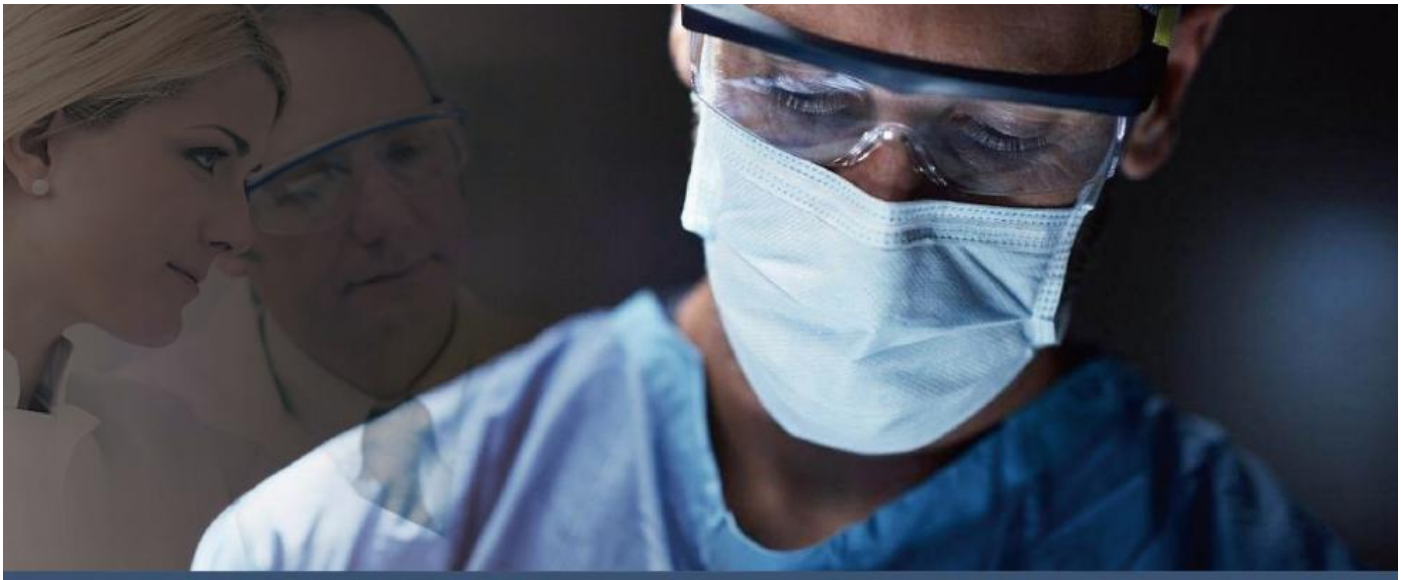
STIG
akciová společnost



COVID-19 IgG/IgM Rapid Cassette (S/P/WB)

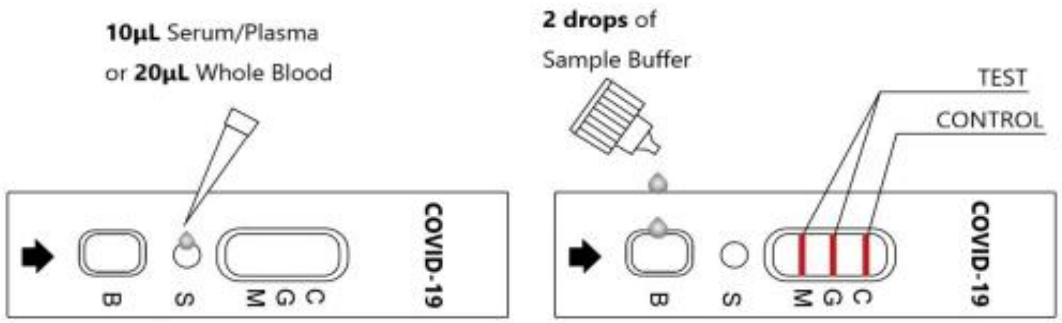
【For the qualitative detection of COVID-19 IgG/IgM Antibody in serum/plasma/whole blood】

Know more, less worried

New crown virus specific IgM / IgG qualitative test or POCT method quantitative test, which is suitable for large-scale screening, a much easier and faster way to diagnose COVID-19.

