

2019-nCoV IgG/IgM WB Device (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADCOV2	20 Tests

Intended Use:

The 2019-nCoV IgG/IgM WB Device is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019-nCoV, a new strain of coronavirus (nCoV), in whole blood samples from a finger prick.

Summary:

Coronaviruses are a large family of viruses that cause disease ranging from common cold symptoms to more severe pneumonia. They are enveloped, single strand RNA viruses. Coronaviruses are zoonotic, they can be transmitted from animals to humans. Existing examples include the Middle East Respiratory Virus (MER-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). Reports of a novel coronavirus began in the Wuhan district of China in December 2019 and in January 2020 the World Health Organisation designated the new strain 2019-nCoV. Symptoms include high temperature, cough and breathing difficulties. In immunocompromised individuals symptoms can be more severe leading to pneumonia, severe acute respiratory syndrome or death.

Test Principle:

The test device has anti-human IgG and anti-human IgM immobilized on the membrane in two distinct areas of the test zone. Particles coated with 2019-nCoV antigen are loaded on the membrane near the sample well. During the test whole blood sample is added to the sample well where it interacts with the antigen coated particles and any antibodies to 2019-nCoV present in the sample will bind to the antigen. The antibody-particle complexes migrate up the membrane by capillary action where they interact with the anti-human IgG and/or anti-human IgM in the test zone and are captured. A positive result is indicated when a coloured line forms at the IgG and/or IgM test line. The absence of any line development at the test zone indicates a negative result. To serve as a procedural control, a coloured line should always appear at the control line area indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagents:

The test device contains anti-human IgG, anti-human IgM, 2019-nCoV antigen and goat anti-mouse IgG on the membrane of the 2019-nCoV IgG/IgM WB Device.

Materials Provided

Individually pouched test devices	Lancets
Droppers	Alcohol swabs
Buffer	Instructions for Use sheet

Materials not provided: Timer

Precautions:

For professional *in vitro* diagnostic use only.
Follow Good Laboratory Practice procedures where samples and kits are handled and treat the device and all samples as if potentially infectious. Follow local regulations for correct disposal of samples.
Wear protective clothing including laboratory coat, disposable gloves and safety glasses when conducting the test.
Humidity and temperature can adversely affect results.

Storage and Stability:

The kit can be stored at room temperature or refrigerated (2 - 30°C). The test device is stable up to the expiry date printed on the sealed pouch. The device must remain in the sealed pouch until use. Do Not Freeze. Do not use after the expiry date. The stability of the buffer is approximately six months after opening the bottle.

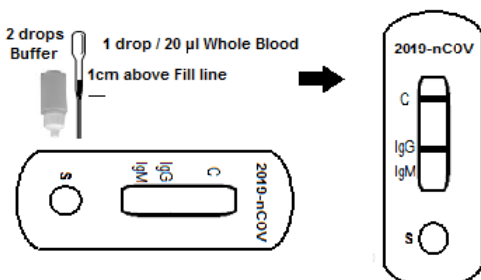
Sample Collection and Preparation:

The 2019-nCoV IgG/IgM WB Device test is performed using whole blood.
To collect Finger prick Whole Blood samples: Clean an area of the patient's fingertip with the swab. Allow to dry. Squeeze the hand gently to encourage blood flow to the finger. Pierce the skin with a sterile lancet and wipe away the first sign of blood. Gently squeeze the hand again then down the finger to release a large drop of blood over the puncture site. Collect the blood drop in the dropper. Do not freeze whole blood samples. Whole blood collected by finger prick must be tested immediately.

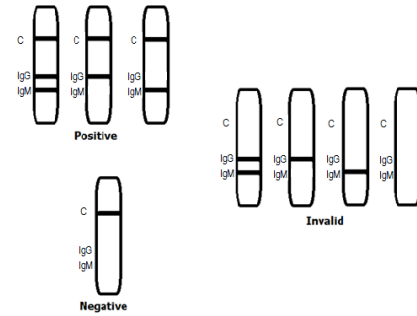
Assay Procedure:

Bring the device, samples, buffer and controls fully to room temperature (15 - 30°C) before starting any testing. Remove the test device from the sealed pouch, place it on a clean and level surface and use it immediately.

