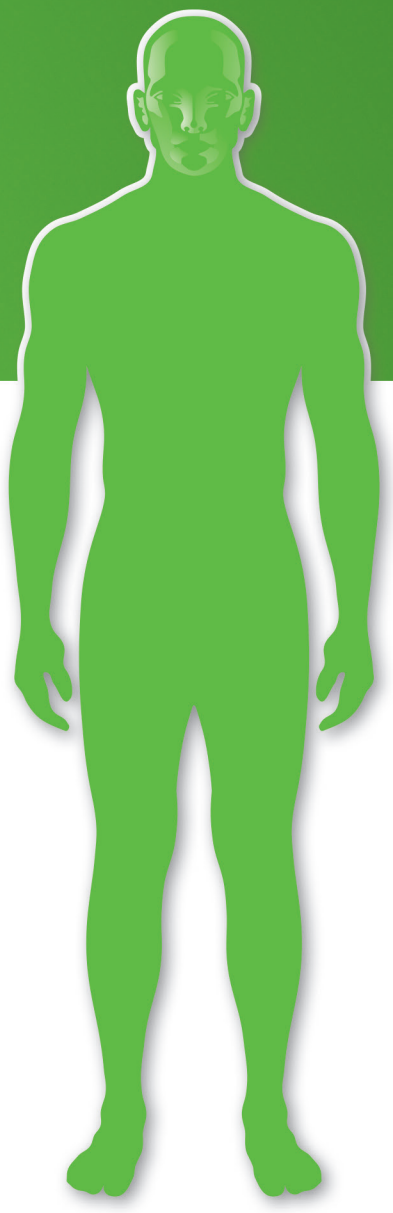
High-Quality Rapid Tests Made in Germany

MEXACARE

A Quick Guide to COVID-19 Diagnostics



Certified Quality System mdc ISO 13485

When you need to know quickly

MEXACARE DIAGNOSTICS

MEXACARE is a company specialized in high-quality and reliable medical devices.

The struggle against the SARS-CoV-2 virus and its consequences places high demands on all parties involved. Therefore, as a certified manufacturer of high quality diagnostic products, we see our mission in constantly adapting our products to the latest state of technology and the very highest quality standards in order to be able to provide the authorities, doctors and laboratories with the best possible product.
MEXACARE GmbH is an ISO 13485 certified manufacturer for medical rapid tests.

We practice what we promise

As a partner company of a raw material manufacturer for the diagnostics industry, we were able to draw on first-hand patient material, among other things. To ensure the quality, reliability and efficacy of our test in the future, additional quality controls are carried out on every product and every batch, and our product is subject to continuous further development. This enables our customers to offer their patients the highest possible level of safety in the current dynamic pandemic situation. In addition, all our products (incl. COVID-19!) are regularly checked by independent interlaboratory tests.

We can do even more for you

Our team will support you with comprehensive know-how, reliable quality management and the experience from many successfully completed projects.

Test with us!

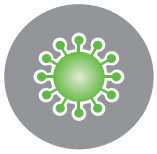
Diagnosis of Infectious Diseases

Reliability and precision through extensive quality controls

Quick Guide to COVID-19 Diagnostics

MEXACARE Antibody Tests

MEXACARE Antigen Rapid Tests



Key Facts about COVID-19

What is SARS-CoV-2?

In late December 2019, an outbreak of a novel coronavirus disease (COVID-19; formerly known as 2019-nCoV) was reported in Wuhan, China, which subsequently spread worldwide. In early 2020, SARS-CoV-2 (Severe acute respiratory syndrome coronavirus type 2), a novel coronavirus from the group of beta-coronaviruses, was identified as the cause. In general, COVID-19 is a mild cold disease, but it can also cause severe pneumonia, which can be fatal. The case fatality rate (CSR) is strongly age-dependent. For patients up to 50 years of age, it is very low, at less than 0.1 %. From this age on, however, it rises increasingly and often exceeds 10 % in patients over 80 years of age. The new coronavirus epidemic in 2019 has been declared an international health emergency by the World Health Organization, which has developed into a pandemic with significant morbidity and mortality.

