QuickTestCorona COVID-19 IgG/IgM

Rapid Test Cassette
(Whole Blood/Serum/Plasma)
Package Insert

DR. ALBERT HEALTH PRODUCTS

A rapid test for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma specimens. For professional in-vitro diagnostic use only.

INTENDED USE

The QuickTestCorona COVID-19 IgG/IgM Rapid Test is a rapid, qualitative and convenient immunochromatographic in vitro assay for the differential detection of IgM & IgG antibodies to the SARS-CoV-2 virus in human serum, plasma or whole blood samples obtained from patients with a COVID-19 infection. The device is designed to aid in the determination of recent or previous exposure to the SARS-CoV-2 virus and tracking the status of the disease after a SARS-CoV-2 Virus infection.

This assay only provides a preliminary result. A positive result does not necessarily mean a current infection, but may represent a different stage of the disease after an infection. IgM positive or IgG/IgM both positive suggest recent exposure, while IgG positive suggests previous infection, or latent infection. A current infection should be confirmed by Real-Time Reverse Transcriptase (RT-PCR) or viral gene sequencing. The test is intended for professional in-vitro diagnostic use only.

SUMMARY & PRINCIPLE

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 general, COVID-19 is an acute resolved disease but it can also be deadly, with a 2% case fatality rate. Severe disease onset might result in death due to massive alveolar damage and progressive respiratory failure. The pathogen has since been identified as a zoonotic coronavirus, similar to SARS coronavirus and MERS coronavirus, and has been named as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The 2019 novel coronavirus (SARS- CoV-2) epidemic has been declared a public health emergency of international concern by the World Health Organization, may progress to a pandemic associated with substantial morbidity and mortality. SARS-CoV-2 is genetically related to SARS-CoV, which caused a global epidemic with 8096 confirmed cases in more than 25 countries in 2002–2003.

The principle of the QuickTestCorona COVID-19 IgG/IgM Rapid Test is an antibody-capture immunochromatographic assay for the simultaneous detection and differentiation of IgM & IgG antibodies to the SARS-CoV-2 in human serum, plasma, or whole blood samples. SARS-CoV-2-specific antigens are conjugated to colloidal gold and deposited on the conjugate pad. Monoclonal anti-human IgM and monoclonal anti-human IgG are immobilized on two individual test lines (T2 and T1) of the nitrocellulose membrane. The IgM line (T2) is closer to the sample well and followed by the IgG line (T1). When the sample is added, the gold-antigen conjugate is rehydrated and the COVID-19 IgM and/or IgG antibodies, if any in the sample, will interact with the gold conjugated antigen. The immunocomplex will migrate towards the test window to the test zone (T1 & T2) where they will be captured by the relevant anti-human IgM (T2) and/or anti-human IgG (T1), forming a visible pink line, indicating positive results. If there are no COVID-19 antibodies present in the sample, no pink line will appear in the test lines (T1 & T2), indicating a negative result.

To serve as an internal process control, a control line should always appear at the Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

MATERIALS

Materials Provided

•25 sealed pouches each containing a test cassette and a desiccant •25 capillary tubes •25 alcohol swabs •25 lancets •1 buffer •package insert

Materials Required but not Provided

•clock or timer •gloves

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not reuse!
- Do not use if the product seal or its packaging is compromised!
- Do not use after the expiration date shown on the pouch!
- Do not mix and interchange different specimens.
- This test should be performed at 15 to 30 °C (59 to 86 °F). If stored refrigerated, ensure that the Test Units are brought to operating temperature before performing testing.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled!
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, regional or national regulations.
- Keep out of children's reach.

SPECIMEN COLLECTION AND PREPARATION

- **Whole Blood** samples may be collected by fingerstick or venipuncture, following routine facility procedures. In summary:

Fingerstick whole blood:

- Clean the area of finger to be lanced with the alcohol swab. Allow to dry.
- Without touching the puncture site, rub down the hand towards the middle or ring finger fingertip.
- Puncture the skin with a sterile lancet and wipe away the first drop of blood.
- Gently rub the hand from wrist to the lanced finger to form a full drop of blood over the puncture site.
- Collect the blood droplet using the included capillary tube.
- Fingerstick whole blood must be tested immediately after collection.

Venous whole blood:

- Collect venous whole blood in a tube with anticoagulant.
- Whole blood samples should be tested immediately after sample collection.
- **For Serum samples**, collect blood in a tube without anticoagulant and allow it to clot.
- **For Plasma samples**, collect blood in a tube containing anticoagulant.

