	Clinical diagnostics Life Sciences	100 μL	Liquid
ANT0091	SARS-CoV-2 Spike S1 Monoclonal Antibody (S71)	Clinical diagnostics Life Sciences	100 μg	Liquid
ANT0092	SARS-CoV-2 Spike S1 - RBD Monoclonal Antibody (S157)	Clinical diagnostics Life Sciences	100 μg	Liquid
ANT0093	SARS-CoV-2 Spike S2 Monoclonal Antibody (S222)	Clinical diagnostics Life Sciences	100 μg	Liquid
ANT0094	SARS-CoV-2 Spike S2 Monoclonal Antibody (S223)	Clinical diagnostics Life Sciences	100 μg	Liquid
REP0072	Recombinant SARS-CoV-2 Nucleocapsid Protein	Clinical diagnostics Life Sciences	100 μg	Liquid
REP0073	Recombinant SARS-CoV-2 Nucleocapsid Protein	Clinical diagnostics Life Sciences	500 µg	Liquid

Placing an Order

Placing an order is simple and can be done in several ways:

Email

You can email your order to crm@diatheva.com.

When ordering please specify:

- Company and contact name
- Product and quantity
- VAT number if EU or ID company number
- Billing and Shipping address

When we receive an order we will check that all details are correct and confirm the order by email.

Technical Support

For technical assistance and product information please visit our website or contact our Technical Service department at techsupport@diatheva.com.

We strive to answer all emails in less than 24 hours.

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