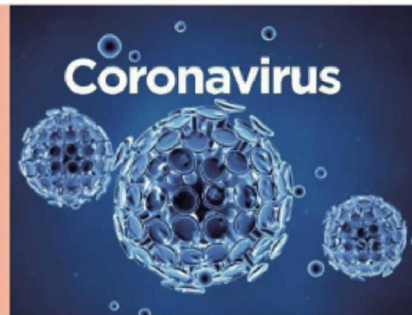


COVID-19



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COVID-19 TEST-KIT

CE & ISO Certified COVID-19 Test-Kit

BOSON

COVID-19



Coronavirus disease 2019 (COVID-19) is defined as an acute respiratory disease caused by the virus SARS-CoV-2. The disease was first detected in December 2019 and has now been detected in almost 70 locations internationally.



Rapid 2019-nCoV IgG/IgM Combo Test kits were designed for detection of SARS-CoV-2 IgG and IgM antibodies in blood samples. IgG/IgM antibody test would be a fabulous supplement detection method for COVID-19 suspected infected patients besides nucleic acid test, which could greatly raise the accuracy of the detection for COVID-19.

Fast, Easy and Convenient

Results in 15 minutes, fastest in 3 minutes
Simple to use
Requires no instruments and special skills

Phase Judgement

Infectious time can be roughly judged
Different phases of patients can be judged

Blood Test

Whole Blood, Serum & Plasma can be used
Easy sampling, steady and reliable
Only 2µl samples needed

Storage

Room temperature storage
18 months shelf life

RAPID 2019-NCOV IGG/IGM COMBO TEST CARD FOR THE QUALITATIVE ASSESSMENT OF IGG AND IGM ANTIBODIES TO 2019 NOVEL CORONAVIRUS IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD Catalog Number: TNSC22

For In Vitro Diagnostic Use Only

INTENDED USE
Rapid 2019-nCoV IgG/IgM Combo Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of IgG and IgM antibodies to 2019 novel coronavirus (2019-nCoV, SARS-CoV-2) in human serum, plasma, or whole blood. Rapid 2019-nCoV IgG/IgM Combo Test Card is a fabulous supplement detection for COVID-19 suspected infected patients besides nucleic acid test, which could greatly raise the accuracy of the detection for COVID-19.

SUMMARY
Coronavirus Disease 2019 (COVID-19) is an acute infectious disease caused by 2019 novel coronavirus (SARS-CoV-2). The incubation period of the disease is 1-14 days, mostly 3-7 days. The incubation period is infectious. Asymptomatic infection may also be the source of infection. Respiratory symptoms and contact are the main routes of transmission. The initial symptoms of the patients were fever, fatigue and cough, and gradually developed dyspnea and other serious manifestations. Most of the patients have a good prognosis. Some of the severe cases may have acute respiratory distress syndrome or septic shock, or even death. At present, there is no specific treatment for the disease.

There are several days of incubation period after infected by 2019-nCoV. IgM antibodies can be detected soon after incubation period and keep for a short time. IgG reaction in blood samples can be an indicator of acute infection. IgG antibodies appear after few days of incubation period and keep for a long time. IgG positive in blood samples can be an indicator of infection or previous infection.

PRINCIPLE
Rapid 2019-nCoV IgG/IgM Combo Test Card utilizes the principle of immunochromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgM line in the test window is closer to the sample well and labeled by IgG dye. As the test sample flows through the membrane within the test device, the colored 2019-nCoV antigen-coated gel conjugate, complexes with specific antibodies (IgM and/or IgG) of 2019 novel coronavirus, if present in the sample. This complex, moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates a positive test result. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has been performed properly, regardless of the presence or absence of anti-2019 novel coronavirus antibodies in the specimen.

MATERIALS PROVIDED

1. Rapid 2019-nCoV IgG/IgM Combo Test Card
2. Sample buffer
3. 2 µl. Volumetric pipette
4. Instructions for Use

MATERIALS REQUIRED BUT NOT SUPPLIED

Close to 80µl, safety vials, alcohol prep pad, specimen collection container, centrifuge, biohazard waste container, disposable gloves, disinfectant.

STORAGE

1. Store the test device at 4 to 30°C in the original sealed pouch. Do Not Freeze.
2. The expiration date indicated on the pouch was established under these storage conditions.
3. The test device should remain in its original sealed pouch until ready for use. After opening, the test device should be used immediately. Do not reuse the device.

PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not use the product beyond the expiration date.
3. Do not use the product if the pouch is damaged or the seal is broken.

4. Handle all specimens as potentially infectious.
5. Follow standard life procedures and biohazard guidelines for handling and disposal of potentially infectious material. When the assay procedure is completed, dispose specimens after autoclaving at 121°C for at least 20 min or treating with 10% Sodium Hypochlorite for 1-2 hours.