How does the SARS-CoV-2 virus spread?

The main mode of transmission is the absorption of virus-containing particles that are produced when breathing, coughing, speaking and sneezing. A distinction is made between larger (droplets) and smaller particles (aerosols). While the larger droplet particles sink to the ground quickly, aerosols remain in the air for a longer period of time and thus spread in closed rooms. However, in addition to the size of the particles, this depends on other factors, e.g. temperature and humidity.

How does a disease with COVID-19 progress?

The most common symptoms include cough, fever, rhinitis and loss of smell and taste. However, the course of the disease varies greatly. Some infected patients remain symptomless, some have only mild disease progressions; however, up to severe pneumonia, which usually occurs in the second week of illness, anything is possible. Approximately 81% of patients who test positive have a mild course. 14 % show a more severe course and around 5 % a critical course. Other symptoms recorded are sore throat, headache and aching limbs, shortness of breath, nausea, vomiting, diarrhea, loss of appetite and swelling of the lymph nodes. Since COVID-19 is still a very new clinical picture, it is not yet possible to make any reliable statements about consequential damages or diseases caused by the treatment (e.g. by artificial respiration in intensive care).

In severe cases, hospitalization (in Germany) takes place on average 4 days after the onset of symptoms. If it is necessary to admit the patient to an intensive care unit, this usually takes place 9 days after the onset of symptoms.

When is a person infected with SARS-CoV-2 contagious?

Exactly when the risk of infection with SARS-CoV-2 begins has not yet been researched. However, it is now considered certain that the highest risk of infection is around the time of onset of symptoms. If the course of the disease is mild or moderate, a patient is usually contagious up to 10 days after the onset of symptoms. In case of more severe courses of the disease, there is still a risk of infection beyond this period.

Who is particularly at risk?

In general, severe progressions can occur in all age groups, as well as in patients with no known previous

illness. However, some groups of people are particularly at risk:

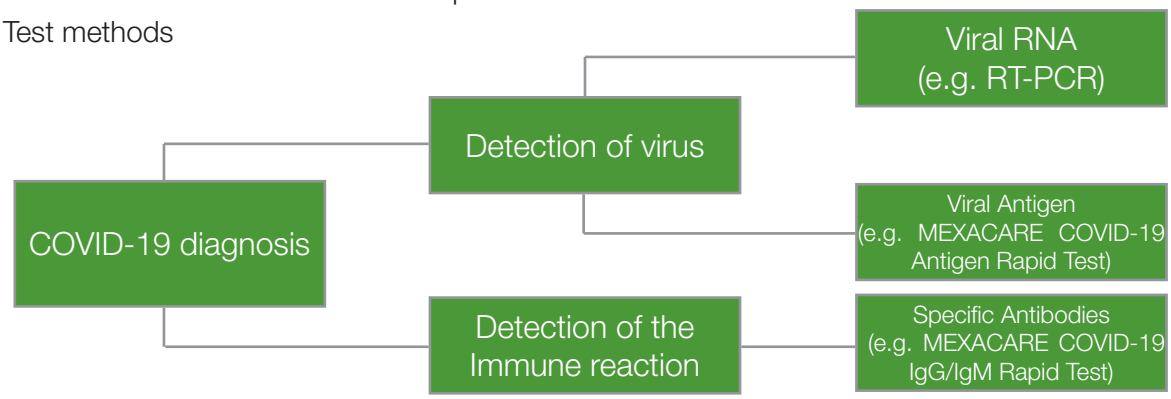
- elderly people (86% of COVID-19 patients who died in Germany were 70 years or older)
- severely overweight people
- patients who suffer from the following pre-existing conditions:
  - cardiovascular diseases
  - chronic lung diseases
  - chronic kidney and liver diseases
  - Diabetes
  - weakened immune system

These categories of people are particularly in need of protection. It is therefore particularly important to test people who come into contact with high-risk groups (e.g. geriatric nurses) carefully and frequently.