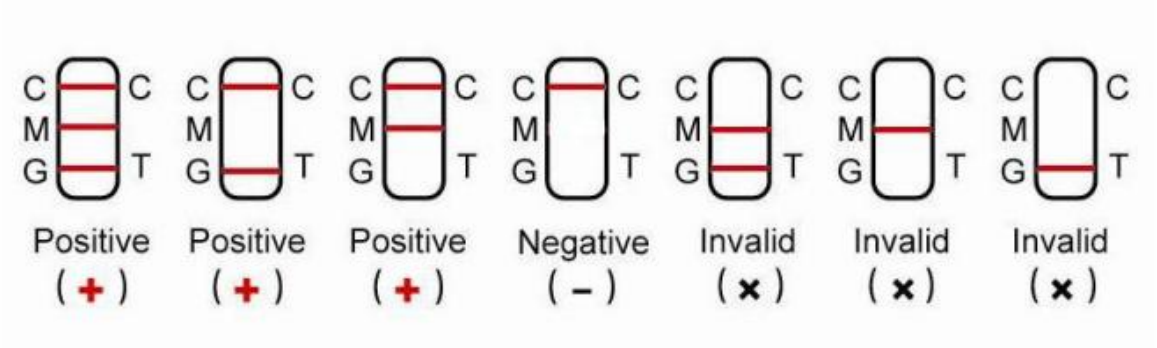
OPERATION PROCESS

- Add the sample

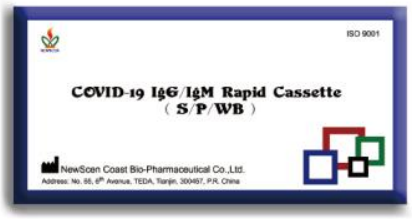


- Observe the result in 15-20minutes

INTERPRETATION OF RESULTS



Product Pictures



Product Instruction

COVID-19 IgG/IgM Rapid Cassette (S/P/WB)

【For the qualitative detection of COVID-19 IgG/IgM Antibody in serum/plasma/whole blood】

INTENDED USE

The NewScen COVID-19(Corona Virus Disease) IgG/IgM rapid test is used to qualitatively detect IgG and IgM antibodies of coronavirus in human serum, plasma or whole blood. This device is intended to be used by professionals as a screening test and as an aid in the diagnosis of infection with 2019 Corona Virus. Any reactive specimen with the NewScen COVID-19 IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

SUMMARY

COVID-19(Corona Virus Disease) is the infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 2% of people with the disease have died. People with fever, cough and difficulty breathing should seek medical attention. People can catch COVID-19 from others who have the virus. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. These droplets land on objects and surfaces around the person. Other people then catch COVID-19 by touching these objects or surfaces, then touching their eyes, nose or mouth. People can also catch COVID-19 if they breathe in droplets from a person with COVID-19 who coughs out or exhales droplets.Most estimates of the incubation period for COVID-19 range from 1-14 days. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of SARS-COV-2 antigen coated colored particles for the detection of IgG and IgM antibodies to SARS-COV-2 in human whole blood, serum, or plasma.

PRINCIPLE

The NewScen COVID-19IgG/IgM rapid test is a qualitative membrane-based immunoassay for the detection of COVID-19antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with COVID-19 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to COVID-19, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. IgM antibodies to COVID-19, if present in the specimen, reacts with the anti-human IgM and the COVID-19 antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region. Therefore, if the specimen contains IgG antibodies to COVID-19, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to COVID-19, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to COVID-19, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

STORAGE

Store the kit between 2°C and 30°C. Do not store the kit in direct sunlight. Only remove and open the number of cassettes to be immediately used. The test kit should be used until the expiration date of the kit. Please refer to the package label for the expiration date.

WARNING AND PRECAUTIONS

1. For Professional Use as a Screening Test Only
2. Any reactive specimen with the NewScen COVID-19 IgG/IgM Rapid Test must be confirmed with alternative testing method(s).
3. Do not use test kit beyond expiration date.
4. Bring all reagents to room temperature (15-30°C) before use.

REAGENTS AND MATERIALS PROVIDED

1. Individual pouched cassette with desiccant and a disposable plastic pipett.
2. Operating instruction.
3. Sample Diluent

MATRIALS REQUIRED BUT NOT PROVIDED

1. Stop watch.
2. Adjustable 5 - 50 µl pipette (adjustable).

SAMPLE COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

1. Have a certified phlebotomist collect whole blood into a purple, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma for testing, or label and store it at 2-8°C for up to one week. Plasma may be frozen at -20°C for three months.

