BelTEST-It !

SARS-COV-2 SPECIFIC IGM / IGG TEST KIT

FOR PROFESSIONAL USE ONLY

INSTRUCTIONS FOR USE

IN-VITRO DIAGNOSTIC

Immunochromatographic rapid test for the qualitative detection of immunoglobins M (IgM) and G (IgG) against the SARS-CoV-2 virus in human whole blood and serum samples.
The test is an aid in the diagnosis of COVID-19 disease.
FOR PROFESSIONAL USE ONLY.

The SARS-CoV-2 IgM / IgG rapid in-vitro diagnostic immunochromatographic assay test is intended for the qualitative detection of possible SARS-CoV-2 antibodies in early (day 4-10) and later (day 11-24 and later) stages of infection. With the aid of this test, healthcare providers can obtain a qualified diagnosis and determination of the immune reaction to coronavirus infection over a period of 4-24 days and longer.

Consult Instructions for Use

IVD In-vitro diagnostic medical device

Product for single-use only / not for re-use

For prescription use only

Package specification:

REF 10.01 - 1 unit per box

REF P10.10 - 10 units per box

REF P10.100 - 100 units per box

UDI 4260463350401

UDI 4260463350418

UDI 4260463350425

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1 INDICATIONS AND USAGE

The Pharmact CoV-2 Rapid Test (SARS-CoV-2 IgM/IgG Test Kit) is an in-vitro diagnostic test for the qualitative detection of IgM and IgG antibodies to the SARS-CoV-2 virus in human serum or whole blood (venipuncture and/or fingerstick) samples collected in CLIA certified laboratories and/or by healthcare workers at the point-of-care.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The CoV-2 Rapid Test is intended for use by trained healthcare professionals. The CoV-2 Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

2 SUMMARY AND EXPLANATION OF THE TEST

When the body has been exposed to the SARS-CoV-2 virus, it produces specific IgM / IgG antibodies in an attempt to defend itself against the infection. By measuring the concentration of those particular antibodies, the SARS CoV-2 Virus Detection Kit can determine in 20 minutes whether a patient has been exposed to the virus within the past 4 to 24 days or longer.

3 PRIMARY TEST STEPS

- Carefully read and follow the enclosed Instructions for Use
- Open the sealed foil package
- Use lancet and pipette to take blood
- Place two drops of blood in specimen window of cassette
- Add two drops of buffer solution
- Read results in exactly 20 minutes
- Interpret results using the table below

4 PRINCIPLE OF THE TEST

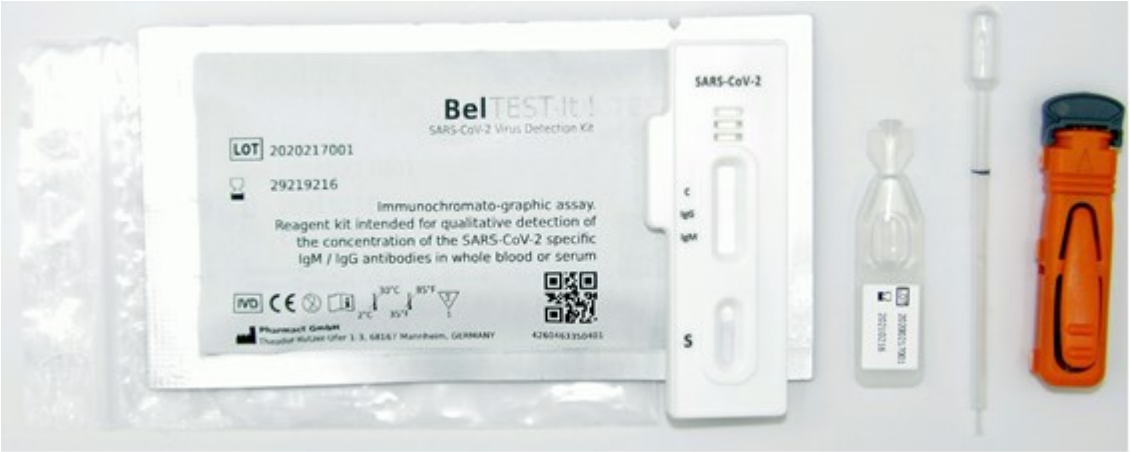
The SARS CoV-2 Virus Detection Kit consists of a cassette containing a test strip with two detection bands, one for IgM and one for IgG. These are coated with mouse anti-human IgM and IgG antibodies, respectively. The test strip also has a control band ("C"), which is coated with a goat anti-mouse IgG antibody.