How can patients with suspected COVID-19 be tested?

Basically, an infection with SARS-CoV-2 can be tested in two different ways. Firstly, the virus particles themselves can be detected in a nasal/throat swab, and secondly, the body's immune response to the corona viruses can be tested in blood samples.

Fig. 1: Test methods



1. RT-PCR

The so-called real-time reverse transcriptase polymerase chain reaction is a laboratory procedure in which the viral genome of the virus is replicated in several cycles with the aid of a machine. By using fluorescent substances, it is then possible to see whether the gene sequence of the virus is present in the sample. Although this method is very accurate, it is comparatively complex and expensive. Special laboratory instruments are required and the patient has to wait 1-2 days for the result, depending on the workload of the laboratory. However, the greatest weakness of RT-PCR is the sample collection! For example, a too cautious swab will introduce sample material into the RT-PCR, which naturally contains no - or only very few - virus particles at all. The stage of the disease at which the throat swab also plays a decisive role.

2. MEXACARE COVID-19 Antigen Rapid Test

This rapid test detects the virus through so-called viral antigens (proteins on the virus envelope). Compared to RT-PCR, the test is very inexpensive, can be performed directly at the point of care and requires no additional instruments. A reliable result is available after only 15 minutes if the test is performed correctly. Since the presence of the virus itself in the nasal/pharyngeal cavity is also checked here, this test can detect the presence of the virus very early in the course of the infection. Antigen rapid tests can also play an important role if there is a suspicion that the PCR test has been falsely negative (e.g. if symptoms persist). Here, further detection of SARS-CoV-2 virus particles in the neck/throat of the patient can be performed quickly and reliably for confirmation.

3. MEXACARE COVID-19 IgG/IgM Antibody Rapid Test

These types of tests differ from the above mentioned ones in that they do not detect the virus itself, but the body's immune response (in the form of antibodies) to the virus infection. In addition, an infection is also detected in a longer period after recovery (via IgG antibodies), even if PCR tests can no longer give a positive result. This can be extremely helpful in tracing infection chains and determining the immunization of a patient. From 7 days after onset of symptoms, antibody tests even exceed the sensitivity of RNA detection. In addition to the acute diagnosis by IgM antibodies, this test is particularly helpful in differentiating COVID-19 from other respiratory infections such as influenza or RSV, as well as in tracking the course of the disease.

IgM antibodies are frequently the body's first reaction to infection. They are usually easily detectable in whole blood, serum and plasma samples shortly after the onset of symptoms. A reliable test result with IgM antibodies is achieved in most patients within 7 days after the onset of symptoms.

IgG antibodies are produced during the regeneration process. They often remain in the body of the recovered patient for a long time and can play an important role in the determination of immunity (e.g. also in the development of vaccines). It can also be helpful in the tracing of infections, as this antibody can also be used to detect undiscovered infections that occurred some time ago.

