



# **EXON SARS-CoV-2 Rapid IgG/IgM Test Kit User Guide**

01.08.2020



	Width (cm)	Depth (cm)	Height (cm)	Weight	Volume	Shelf life
<b>Technical Characteristics of the Product</b>	14.5	17.5	7.8	90-120 gr	1 rxn	Minimum 2 degrees

## Intended use

EXON SARS-CoV-2 Rapid IgG IgM Test Kit is a rapid chromatographic immunologic test that helps the diagnosis of primary and secondary SARS-COV-2 infections via the qualitative determination of IgG and IgM antibodies against SARS-COV-2 in whole human blood, serum, or plasma.

## Summary

COVID-19 (Corona Virus Disease) is the infectious disease caused by the latest discovered type of corona virus. This novel virus and disease was not known before the pandemic started in Wuhan, China in December 2019. Most frequent symptoms of COVID-19 are fever, fatigue, and dry cough. Some of the patients may have pain and ache, nasal congestion, nasal flow, sore throat, or diarrhea. These symptoms are generally mild, and they get started slowly. Some people are infected, they do not feel good but do not have any symptoms. Most of the people (approximately 80%) have the disease without requiring any special treatment. Approximately 1 of each 6 COVID-19 patients gets seriously ill and has difficulty in breathing. Elder people and those having underlying medical problems such as high blood pressure, heart problems, or diabetes are more prone to develop serious illness. Mortality rate of infected people is approximately 2%. People having fever, cough, and difficulty in breathing should get medical assistance. Human may get COVID-19 from other people infected with the virus. The disease may spread by small droplets from the nose or mouth when a person with COVID-19 sneezes or breathes out. These droplets fall on the objects and surfaces around the person. Then, other people are infected by COVID-19 when they touch these objects or surfaces and then their eyes, nose, or mouth. At the same time, the people may also get COVID-19 when they inhale the droplets of a person with COVID-19 who release such droplets by cough or other ways. Incubation period for COVID-19 varies between 1 and 14 days approximately. EXON SARS-CoV-2 Rapid IgG IgM Test Kit is qualitative membrane-based immunologic test for the determination of colored SARS-COV-2 antibodies that are coated with SARS-COV-2

## Working Principle of the Test

antigen regarding the determination of IgG and IgM antibodies against SARS-COV-2 in whole human blood, serum, or plasma. This test consists of two components as one IgG component and one IgM component. IgG test line region in the IgG component is coated with anti-human IgG. During the test, the sample reacts with the particles coated with SARS-CoV-2 antigen in the test cassette. The mixture then moves upwards on the membrane chromatographically via a capillary movement and reacts with the anti-human IgG in the IgG test line region. If the sample includes IgG antibodies against SARS-CoV-2, a colored line will be shown in the IgG test line region. IgM test line region in the IgM component is coated with anti-human IgM. During the test, the sample reacts with anti-human IgG. If the IgM antibodies against SARS-CoV-2 are present in the sample, they react with the particles coated with SARS-CoV-2 antigen and anti-human IgM in the test cassette. This complex is caught by the anti-human IgM and forms a colored line in the IgM test line region. Thus, a colored line will be shown in the IgG test line region if the sample consists of IgG antibodies against SARS-CoV-2. If the sample consists of IgM antibodies against SARS-CoV-2, a colored line will be seen in the IgM test line region. In case the sample does not consist of any antibodies against SARS-CoV-2, no colored line showing a negative result is shown in any of the test line regions. For a procedural control, a colored line shown in the control line region specifies that suitable amount of sample is added, and a membrane wick is formed.

## Test Reagents

Test cassette consists of gold colloid particles bind with specific antigen and coated anti-human IgG on the membrane.

## Precautions

- The kit is only for professional in vitro diagnostic use. Do not use after the expiry date.
- Do not eat, drink or smoke in the area where the samples or kits are used.
- Use all the samples as if they consist of transmissible agents. During the procedure, take the measures specified against microbiological hazards and follow standard procedures for appropriate disposal.
- While testing the samples, wear a lab coat, disposable gloves, and protective clothes such as eye protectors.
- Dispose the tests used, samples and potentially contaminated materials according to local regulations.
- Humidity and temperature results may negatively affect the results.

