

2019-nCoV IgG/IgM Rapid test Whole blood/serum/plasma

CE Marking

Description

Sample: Whole blood/serum/plasma, whole blood sample

Storage: 2-30°C

Certificate: CE format, ISO13485: Cassette

The rapid 2019-nCoV IgG/IgM test cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma, and also in a lanced whole blood sample.

SUMMARY

In early January 2020, a new coronavirus (2019-nCoV) was identified as the infectious agent causing an outbreak of viral pneumonia in Wuhan, China, where the first cases had their onset of symptoms in December 2019.

Coronaviruses are enveloped RNA viruses that are widely distributed among humans, other mammals and birds and cause respiratory, enteric, liver and neurological diseases. Six species of coronavirus are known to cause disease in humans . Four viruses - 229E, OC43, NL63 and HKU1 - are prevalent and often cause symptoms of the common cold in immunocompetent people. The other two strains - Severe Acute Respiratory Syndrome Coronavirus (SARS-CSR) and Middle Eastern Respiratory Syndrome Coronavirus (MERS-CSR) - are of zoonotic origin and have been linked to sometimes fatal diseases.

Coronaviruses are zoonotic, which means they are transmitted between animals and humans. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In the most severe cases, the infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death.

Standard recommendations to prevent the spread of infection include regular hand washing, covering your mouth and nose when coughing and sneezing, and thorough cooking of meat and eggs. Avoid close contact with anyone who shows symptoms of respiratory disease such as coughing and sneezing.

NOT SUITABLE FOR DOMESTIC USE

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INSTRUCTIONS FOR USE

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

1. Remove the test cassette from the foil pouch and use within one hour. Best results will be obtained if the test is performed immediately after opening the foil bag.
2. Place the cassette on a clean, level surface.

- For serum or plasma sample:

To use an eyedropper: Hold the eyedropper in an upright position, drag the sample to the fill line

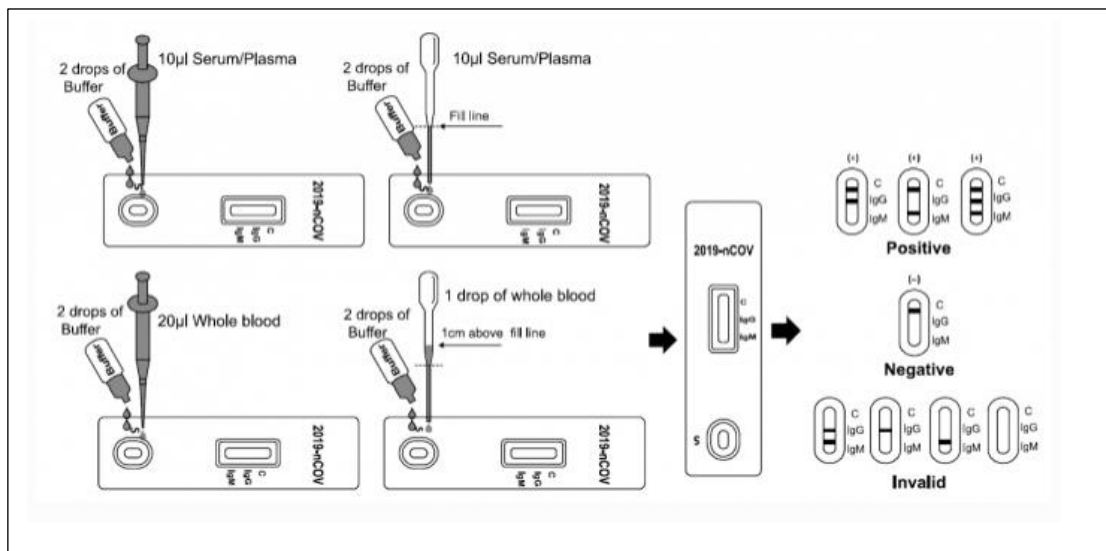
(Approximately 10 µL), and transfer the sample to the sample well (S), then add 2 drops of buffer (approximately 80 µL), and start the timer.

To use a pipette: To transfer 10 µL of the sample to the sample well (S), then add 2 drops of buffer (approximately 80 µL), and start the timer.

- For the whole blood sample from the venepuncture:

To use an eyedropper: Hold the eyedropper upright, draw the sample approximately 1 cm above the fill line and transfer 1 full drop (approximately 20 µL) of the sample into the sample well(S). Then add 2 drops of buffer (approx. 80 µL) and start the timer.

To use a pipette: To transfer 20 µL of whole blood to the sample well(s), then add 2 drops of buffer (approximately 80 µL) and start the timer.



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- **For the whole blood swab specimen:**

To use an eyedropper: Hold the eyedropper upright, withdraw the sample approximately 1 cm above the fill line and transfer 1 full drop (approximately 20 µL) of the sample to the sample well(s). Then add 2 drops of buffer (approx. 80 µL) and start the timer.

To use a capillary tube: Fill the capillary tube and transfer approximately 20 µL of the whole blood sample from the finger prick to the sample well (S) of the test cassette, then add 2 drops of buffer (approximately 80 µL) and start the timer. See illustration below.

Wait for the coloured line(s) to appear. 4. Read the results after 10 minutes. Do not interpret the result after 20 minutes.

Note: It is suggested not to use the tampon, beyond 6 months after opening the bottle.

INTERPRETATION OF RESULTS

POSITIVE IgG:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

IgM POSITIVE:* Two colored lines appear. One colored line must always appear in the control line region (C) and another line must be in the IgM line region.

IgG and POSITIVE IgM:* Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and the IgM line region.

*The color intensity in the test line regions may vary depending on the concentration of 2019-nCoV antibodies present in the sample Therefore, any colour tone in the region of the test line should be considered positive.

NEGATIVE: A colored line appears in the control line region (C). No line appears in the IgG and IgM region.

INVALID: The control line does not appear. 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. If the problem persists, discontinue use of the test kit immediately

Reference: RPPCOV19-25: 25 tests

Product manufactured by: Hangzhou AllTest Biotech Co.,Ltd

For more information, contact us at international@durviz.com

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