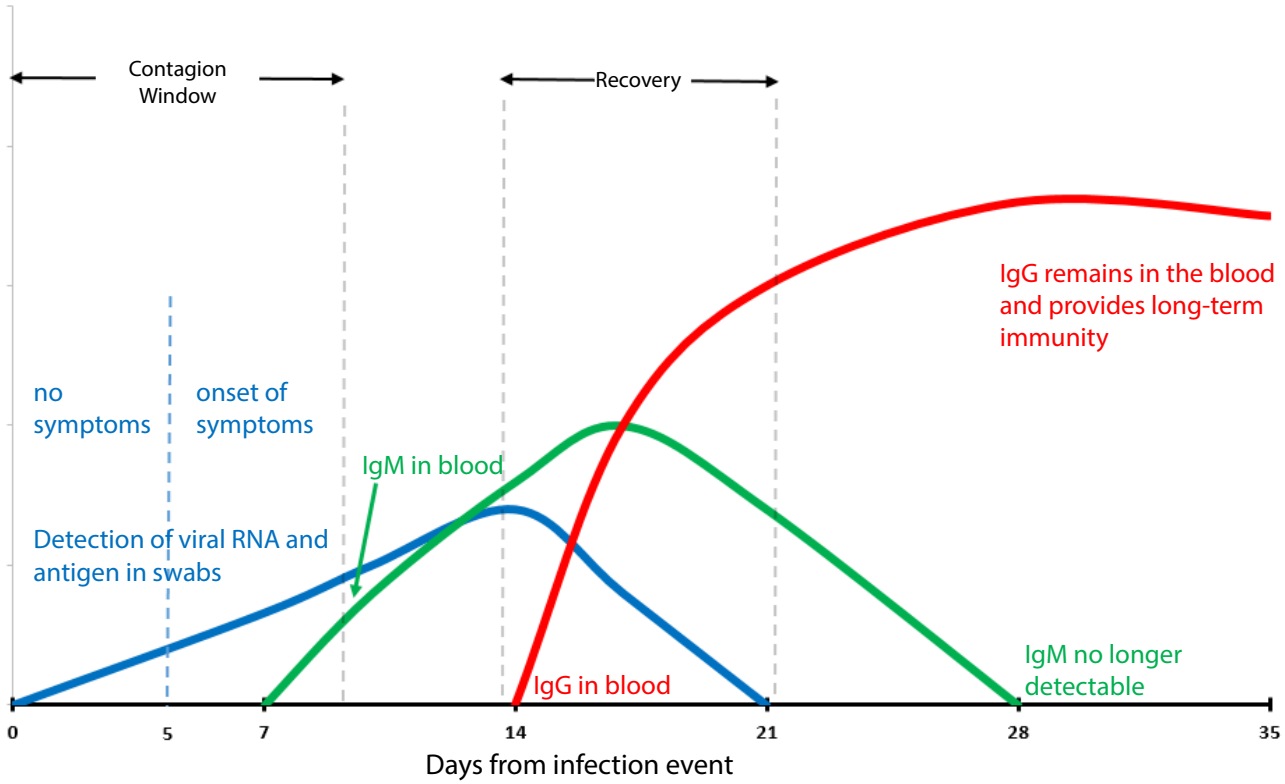


Fig. 2 Typical course of antibody concentration in blood

Fig. 3 Summary of the different test methods and when their application is recommended

Test Methods				Clinical stage of the patient
RT-PCR	Antigen	IgM Ab	IgG Ab	
+	+	-	-	Patient is in the incubation period
+	+	+	-	Patient is in an early stage of infection
+	+	+	+	Patient has symptoms/is sick
+	+	-	+	Patient is at a later stage of infection or in recovery
-	+	+	-	Patient is in the early phase of infection and/or PCR is suspected false negative
-	-	-	+	Patient possibly had an infection, but has recovered
-	+	+	+	Patient ist im Genesungsprozess und/oder die PCR vermutlich falsch negativ

What is the difference between a good and a less good rapid test?

Critical to the evaluation of a test is the so-called "diagnostic **sensitivity**" and "**specificity**" as well as the resulting "accuracy". In this performance evaluation, a certain number of clinical samples are tested with the rapid test as well as with another test, a recognized gold standard or a widely used laboratory method. In the case of COVID-19, the so-called RT-PCR (see above) is usually used here. **The better the agreement with this test, the better the rapid test you have.**

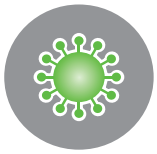
An example: A rapid test is made with 100 clinical samples that have been previously identified as positive by RT-PCR. The rapid test detects 95 of these samples as positive, but 5 as negative, so 95% of the positive samples (confirmed by RT-PCR) were also detected as positive. The rapid test therefore has a diagnostic sensitivity of 95 %. The specificity is calculated accordingly from the amount of negative samples which are also detected as negative by the rapid test.