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

Whole blood in an anticoagulant tube and serum and/or plasma in clean test tubes may be stored at 2 °C to 8 °C for up to 7 days if the tests cannot be performed immediately. For long-term storage, serum/plasma may be kept at -20 °C for six months, but repeated freezing and thawing should be avoided. If the specimen must be transported, whole blood should be packed in a spill-resistant anticoagulation test tube; serum or plasma in a spill-resistant test tube. The transport must be carried out refrigerated (approx. 2 - 8 °C). Bring the sample to room temperature (without heating) before use.

DIRECTIONS FOR USE

Allow the test, specimen and buffer to reach room temperature (15-30°C) prior to testing.

1. Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a flat, dry surface.
2. **For fingerstick whole blood:**
   Using a capillary tube, collect the fingerstick whole blood till the black line.
   For venous whole blood:
   Using a pipette or a capillary tube, collect the venous whole blood (20µl).
   For serum/plasma:
   Using a pipette, collect the serum/plasma (10µl).
3. Add the collected serum/plasma/whole blood to upper area (close to test window) of sample well on the test device without air bubbles (hold the capillary tube/ pipette vertically and gently touch the end against the pad within the sample well for transferring).
4. Wait for 20-30 seconds; add 2 drops (around 90µl) of the sample buffer to the sample well of the test device.
5. Read the results after 15-20 minutes. Strong positive specimens may produce positive result in as little as 1 minute.
   DO NOT INTERPRET RESULTS AFTER 30 MINUTES!

INTERPRETAION OF RESULTS

NEGATIVE:

A pink colored band appears only at the control region (C), indicating a negative result for COVID-19 infection.

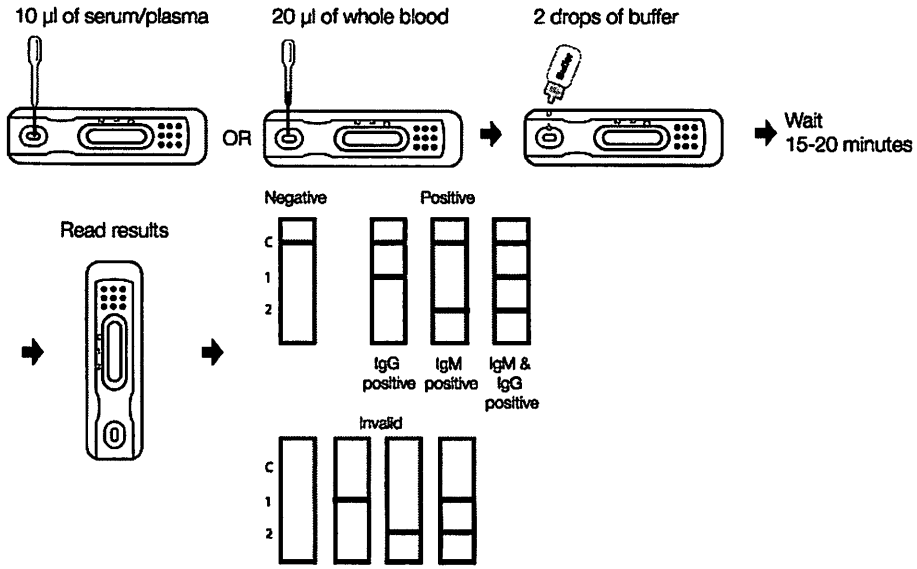
POSITIVE:

Pink colored bands appear at the control region (C) and T1 and /or T2 region.

1) **IgM and IgG positive**, visible bands at T2 and T1, indicating positive result for a possible COVID-19 infection.
2) **IgM positive**, a visible band at T2 region, indicating positive result for a possible COVID-19 infection.
3) **IgG positive**, a visible band at T1 region, indicating a positive result for a possible COVID-19 infection.

INVALID:

No visible band at the control region (C). Repeat with a new test device. If test still fails, please contact the distributor with the lot number.



WHAT DOES MY RESULT MEAN?

NEGATIVE: You probably haven't been infected with SARS-CoV-2. However, if symptoms persist or worsen, contact a physician for further diagnostic measures! (see limitations)

IgM POSITIVE: IgM antibodies are formed in the body very shortly after an infection. This means that you have probably recently been infected with SARS-CoV-2 (approx. last 2-3 weeks) if the result is exclusively IgM positive. Contact a doctor and have the result confirmed by further diagnostic measures!