The test requires a specimen of whole blood or serum (50µL) to be placed in the "specimen field" of the cassette along with a buffer solution (50µL). The specimen than migrates along the strip. After twenty minutes, a purplish-red line at the IgM line indicates the presence of the IgM antibody, suggesting an early infection stage (within the past 4 to 10 days). Even a faint line indicates infection.

A purplish-red line appearing at the IgG line indicates the presence of IgG, suggesting a later infection phase (within the past 11 - 24 days) or past infection. Even a faint line indicates infection.

A clearly visible purplish-red line must appear in the control region in order for the test results to be valid.

5 OVERIEW MATERIALS PROVIDED



6 MATERIALS REQUIRED BUT NOT SUPPLIED

- Stopwatch or watch
- Topical antiseptic
- Sterile gauze or cotton ball

7 WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only

- Read all directions before use.
- Wear protective gloves, clothing and eyewear when performing the test.
- The test is for single use only and is disposable
- Do not eat, drink, or smoke while handling specimens and performing the test.
- Blood specimens must be transported in accordance with applicable law.
- Do not interchange or mix components of different lots
- Do not use test after the stated Expiration Date
- Follow your clinical and/or laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens, including the items supplied with this test
- Follow all directions carefully. Do not end the test halfway. If the test is half finished, it should not be resumed.

NOTE: The rapid test may be infectious after use. Please use the enclosed plastic bag for disposal of used test materials.

8 STORAGE AND STABILITY:

- Unused tests must be stored in a dark, dry location between 2° and 30°C (36° and 85°F)
- Do not freeze test components
- Do not remove test components from sealed foil package until ready to perform test
- Test must be performed at least within 30 minutes of opening the sealed foil package
- Do not use test if it appears damaged or if the foil package is unsealed.

9 SPECIMEN COLLECTION AND PREPARATION

The SARS CoV-2 Virus Detection Kit may be performed with specimens of whole blood from the fingertip, whole blood directly from a venipuncture site, or serum.

Do not store specimens at room temperature for extended lengths of time.

Do not use the test with severely hemolytic, severely lipemia or jaundiced specimens.

Capillary Blood:

- Sterilize a finger with a topical antiseptic. Remove the cap from the sterile lancet, press the lancet against the side of a fingertip, then press the back of the lancet to prick the fingertip. Wipe away the first drop of blood from the fingertip with sterile gauze or cotton ball
- Collect two drops (50 µL) of blood with pipette.
- (Alternatively, two hanging drops of blood from the fingertip can be used.)
- [MOVE PICS HERE FROM BELOW? - SEE COMMENT – THEY SEEM TO FIT BETTER HERE?]
- Follow Test Procedure (below).

Venous blood:

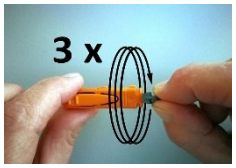
- Take two drops of venous blood and place them directly into the specimen window (“S”) (Figure 1), then follow test procedure.

Serum:

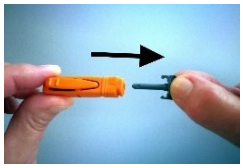
- If serum specimens are not used immediately, they should be stored at -20°C (-4°F) or below. Frozen specimens should be thawed slowly and completely, brought to room temperature (15°-30°C; 60°–85°F) and mixed well before use.
- Serum specimens should not be used for severe hemolysis, severe lipaemia, or high bilirubin concentration.
- If a serum specimen contains fibrin, particles or red blood cells, it should be agglutinated and centrifuged. Specimens should not be repeatedly frozen and thawed.

10 SPECIMEN TEST PROCEDURE

The cassette is contained in a protective foil package. The foil package also contains a transfer pipette for applying the blood sample. The test kit also contains an ampoule with buffer solution, a sterile lancing device for the pricking the fingertip and this Instructions for Use.



1 Preparing the lancing



2 Unlocking the device

3 Prick the fingertip

4 Taking blood with pipette

5 Buffer solution

1. Bring all test components, the buffer solution and the specimen to room temperature (15°- 30°C; 60° – 85°F).
2. Set stopwatch

3. Open the sealed foil package. The test must be performed as soon as possible (no longer than 30 minutes) after the package is opened.
4. Remove the test strip cassette (Figure 1) and mark it with a specimen ID (e.g. Name, Date).
5. Place the test strip cassette on a level table.
6. Wipe away the first drop of blood from fingertip with a sterile gauze pad or cotton ball.
7. Using the pipette, take two drops of capillary blood, venous blood, or serum (50µL) and place them directly into the specimen window ("S") (Figure 1).
8. Add two drops of buffer solution to the specimen window ("S") (Figure 1 below). Avoid formation of air bubbles in the specimen window.