What is the Ct-value and why is it so important?

With RT-PCR, another parameter, the so-called Ct-value, becomes relevant.

When coronavirus is detected with a PCR test, the genetic material (RNA) present in a clinical sample is amplified. The Ct-value (cycle-threshold) in this method refers to the measurement cycle in which a clinical sample was detected as positive. The lower this measuring cycle, the higher the viral load (i.e. the amount of virus present in the nasal/pharyngeal cavity).

This value is usually in the range between 20 and 35. If the Ct value is 20 in a PCR test, then this patient has a very high viral load. If the Ct value is > 30, on the other hand, a lower one. (The patient has "less" viruses in his nasopharynx). These patient samples usually come from patients who already have declining symptoms or from infections with only a small amount of virus. A test is therefore particularly sensitive if it still provides reliable results even in the higher Ct-value range, i.e. when the so-called viral load is already lower.



COVID-19 IgG/IgM Rapid Test

What is the COVID-19 IgG/IgM Rapid Test?

The COVID-19 IgG/IgM Rapid Test is a rapid, qualitative immunochromatographic in vitro test for the differential detection of IgM & IgG antibodies against the SARS CoV-2 virus in human serum, plasma or whole blood samples. The test is intended for the determination of a current or past infection with the SARS-CoV-2 virus and for monitoring the disease status after SARS-CoV-2 virus infection. To evaluate the performance of the MEXACARE COVID-19 IgG/IgM Rapid Test, a total of 1,615 patient samples were tested in several clinical studies in the USA, Canada, China and Germany. The MEXACARE COVID-19 IgG/IgM Rapid Test shows a sensitivity of 99.03 % and a specificity of 99.53 % only 7 days after the onset of symptoms.

RT-PCR	MEXACARE COVID-19 IgG/IgM Rapid Test		
	Positive	Negative	Total
Positive	307	3	310
Negative	18	1287	1305
Total	325	1290	1615

The accuracy of the test is thus 99.28 %.

When should I test with the COVID-19 IgG/IgM Rapid Test?

The COVID-19 IgG/IgM Rapid Test is intended to complement the RT-PCR tests, which are currently performed in large numbers by doctors, laboratories and public health authorities throughout the world in the fight against the novel Corona-Virus SARS-CoV-2.
During the earliest stages of the disease - in the incubation period (according to WHO around 5-6 days on average) and on the first 2-3 days after the onset of symptoms - only RT-PCR can give you satisfactory test results as the body has not produced antibodies in detectable quantities.
5-7 days after the onset of the disease symptoms (cough, slight fever, sore throat) IgM antibodies can already be detected in the blood. After this period of approx. 7 days, we recommend testing with the COVID-19 IgG/IgM rapid test, as positive results can now be obtained with a high degree of certainty. IgG antibodies are later produced by the immune system and can be detected in the body long after recovery. In this way, undetected infections (e.g. infections without symptoms) or the serological protection of the test subject can be determined.

Why are antibody tests useful?