## Storage Conditions

The kit can be stored at room temperature or in a refrigerator (2-30°C). Test cassette is stable until the expiry date that is written on the closed package. Test cassette should be stored in the closed pouch until use. DO NOT FREEZE. Do not use after the expiry date.

## Materials provided

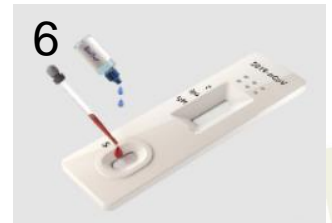
1. Sterile Single-use Lancing Needle
2. Test cassette
3. Transfer pipette (for the transfer of the blood sample)
4. Alcohol-soaked cloth
5. Indicator bottle including the buffer solution



### Usage instructions

EXON SARS-CoV-2 Rapid IgG IgM Test Kit is used with the blood sample. Before conducting the test, allow the test cassette and the buffer solution reach the room temperature (15-30 ° C).

1. Clean the hand of the patient with the alcohol-soaked cloth in order to collect the blood samples via the lancing needle. Wait for the alcohol to dry for 2-3 seconds.
2. Rub the index finger, middle finger or ring finger of the hand of the patient towards the fingertip and massage without touching the needling site.
3. Open the lancing needle by rotating the endpiece. Needle the finger skin rapidly but slightly by using the lancing needle.
4. In order to create a circular blood drop on the needling site, slightly apply pressure on the finger without touching the needling site.
5. Draw 1 drop of blood sample by using the transfer pipette.
6. Add the blood sample in the transfer pipette as 1 drop on the S-well on the test cassette. Then, add 2 droplets of buffer solution on the S-well from the indicator bottle consisting of the buffer solution. Observe the progress of the buffer solution in the strip regions. If the fluid does not reach the end, add 1 more buffer solution droplet. Avoid the air bubbles in the well. Test should be done immediately after the sample is taken. Do not leave the samples at room temperature for a long time.



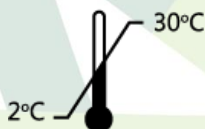
### Symbols

**REF**

Catalog Number: SCVC01



Expiry Date: 2022-08-30



Storage Conditions

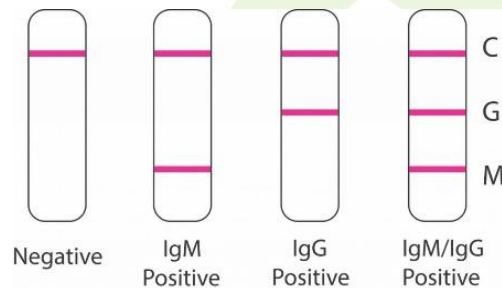
**IVD**

*In vitro* diagnostic medical device

**CE**



## Evaluation of the Results



**IgG and IgM Positive:** There should be three lines. There should be one colored line in the control line region (C) and two colored lines should be seen in the IgG test line region and IgM test line region. It is not required to have the color densities of the lines match. The result is positive for IgG and IgM antibodies and is an indicator of a secondary SARS-CoV-2 infection.

**IgG Positive:** There should be two lines. There should be one colored line in the control line region (C) and one colored line should be seen in IgG test line region. The result is positive for IgG-specific for SARS-CoV-2 virus and possibly an indicator for secondary SARS-CoV-2 infection.

**IgM Positive:** There should be two lines. There should be one colored line in the control line region (C) and one colored line should be seen in IgM test line region. The result is positive for IgM antibodies that are specific for SARS-CoV-2 virus and is an indicator of primary SARS-CoV-2 infection.

**\*NOTE:** The density of the color in the IgG and/or IgM test line regions will vary according to the concentration of the SARS-COV -2 antibodies in the sample. Thus, any color tone in the IgG and/or IgM test line region should be accepted as positive.

**Negative:** There should be one colored line in the control line region (C). There should be no lines in the IgG and IgM test line regions.

**Invalid:** Absence of a control line. Insufficient buffer volume or wrong procedure techniques are the most possible reasons for the absence of a control line. Review the procedure and repeat the procedure by using a new test cassette. If the problem continues, stop using the test kit and contact with the authorized company.

