DELTA CHEMIE BIOTECHNOLOGY

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One Check

OneCheck COVID-19 Ag

Rapid test for the detection of SARS-CoV-2 antigen in nasopharyngeal swab samples

AN EFFECTIVE **SUPPORT FOR THE RAPID DIAGNOSIS OF COVID-19 IN PATIENTS WITH SYMPTOMS OF INFECTION** AND A VALID AID FOR MASS SCREENING

The COVID-19 Ag Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Sars-CoV-2 Antigen in human **nasopharyngeal swab specimen** as an aid in the rapid diagnosis in individuals with symptoms of SARS-CoV-2 infection.

This test is for professional and in vitro diagnostic use only and it is intended for use by trained clinical laboratory personnel.

CATALOG REF.: TR186

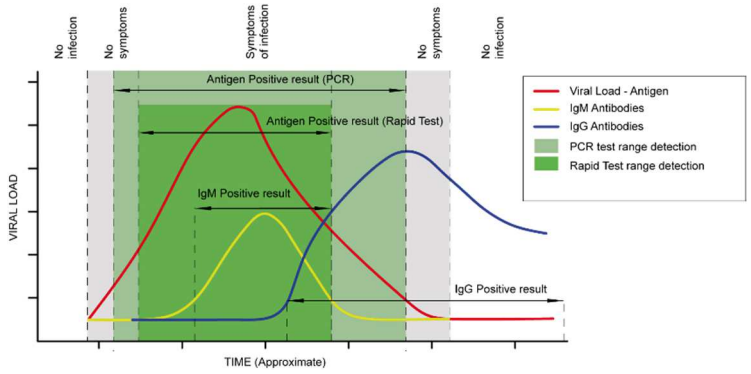
PACKAGE: 20 testS

METHOD: Lateral flow

SAMPLES: Nasopharyngeal swab

TIME TO RESULT: 15 minutes

Antigen is generally detectable in upper respiratory specimens during the acute phase of infection.
Unlike antibodies, which take several days from infection to form and be detectable in the sample, the antigen is present in the patient from the initial stages of infection.
If in sufficient quantity to be detected by the test, it is the most reliable and direct indicator of the presence of the virus and the most effective system for the early diagnosis of COVID-19.



The graph show the evolution of the disease compared with the range of antigen and antibodies detection

✓ **No additional equipment needed**
All the devices for sample collection and performing the test are included in the kit

✓ **Low costs**
Compared to the reference method RT-PCR

✓ **Fast results**
Result in 10 minutes

✓ **Simple use and interpretation**
The appearance of a colored line indicates a positive result

ATTENTION: Carefully read the User Manual in its entirety, in particular the sections "Intended use" and "Limitations". Rapid test method is not a substitute for the reference RT-PCR method.

ICIM UNI EN ISO 9001:2015 CERTIFIED MANAGEMENT SYSTEM

ICIM UNI EN ISO 13485:2016 CERTIFIED MANAGEMENT SYSTEM

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OneCheck COVID-19 Ag Rapid Test

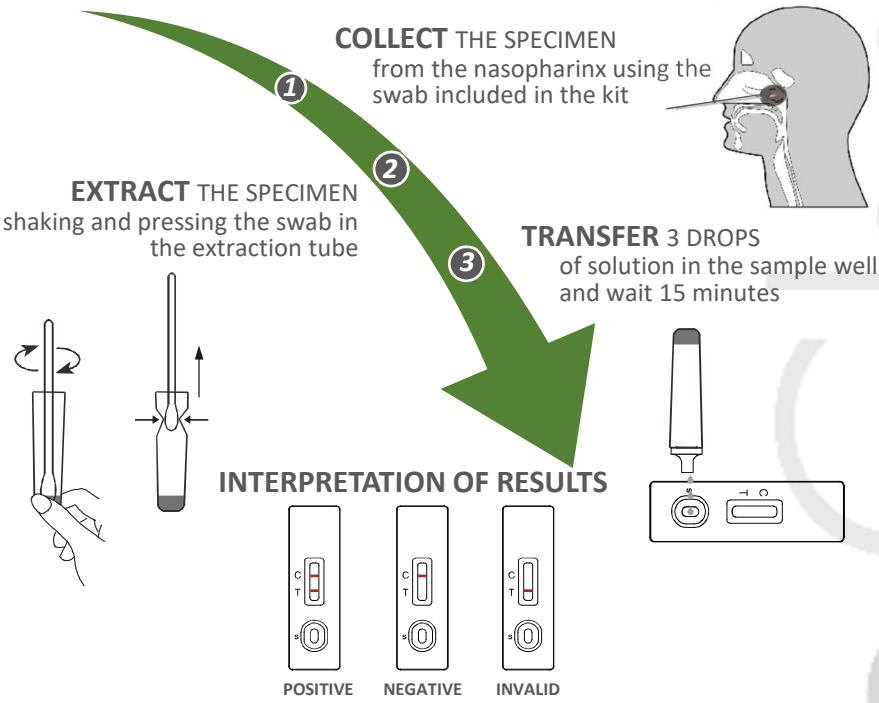
This test is a simple and valid diagnostic aid in all those cases of symptoms of suspected infection, when it is not possible to use laboratory equipments or when an initial analysis is required in a short time (emergency cases or mass screening).

In combination with the Rapid Test for the detection of antibodies, it allows a large-scale control of the infection and the identification of asymptomatic subjects.

THE DISEASE

COVID-19 is an acute respiratory infectious disease caused by the novel coronavirus SARS-CoV-2. The incubation period of the disease is 1 to 14 days, mostly 3-7 days.
Currently, the patients infected by the novel coronavirus, symptomatic and asymptomatic, are the main source of infection. An infected person can be contagious even during the incubation period.
The main manifestations include fever, fatigue and dry cough, breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.
IgM antibodies can be detected a few days after the incubation period and the appearance of the first symptoms. They remain present for a short time and can be an indicator of acute infection. IgG antibodies appear after several days and remain present for a long time.
The Antigen is present before the formation of antibodies and its detection is the most suitable test for an early diagnosis of the infection.

PROCEDURE



LIMITATIONS

Samples collected before or after the acute phase may contain antigenic titers below the minimum detection limit of the test.

Proper sample collection is critical for optimal test performance. Collect the sample correctly and accurately.

The sample collection must be carried out by expert and specially trained personnel. An inaccurate sample collection can give false negative results.

DIAGNOSTIC MEANING

This test detects the SARS-CoV-2 antigen in nasopharyngeal swab samples.

- **A positive result must be confirmed by the reference method (RT-PCR).**
- **A negative result does not exclude an infection with certainty. If clinical symptoms persist** or in case of suspected contagion, it is recommended to make a new sample collection or to analyze the sample with the RT-PCR method.

PERFORMANCE		
SENSITIVITY	SPECIFICITY	ACCURACY
96,4 %	99,2 %	98 %

Data obtained by comparing Rapid Test with RT-PCR test.

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...trust in diagnosis...