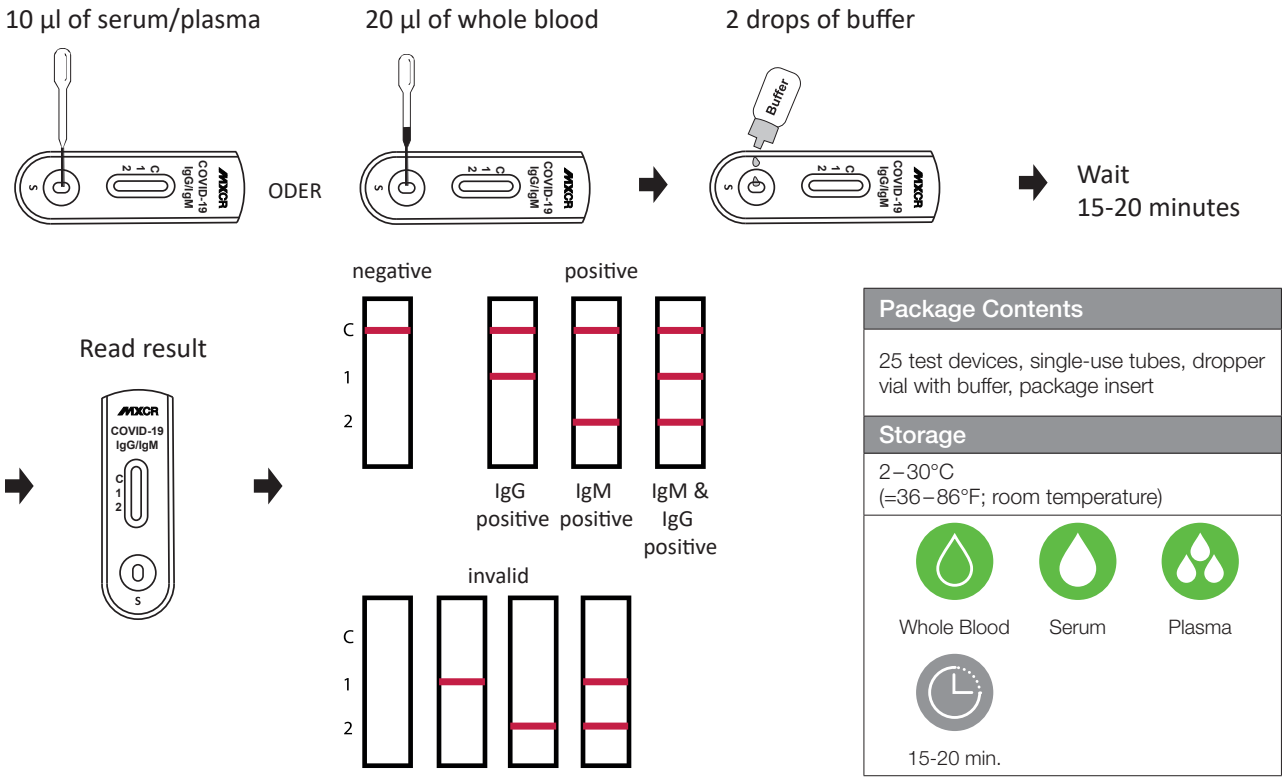
Antibody tests can fill a diagnostic gap. In the earlier phases of the disease - several days after the onset of symptoms - the IgM antibody test can be used to screen for active infections with SARS-CoV-2 and help to distinguish between COVID-19 and other respiratory diseases such as influenza or RSV. In the later stages, the IgG antibody test can help to detect previously undetected infections and screen the serological immunity of large numbers of the population. In addition, the IgG antibodies remain in the body for a long time after the patient has recovered. Therefore, the result is a marker for successful convalescence in ONLY IgG-positive patients.
Since antibody tests are much faster and easier to perform, the extended use of these tests could relieve the laboratories and help to keep capacity at the same level.

The benefits of the MEXACARE COVID-19 IgG/IgM Rapid Test:

- √ Test device for qualitative and selective detection
- √ Fast, easy, inexpensive - No lab equipment needed
- √ Safe point of care test with result within 15-20 minutes
- √ High sensitivity (>99%) as early as 7 days after the onset of symptoms
- √ High specificity (>99%) enables rapid detection of infected persons
- √ Detection of antibodies even in patients without symptoms
- √ Complements MEXACARE Corona Antigen Rapid Test and RT-PCR as a powerful tool for comprehensive assessment of virus distribution
- √ Approved reliability through extensive clinical studies (more than 1600 subjects from 4 countries)
- √ Important diagnostic gap for the detection of an earlier immune reaction is closed
- √ Proof of immunity of patients, and to lift quarantine measures
- √ Offers the possibility of effective screening of large parts of the population
- √ Compared to competitive products, the COVID-19 IgG/IgM Antibody Test has clearer bands, which makes it easier to read