Serum

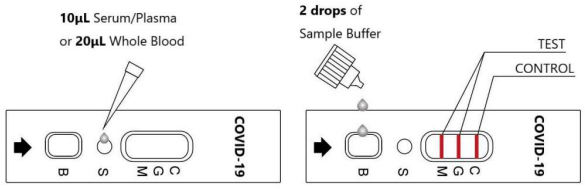
1. Have a certified phlebotomist collect whole blood into a red top collection tube (containing no anticoagulants) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum for testing or label and store it at 2-8°C for up to one week. Serum may be frozen at -20°C for three months

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Whole Blood

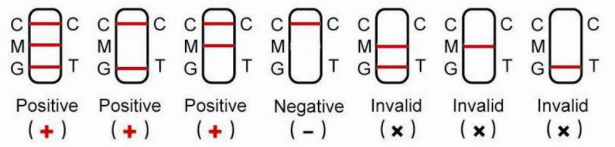
Blood Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use hemolized blood for testing.
specimens should be stored in refrigeration (2°C - 8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE



1. Bring the specimen and the test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing assay. Specimen extraction
2. When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
3. Label device with the specimen's ID number.
4. For Serum or Plasma or Whole Blood Specimens
5. Pipette and dispense 10uL serum/plasma or 20uL whole blood, and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of Sample Buffer to the buffer well (B) and start the timer. Avoid trapping air bubbles in the specimen well.
6. Wait for the colored line(s) to appear. The test result should be read at 15-20 minutes. **Do not interpret the result after 20 minutes. To avoid confusion, discard the test device after interpreting the result**

INTERPRETATION OF RESULTS



IgG & IgM POSITIVE:*Three lines appear. One colored line should be in the control line region (C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary SARS-COV-2 infection.

IgG POSITIVE:*Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG and is probably indicative of secondary SARS-COV-2 infection.

IgM POSITIVE:*Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies and is indicative of primary SARS-COV-2 infection.

**NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.*

NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).

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

CLINICAL EVALUATION

1. Sensitivity and specificity

The NewScen COVID-19 IgG/IgM Rapid Test Cassette was compared with a leading commercial PCR. The study included 361 specimens for IgG and IgM.

NewScen	Diagnosed Sample				Total	
	Positive		Negative			
Positive	A	86	B	9	A+B	95
Negative	C	8	D	258	C+D	266
Total	A+C	94	B+D	267	ABCD	361

Sensitivity = A/(A+C)% = 91.49%
Specificity = D/(B+D)% = 96.63%
Total Accuracy = (A+D)/(ABCD)% = 95.29%

2. Cross Reactivity

The COVID-19 IgG/IgM Rapid Test Cassette (whole blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis,anti-H. Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

3. Interfering Substances

The following potentially interfering substances were added to SARS-CoV-2 negative and positive specimens.Acetaminophen: 20 mg/dL Caffeine: 20 mg/dLAlbumin: 2 g/dLAcetylsalicylic Acid: 20 mg/dLGentisic Acid: 20 mg/dLEthanol: 1% Ascorbic Acid:2g/dL Creatine: 200mg/dlBilirubin: 1g/dL Hemoglobin: 1000mg/dlOxalic Acid: 60mg/dLUric acid: 20mg/ml None of the substances at the concentration tested interfered in the assay.

LIMITATION

1.The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.

2.The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of SARS-COV-2 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of SARS-COV-2.

3.In the early onset of fever, anti-SARS-COV-2 IgM concentrations may be below detectable levels.

4.The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.

5.Results from immuno suppressed patients should be interpreted with caution.

6.As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

7.If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of SARS-COV-2 infection.

Recommended Products

Product Name	Format			Specimen					Approval
	Cassette	Strip	Uncut sheet	Blood	Serum / Plasma	Urine	Secretion	Stool	
Infectious Disease									
HIV 1/2 3 lines	√	√	√	√	√				CE/NMPA
TB	√		√		√				NMPA
Syphilis (TP)	√	√	√	√	√				NMPA
HAV IgM	√	√	√		√				
HBsAg	√	√	√	√	√				NMPA
HBsAb	√	√	√	√	√				
HCV	√	√	√	√	√				CE/NMPA
HEV	√		√		√				NMPA
H.Pylori (Ab)	√	√	√	√	√				NMPA
H.Pylori (Ag)	√	√	√					√	NMPA
Hot Items									
Dengue IgG/IgM	√		√	√	√				
Dengue NS1	√		√	√	√				
Zika IgG	√		√		√				
Zika IgM	√		√		√				
Zika NS1	√		√		√				
Marlaria Pf/Pan	√		√	√					