ScheBo® • SARS-CoV-2 Quick™ IgM/IgG 2in1 rapid test for professional use

SARS-CoV-2 IgM and IgG antibody detection from human whole blood, serum and plasma samples

The ScheBo® • SARS-CoV-2 Quick™ is a combined immunochromatographic lateral flow test for the simultaneous detection of SARS-CoV-2 IgM and IgG antibodies.

ScheBo® • SARS-CoV-2 Quick™ IgM/IgG:

- Combined antibody test for the simultaneous detection of SARS-CoV-2 IgM and IgG
- Sample material: whole blood, serum or plasma
- Rapid test results after 15 minutes
- CE approval as medical device
- No additional equipment needed

INTENDED USE

The ScheBo® • SARS-CoV-2 Quick™ is a visual immunochromatographic rapid test for the qualitative detection of SARS-CoV-2 IgM- and IgG-antibodies from human serum, plasma and whole blood samples. It is an in-vitro diagnostic test exclusively for professional use.
The ScheBo® • SARS-CoV-2 Quick™ is an aid in the diagnosis of a SARS-CoV-2 infection and for its early adaptive immune respond.
At the end of December 2019, Chinese public health authorities reported several cases of acute respiratory syndrome in Wuhan City, Hubei province, China. Chinese scientists soon identified a novel coronavirus as the main causative agent. The disease is now referred to as Coronavirus Disease 2019 (COVID-19), and the causative virus is called Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). It is a new strain of coronavirus that has not been previously identified in humans. The most common signs of infection are fever, cough, shortness of breath, muscle / joint pain, sore throat, headache, nausea and vomiting. In more severe cases, infection can lead to pneumonia, severe acute respiratory syndrome, kidney failure and even death. The main transmission takes place via droplets which arise when coughing and sneezing. These droplets are absorbed by the other person through the mucous membranes of the nose, mouth and possibly the eye. A transmission through contaminated surfaces cannot be ruled out, especially in the immediate vicinity of the infected person.

TEST PRINCIPLE

The ScheBo® • SARS-CoV-2 Quick™ is based on the immunochromatographic method. The SARS-CoV-2 IgM/IgG specific antibodies are detected by the SARS-CoV-2 recombinant antigen and the monoclonal anti human IgM/IgG antibody. SARS-CoV-2 IgM/IgG in the sample reacts with the SARS-CoV-2 recombinant antigen bound to gold particles. This complex migrates along the membrane and reaches the IgM/IgG test lines which have a monoclonal anti human IgM/IgG antibody against SARS-CoV-2 IgM/IgG complex attached.
When the result is positive, the gold-labelled SARS-CoV-2 recombinant antigen-antibody complex binds to the IgM/IgG test line and a pink color develops. When the result is negative, the sample does not contain any SARS-CoV-2 recombinant antigen-antibody complex that can bind to the IgM/IgG test line, so no color becomes visible. Development of a control line (C) guarantees that sample application and migration have taken place correctly and that the test has been properly performed.

Report Adverse events in the USA, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 or by calling 1-800-FDA-108