IgG POSITIVE: IgG antibodies are not formed in the body until about 1-2 weeks after the onset of symptoms and are still detectable in the blood for a long time after infection. If your result is exclusively IgG positive, you have probably been infected with SARS-CoV-2 for some time without symptoms or you have already recovered from the disease. In the case of a viral infection, no IgM antibodies and only IgG antibodies are usually detectable after about 5 weeks. According to the current state of knowledge, you are now probably no longer infectious and therefore immune to SARS-CoV-2. Contact a doctor and have the result confirmed by further diagnostic measures!

IgG & IgM POSITIVE: Both IgM and IgG antibodies are detectable in your body. You were probably infected with SARS-CoV-2 about 3-5 weeks ago. Contact a doctor and have the result confirmed by further diagnostic measures!

INVALID: Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- The test device in the sealed pouch should be stored at 2 - 30 °C. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2 - 30 °C.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- The reagent can only be used to determine the immune status of the body to SARS-COV-2 after infection, but not directly to diagnose current SARS-COV-2 infection.
- Use in conjunction with the testing strategy outlined by public health authorities in your area. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the test early after infection is unknown.
- Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. At this time, it is unknown how long IgM or IgG antibodies may persist following infection.
- Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection [and successful immune response to a vaccine, once developed].
- False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
- The presence of specific antibodies are a sign of previous or current infection, and can also be used to determine the efficacy of treatment.
- Laboratories are required to report all positive results to the appropriate public health authorities.
- Test-specific limitations, as required.
- Although the test demonstrates superior accuracy in detecting antibodies against COVID-19 virus, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by thephysician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS & CROSS-REACTIVITY

Total 468 samples were collected including 40 RT-PCR confirmed SARS-COV-2 positive samples and 428 SARS-COV-2 negative samples. Among the 40 samples, there were 13 fingerstick whole blood specimens, 10 venous whole blood specimens and sera from the same patients, 17 sera/plasmas. All the 40 positive samples were tested positive to IgM and/or IgG by QuickTestCorona COVID-19 IgM/IgG Antibody Test. The diagnostic sensitivity was 100 %(40/40). There were 16 only IgM positive, 3 only IgG positive, 21 both IgM & IgG positive. 13 fingerstick whole blood samples in positive samples showed positive; 10 venous whole blood in positive samples showed positive and no significant difference between venous whole blood specimen and serum specimen. Among the 428 negative samples, 2 of them showed IgM false positive with QuickTestCorona COVID-19 IgM/IgG Antibody Test. The diagnostic specificity was 99.53%. The overall agreement was 99.57%.

Table 1:

		QuickTestCorona COVID-19 IgG/IgM				Total
		IgM (+)	IgG (+)	IgM & IgG (+)	IgM & IgG (-)	
RT-PCR SARS-COV-2 positive samples	Serum/plasma	4	2	11	0	40
	Fingerstick whole blood	8	1	4	0	
	Venous whole blood & serum	4	0	6	0	
	Subtotal	16	3	21	0	
SARS-CoV-2 negative samples		2	0	0	426	428
Total		18	3	21	426	468

Table 2: Diagnostic sensitivity & specificity

RT-PCR	QuickTestCorona COVID-19 IgG/IgM Schnelltest		
	positive	negative	Total
positive	40	0	40
negative	2	426	428
Total	42	426	468

Diagnostic sensitivity: > 99,9 %
Diagnostic specificity: 99,53%
Overall agreement: 99,57%

BIBLIOGRAPHY

- *Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected, Interim guidance, World Health Organization, 13 March 2020.*
- *Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19), World Health Organization, 16-24 February 2020.*
- *Chinese Center for Disease Control and Prevention. The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19), CCDC Weekly, 2(8):113-122, 2020.*
- *Wang C et al. A novel coronavirus outbreak of global health concern. Lancet, 395(10223): 470-473, 2020.*

Consult instructions for use	Test per kit	Do not reuse
IVD For in vitro diagnostic use only	Use by	Manufacturer
Store between 2-30°C	LOT Lot Number	REF Catalog #

MEXACARE GmbH
Hans-Bunte-Straße 6
69123 Heidelberg
GERMANY

CE

Version 1.0 ENG, as of : 2020-05-05

Distributor:
Dr. Alber Health Products
Schweizerweg 3
69120 Heidelberg, Germany

Safety lancet:
Owen Mumford GmbH
Alte Häge 1
63762 Großostheim
GERMANY
CE 0123

Alcohol pads:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen,
GERMANY
CE