## Quality Control

An internal procedure control is included in the test. A colored line in the control line region (C) is an internal valid procedure control and it verifies the sufficient membrane quality. This mass control standards are not given, however, it is recommended to test the positive and negative controls in order to approve the test procedure and to verify the suitable test performance as a good laboratory application.

## Use Limits

1. EXON SARS-CoV-2 Rapid IgG IgM Test Kit is only for in vitro diagnostic purposes. The test should be used for the determination of SARS-CoV-2 antibodies in whole blood, serum, or plasma. Quantitative value or increase ratio in the SARS-COV-2 antibody concentration cannot be determined by this qualitative test.
2. EXON SARS-CoV-2 Rapid IgG IgM Test Kit will only show the presence of SARS-CoV-2 antibodies in the sample and should not be used as the only criteria for the diagnosis of SARS.
3. At the early onset of fever, the anti-SARS-COV-2 IgM concentrations can be under the detectable limits.
4. The ongoing presence or absence of the antibodies cannot be used to determine the success or failure of the treatment. The results obtained from immuno-compromised patients should be interpreted with care.
5. As in all the diagnostic tests, all the results should be considered together with other clinical data provided to the doctor.
6. Negative results does not exclude the SARS-CoV-2 infection, especially in people who are in contact with the virus. In order to exclude infection in such people, follow-up test with molecular diagnosis should be considered.
7. Positive results may be caused by the previous or current infections related to the strains of the corona virus excluding SARS-CoV-2 such as corona virus HKU1, NL63, OC43, or 229E.
8. The results obtained from the antibody test, the results should not be used as the single basis in order to diagnose or exclude the SARS-CoV-2 infection or to notify the infection status.

## Expected Values

Primary SARS-CoV-2 infection is characterized by the presence of detectable IgM antibodies 3-7 days the onset of the infection. Secondary SARS-COV-2 infection is characterized by the IgG increase that is specific to SARS-CoV-2. In most of the cases, this is accompanied by high IgM levels.

Method	Clinical diagnosis (Approved)			
	Result	Positive	Negative	Total
EXON SARS-CoV-2 Rapid IgG IgM Test Kit (for IgG)	Positive	75	2	77
	Negative	0	369	369
	Total	75	371	446
EXON SARS-CoV-2 Rapid IgG IgM Test Kit (for IgM)	Positive	78	3	81
	Negative	7	368	375
	Total	85	371	456

## Shipment Information

<p><b>HOW MANY PRODUCTS IN A BOX?</b></p>	<p><b>2 Different Forms Available</b></p> <ul style="list-style-type: none"> <li>• 10 Pieces / Box (Each Kit Is Packed Separately)</li> <li>• 25 Pieces / Box (Suitable for Batch Scanning)</li> </ul>
<p><b>BOX SIZES</b></p>	<p><b>2 Different Forms Available</b></p> <ul style="list-style-type: none"> <li>• 10 Pieces / Box (135 * 70 * 17 mm)</li> <li>• 25 Pieces / Box (170 * 130 * 80 mm)</li> </ul>
<p><b>HOW MANY PRODUCTS IN A PACKAGE?</b></p>	<p><b>Package Dimensions</b></p> <ul style="list-style-type: none"> <li>• Box of 10 - 1 Package = 40 Boxes (400 Pieces Kit)</li> <li>• 25 Boxes - 1 Package = 40 Boxes (1000 Pieces Kit)</li> </ul>
<p><b>HOW MANY PRODUCTS IN A PALLET?</b></p>	<p><b>Pallet Dimensions 80 * 120 * 12 cm</b></p> <ul style="list-style-type: none"> <li>• 10 Boxes - 1 Pallet = 20 Boxes (8000 Pieces Ki)</li> <li>• 25 Boxes - 1 Pallet = 20 Boxes (20.000 Pieces Kit)</li> </ul>
<p><b>HOW MANY PRODUCTS IN 1 CONTAINER</b></p>	<p>Container of 20 = 11 Pallets (88,000 Kits / Box of 10)</p> <p>Container of 20 = 11 Pallets (220,000 Kits / Box of 25)</p> <p>Container of 40 = 24 Pallets (192,000 Kits / Box of 10)</p> <p>Container of 40 = 24 Pallets (480,000 Kit (Box of 25)</p>





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