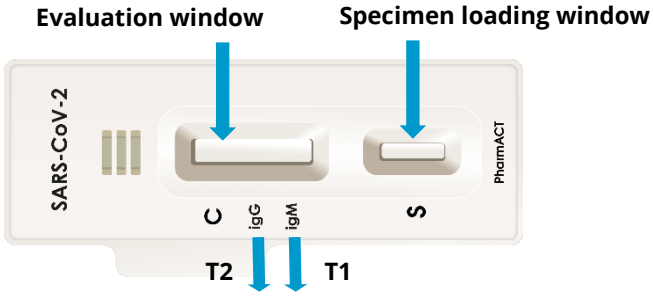


Figure 1. Test cassette including stripes and marking

9. Start the stopwatch or notice time at watch.
10. After approximately 30 seconds a red-pink color front will form and move across the strip in the evaluation window. If that does not occur, add another drop of buffer solution to the specimen window.
11. Read the result exactly 20 minutes after the specimen has been added. Never read the result after twenty minutes have elapsed.
12. Place all test components and other materials used for the test (topical antiseptic, gauze, etc.) in the plastic bag provided and dispose of them in accordance with your protocol for disposing of hazardous materials.

11 READING TEST RESULTS

Positive Result:

- After twenty minutes, a purplish-red line appearing at the "IgM line" (T1) indicates the presence of IgM antibodies, suggesting an early infection phase of SARS-CoV-2 (see Figure 2, below).
- A purplish-red line appearing at the "IgG line" (T2) indicates the presence of IgG, suggesting a later infection phase or past infection (see Figure 2, below).
- Even a faint line at IgM or IgG indicates a positive result (see Figure 2, below).

Negative Result:

- If the test has not detected IgM or IgG antibodies there will not be purplish-red lines at either "IgM" or "IgG" (see Figure 2, below).

Invalid Result:

- If there is no clearly visible purplish-red line at the control line ("C") within 5 to 10 minutes, the test is invalid and should be repeated using a new kit (see Figure 2, below).

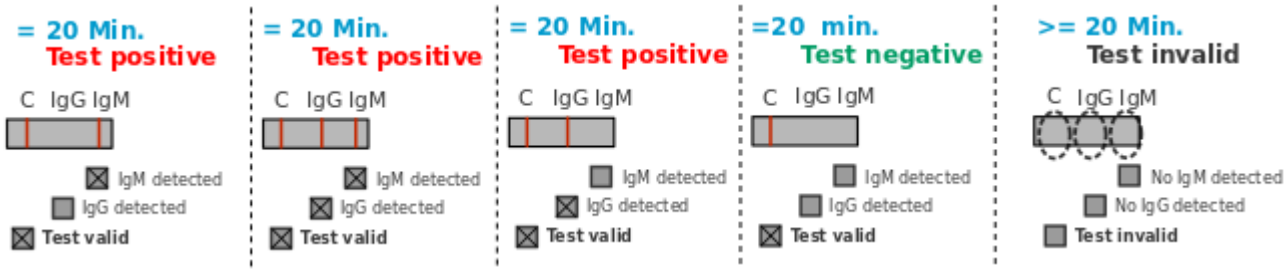


Figure 2. Interpretation of Test Results

12 CLINICAL SYMPTOMS INTERPRETATION

Antibodies are proteins produced and secreted by B-lymphocytes. They bind to foreign substances that invade the body, such as the SARS-CoV-2 virus.

The term "antibody" refers to its function, which is to bind to an antigen, e.g. a specific protein structure on the virus outer membrane. The antibody types measured with this test are IgM and IgG.

IgM usually circulates in the blood, accounting for about 10% of human immunoglobulins. IgM has a pentameric structure in which five basic Y-shaped molecules are linked together. B cells produce specific IgM first in response to a viral invasion. Although IgM has a lower affinity for antigens than IgG, it has higher avidity for antigens because of its pentameric/hexametric structure. IgM, by binding to the cell surface receptor, also activates cell signaling pathways. IgM is he indicator of early virus exposure. After an initial rise during the first 7 to 10 days of an infection, the levels of IgM decrease and disappear within the next 4-6 weeks (see Figure 3 below).