Using the dropper take in whole blood to 1 cm above the fill line then expel 1 full drop (approximately 20 µl) into the sample well. Add 2 drops of buffer to the sample well (approximately 80 µl) and start the timer.
Wait for coloured lines to appear. Read the results at 10 minutes. Do not interpret any result after 20 minutes.



Interpretation of Results:



IgG Positive: Two distinct coloured lines appear. One band appears at the control line (C) and another band develops at the IgG test line (IgG).

IgM Positive: Two distinct coloured lines appear. One band appears at the control line (C) and another band develops at the IgM test line (IgM).

IgG and IgM Positive: Three distinct coloured lines appear. One band appears at the control line (C), one band develops at the IgG test line (IgG) and one band develops at the IgM test line (IgM).

NOTE: The intensity of colour development at the test lines will vary depending on the concentration of anti-2019-nCoV IgG or anti-2019-nCoV IgM present in the sample. Therefore, any shade of colour developing at the test lines should be considered positive.

Negative: One coloured line appears in the control region (C). No apparent coloured line appear in the test zones.

Invalid: Control line fails to appear. Insufficient specimen 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Quality Controls:

A procedural control is included in the test. A coloured line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit.

Limitations of the Test:

The Assay Procedure and the Assay Result Interpretation must be followed closely when testing for the presence of antibodies to 2019-nCoV in whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.

The 2019-nCoV IgG/IgM WB Device is limited to the qualitative detection of anti-2019-nCoV IgG and IgM antibodies in whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.

A negative result for an individual subject indicates absence of a detectable level of anti-2019-nCoV IgG and anti-2019-nCoV IgM antibody or that the antibodies are not present during the stage of disease at which the sample was collected. However, a negative test result does not preclude the possibility of exposure to or infection with 2019-nCoV.

The results obtained with this test should not be used as the sole criterion for diagnosis of 2019-nCoV infection, but be used in conjunction with other diagnostic procedures and clinical findings.

Hematocrit value of whole blood samples can affect test results. For accurate results the haematocrit level must lie between 25% and 65%.

Performance Characteristics:

The 2019-nCoV IgG/IgM WB Device has been compared with a commercial PCR test the results indicating high specificity and sensitivity.

IgG Results

2019-nCoV IgG/IgM WB Device	Method	PCR		Total Results
	Results	Positive	Negative	
	Positive	20	1	21
	Negative	0	49	49
Total Results		20	50	70

Relative Sensitivity: 100% (CI*: 86.0% - 100%) *Confidence Intervals

Relative Specificity: 98.0% (95% CI*: 89.4% - 99.9%)

Accuracy: 98.6% (95%CI*: 92.3% - 99.96%)

IgM Results

2019-nCoV IgG/IgM WB Device	Method	PCR		Total Results
	Results	Positive	Negative	
	Positive	17	2	19
	Negative	3	48	51
Total Results		20	50	70

Relative Sensitivity: 85.0% (95%CI*: 62.1% - 96.8%)

Relative Specificity: 96.0% (95% CI*: 86.3% - 99.5%)

Accuracy: 92.9% (95% CI*: 84.1% - 97.6%)

Cross-reactivity

The 2019-nCoV IgG/IgM WB Device has been tested using samples positive for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-adenovirus, HBsAg, anti-syphilis, anti-H pylori, anti-HIV and anti-HCV. The results showed no cross-reactivity of these samples in the test.

Interfering Substances

Potentially interfering substances commonly found in whole blood samples were added to samples at the concentrations stated below and used in the test to identify their effects on the assay. No interference was observed.









Triglyceride: 50 mg/dl
Haemoglobin: 1000 mg/dl
Cholesterol: 6 mg/dl

Ascorbic Acid: 20 mg/dl
Bilirubin: 60 mg/dl

References:

1. World Health Organisation Statement regarding cluster of pneumonia cases in Wuhan, China: 9 January 2020.
2. Weiss SR, Lebowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164.
3. World Health Organisation. Coronavirus. www.who.int/health-topics/coronavirus.

Glossary of Symbols:

	Catalogue number		Temperature limitation
	Consult instructions for use		Batch code
	<i>In vitro</i> diagnostic medical device		Use by
	Manufacturer		Do not reuse