SPECIMEN COLLECTION AND PREPARATION

1. The serum or plasma specimen should be collected under standard laboratory conditions.
2. After inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
3. Patient samples were the best performance serum tested immediately after collection. If specimens are to be stored, the red blood cells should be removed to avoid hemolysis. If the assay is not performed immediately, serum or plasma specimens may be refrigerated at 2-8°C up to 10 days. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods. Allow samples to reach room temperature before proceeding.
4. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with the test kit are commercially available.

PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the Card. Once opened, the test card must be used immediately.
3. Label the test card with patient identity.
4. Withdraw the blood specimen with the codedly pipet, provided. Gently squeeze out the entire specimen to leave 2µl in the pipet as marked with the scale. The Apply 2µl of blood specimen to the 'S' area as marked.
5. Add 2 drops of buffer.
6. Read the result at 15 minutes. A strong positive sample may show test earlier.
Note: Results after 20 minutes may not be accurate.

RAPID 2019-NCOV IGG/IGM COMBO TEST CARD
FOR THE QUALITATIVE ASSESSMENT OF IGG AND IGM ANTIBODIES TO
2019 NOVEL CORONAVIRUS IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD
 Catalog Number: 1N38C2
For In Vitro Diagnostic Use Only

INTENDED USE

Rapid 2019-nCoV IgG/IgM Combo Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of IgG and IgM antibodies to 2019 novel coronavirus (2019-nCoV, SARS-CoV-2) in human serum, plasma, or whole blood. Rapid 2019-nCoV IgG/IgM Combo Test Card is a fabulous supplement detection for COVID-19 suspected infected patients besides nucleic acid test, which could greatly raise the accuracy of the detection for COVID-19.

SUMMARY

Corona Virus Disease 2019 (COVID-19) is an acute infectious disease caused by 2019 novel coronavirus (SARS-CoV-2). The incubation period of the disease is 1-14 days, mostly 3-7 days. The incubation period is infectious. Asymptomatic infections may also be the source of infection. Respiratory droplets and contact are the main routes of transmission. The initial symptoms of the patients were fever, fatigue and cough, and gradually developed dyspnea and other serious manifestations. Most of the patients have a good prognosis, some of the severe cases may have acute respiratory distress syndrome or septic shock, or even death. At present, there is no specific treatment for the disease.

There are several days of incubation period after infected by 2019-nCoV. IgM antibodies can be detected soon after incubation period and keep for a short time. IgM positive in blood samples can be an indicator of acute infection. IgG antibodies appear after few days of incubation period and keep for a long time. IgG positive in blood samples can be an indicator of infected or previous infection.

PRINCIPLE

Rapid 2019-nCoV IgG/IgM Combo Test Card utilizes the principle of Immuno-chromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgM line in the test window is closer to the sample well and followed by IgG line. As the test sample flows through the membrane within the test device, the colored-2019-nCoV antigen-colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) of 2019 novel coronavirus, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti-2019 novel coronavirus antibodies in the specimen.

MATERIALS PROVIDED

1. Rapid 2019-nCoV IgG/IgM Combo Test Card
2. Sample buffer
3. 2 µL capillary pipet
4. Instructions for Use

MATERIALS REQUIRED BUT NOT SUPPLIED

Clock or timer, safety lancets, alcohol prep-pad, specimen collection container, centrifuge, biohazard waste container, disposable gloves, disinfectant.

STORAGE

1. Store the test device at 4 to 30°C in the original sealed pouch. Do Not Freeze.
2. The expiration date indicated on the pouch was established under these storage conditions.
3. The test device should remain in its original sealed pouch until ready for use. After opening, the test device should be used immediately. Do not reuse the device.

PRECAUTIONS

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5. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infectious material. When the assay procedure is completed, dispose specimens after autoclaving at 121° C for at least 20 min or treating with 0.5% Sodium Hypochlorite for 1-2 hours.

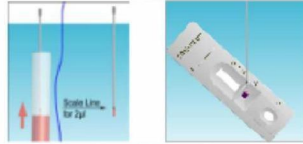
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2	Open the pouch and remove the Card. Once opened, the test card must be used immediately.		
3	Label the test card with patient identity.		
4	 Withdraw the blood specimen with the capillary pipet provided, gently squeeze out the extra specimen to leave 2µL in the pipet as marked with the scale line. Apply 2µL of blood specimen to the "S1" area as marked.		
5	 add 2 drops of buffer	6	 20-min
Add 2 drops of sample buffer (approximately 80-100µL) to well marked as "S".		Read the result at 15 minutes. A strong positive sample may show result earlier. Note: Results after 20 minutes may not be accurate.	



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Products description:
COVID-19 Self-test Kit

Production capacity:

5.1.1c

Price per unit:

5.1.1c

Packaging:

1.000 COVID-19 Test-Kit per carton (box)

Delivery & Duties:

Included in the costs

Product Classification:

Class 1

Related Directive:

EN: ISO 13455:2016

Medical Standard:

YES

CE certifications:

YES



Certificates