IgG is the most abundant antibody isotype in the blood (plasma), accounting for 70-75% of human immunoglobulins. IgG detoxifies harmful substances and is important in the recognition of antigen-antibody complexes by leukocytes and macrophages. IgG indicates that the body has been exposed to a virus in the past and can be measured even years after the infection. For many viruses, the determination of gigs isolated IgG titers after an occurred infection (or vaccination!) is also an indicator of immunity of the affected patient. (see Figure 3 below)

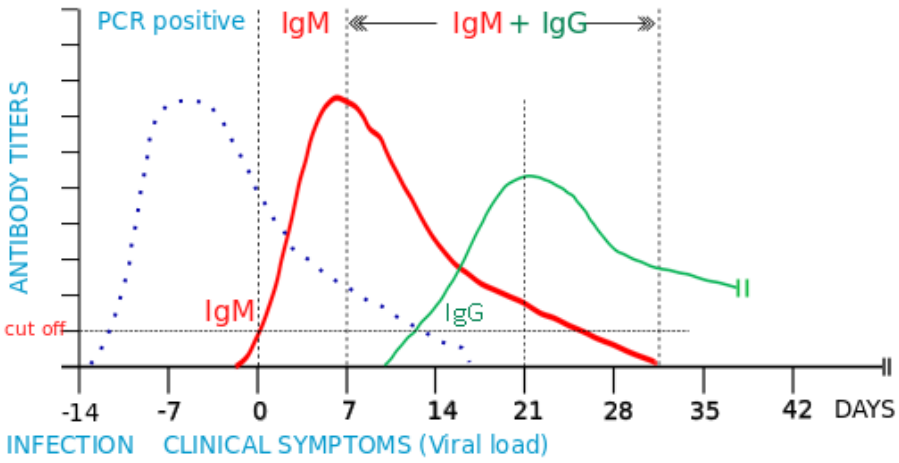


Figure 3. Illustration of course and concentration of IgM and IgG in human blood/serum after infection with SARS-CoV-2

13 TEST CHARACTERISTICS

The clinical cross-matching was performed using the PCR swab method.

Of note: It is important to understand that the PCR swab method determines the presence of coronavirus RNA in a swab sample taken from the buccal area of patients who were subsequently tested with this rapid test.

The PCR method does not show the immune response to this viral exposure.

In the absence of available immunoassays for SARS-CoV-2 IgG and IgM, the PCR test had to be used to evaluate the clinical suitability of the SARS-SARS CoV-2 Virus Detection Kit to determine the infection status of a patient.

Specificity:	99.85% conformity rate for 332 negative controls (subjects not currently or previously infected with SARS-CoV-2)	
Sensitivity:	At early stages of infection (day 4-10):	IgM 70.0%.
	At late stages of infection (day 11-24):	IgM 92.3%
	At late stages of infection (day 11-24):	IgG 98.1%
Accuracy:	The QC sample (quality control) of 98.6% for IgG (day 11-24), 90% for IgM (day 4-10) and 94.4% (day 11-24)	
Stability:	The test met all requirements for linearity, repeatability, negative reference agreement, specificity and sensitivity of the test kit 10 days after annealing at 37° C. The test was performed at a temperature of 10°C after annealing.	
Reproducibility:	The coefficient of variation is less than 15% when the QC sample is measured 10 times.	

14 LIMITATIONS

As with all diagnostic assays, the results obtained with this test kit yield data that must only be used as an adjunct to other information available to the healthcare professional. A positive test result in this screening assay should be confirmed by an accepted reference method (e.g. PCR).

This medical device is intended for in-vitro diagnostic use under professional supervision. The result is for use as a clinical reference only. Treatment of patients should be based on a combination of symptoms, clinical signs, medical history, other laboratory tests and therapeutic responses.

Moisture and incorrect temperature will adversely affect test results.

The test includes products of animal origin. The manufacturer possesses certificates on the origin and/or health status of the animals involved but cannot completely guarantee the absence of transmissible pathogenic components.

Icteric, lipemic, hemolyzed, heat-treated and contaminated whole blood specimens may give false results. In those instances, the test should be repeated using serum and a new test device. There is a small possibility that some whole blood samples with a very high viscosity or whole blood samples that have been stored for more than 2 days will yield false test results.

Due to differences in methodology or antibody specificities, assays from different manufacturers may produce different values even when using the same specimen. Measurements from different manufacturers are not directly comparable for clinical interpretation.

15 BIBLIOGRAPHY

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16 SYMBOLS

REF	Catalogue number / Produktnummer	CE	CE marked as per Annex III of Directive 98/79/EC of the European Parliaments and Council of Oct. 27. 1998.
	Single-use only / Do not re-use / Nur zur Einmalverwendung		
LOT	Batch code / Chargennummer	STERILE R	Sterile product [OX20 1TU, UK c 0120 OX20 1TU]
	Expiration date / Verfallsdatum		Manufacturer / Hersteller
IVD	In-vitro diagnostic		Instructions for Use / Nutzungsanweisung
2° 30°	Storage conditions / Lagervoraussetzung	Σ 1	Package size / Packungsgröße

17 MANUFACTURER

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