Sources:
(1) C. Wedtner - Schwabing Hospital; C. Drosten - Charité; R. Wölfel - Microbiology of the German Armed Forces; RKI
(2) RKI;
(3) I. Eckert - University Hospital Geneva;
(4) Lauer, S. et al., 2020. The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. Annals of Internal Medicine;
(5) National Health Commission of the People's Republic of China, New Coronavirus Pneumonia Diagnosis and Treatment Program

Fast and easy test procedure



Package Contents
25 test devices, single-use tubes, dropper vial with buffer, package insert
Storage
2–30°C (=36–86°F; room temperature)
Whole Blood · Serum · Plasma
15-20 min.

COVID-19 Antigen Rapid Test

What is the MEXACARE COVID-19 Antigen Rapid Test?

The MEXACARE Coronavirus Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in the human nasopharynx. One antigen (protein of COVID-19) is usually detectable in upper respiratory tract samples during the acute phase of infection. Positive results indicate the presence of viral antigens.

Relative Sensitivity	93,48% (95 % CI*: 88,4 %-98,5%)
Relative Specificity	99,62% (95 % CI*: 98,9%->99,9%)
Accuracy	98,01% (95 % CI*: 96,6%-99,47%)

When should I test with the MEXACARE COVID-19 Antigen Rapid Test

Like the RT-PCR test. which is currently the gold standard. an antigen test is able to detect infection with the novel coronavirus SARS-CoV 2 very early after infection.

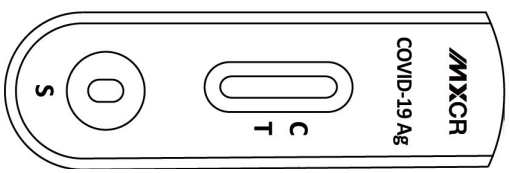
In the earliest stages of the disease - during the incubation period (according to the WHO an average of 5-6 days) and in the first 2-3 days after the onset of symptoms. a test with the MEXACARE COVID-19 Antigen Rapid Test is therefore recommended. Since the test detects protein components of the actual virus (so-called antigens) and not antibodies (the immune reaction of the human body against the virus). acute infections with SARS-CoV-2 can be detected at this early stage.

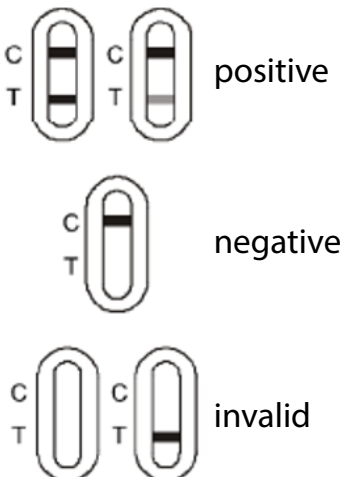
The benefits of the MEXACARE COVID-19 Antigen Rapid Test

- √ **Very high sensitivity (>93 %) and specificity (>99 %)**
- √ **Fast availability of test results (approx. 15 minutes)**
- √ **No expensive laboratory equipment needed**
- √ **No additional reagents required**
- √ **All materials for direct on-site testing included (Point-of-Care)**
- √ **No need to transport samples to the laboratory**

Fast and easy test procedure

3 drops of extracted specimen





Package Contents

20 Sealed pouches each containing one test cassette and one desiccant
20 Sterile swabs
20 Specimen collection containers with extraction buffer
1 Workstation
1 Package insert

Storage

2–30°C (Room Temperature)

Swab

15 min.

How well does the MEXACARE COVID-19 Antigen Rapid Test perform at different Ct values?
In order to determine the sensitivity of the COVID-19 Antigen Rapid Test at different Ct values, MEXACARE conducted a comparative study with patient samples in Austria that were confirmed positive by RT-PCR (including determination of the Ct value). In this study the MEXACARE COVID-19 Antigen Rapid Test achieved the following results:

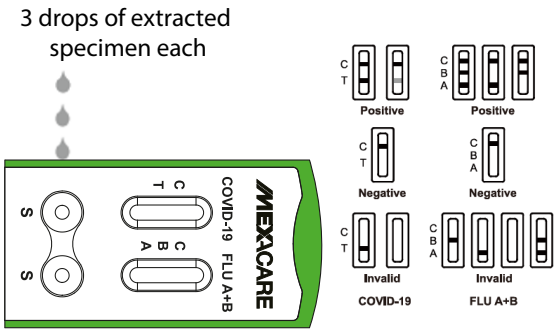
RT-PCR Ct-values	Sensitivity of MEXACARE Covid-19 Antigen Rapid Test
20-30	100 %
20-31	96.2 %
20-32	96.3 %
20-33	90.0 %
20-34	90.3 %

In the particularly important Ct range between 20 and 30, the MEXACARE rapid test achieved a perfect result with 100% sensitivity.
All samples confirmed positive by RT-PCR were detected as positive in this study. Most positive patient samples are found in this area and the viral load in the patients is rather high. Various studies (e.g. La Scola, B. et al. Viral RNA load as determined by cell culture as a management tool for discharge of SARS-CoV-2 patients from infectious disease wards. Eur J Clin Microbiol Infect Dis 39, 1059-1061 (2020).) suggest that among these patients, infectivity is probably also particularly high.

COVID-19 & Influenza A+B Ag Combo

Infectious disease marker

The MEXACARE COVID-19 & Influenza A+B Ag Combo Rapid Test is a rapid chromatographic immunoassay for the selective and qualitative detection of SARS-CoV-2, Influenza A and Influenza B virus antigens in the human nasopharynx.



Additional facts: The MEXACARE COVID-19 & Influenza A+B Antigen Combo Rapid Test greatly facilitates the diagnosis of conspicuous respiratory symptoms. A single smear is sufficient to test patients for both COVID-19 and influenza A+B. Due to the similarity of symptoms of both infections (cough, rhinitis, neck scratching, fever) it is recommended to perform the test for both infections.

Influenza A	
Sensitivity	94.1 %
Specificity	98.4 %
Accuracy	97.5 %
Influenza B	
Sensitivity	91.7 %
Specificity	> 99.9 %
Accuracy	98.8 %

Package Contents

20 Sealed pouches each containing one test cassette and one desiccant
20 Sterile swabs
20 Specimen collection containers with extraction buffer
1 Workstation
1 Package insert

Storage

2–30°C (Room Temperature)

Swab

15 min.

Customized rapid tests for your portfolio

In the field of Rapid Tests we offer you a wide range of products where you can put together your assortment to meet your individual needs: Single tests as cassettes and combination tests as panels with accessories.

Detection based on

Whole Blood | Serum | Plasma | Swab

Versions

- For professional in-vitro-diagnostics only
- We can also offer you an individual product line
- Contact us and receive an individual offer, specially tailored to the needs of your surgery or facility

Certified quality

Certified Quality System mdc ISO 13485

CE

Our friendly staff is available for you

9 a.m. to 4 p.m. CET from Mondays to Fridays under
06221-90682-41 or **kontakt@mexacare.com**

Product Index COVID-19

Catalogue No.	Description	Quantity/PU
3011027	MEXACARE COVID-19 IgG/IgM Rapid Test	25
3011030	MEXACARE COVID-19 Antigen Rapid Test	20
3011033	MEXACARE COVID-19 & Influenza A+B Ag Combo Rapid Test	20
All tests are CE certified		

With our rapid tests you will receive a wide range of point-of-care diagnostic systems:

- No additional equipment is required
- You get results within minutes
- There are no maintenance or follow-up costs
- Store at room temperature
- Clean and hygienic application
- Best quality at competitive prices

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