2019-nCoV IgG/IgM WB Device (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADCOV2	20 Tests
RADCOV2	2 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 SARS-CoV-2 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 against SARS-CoV-2 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, SARS-CoV-2 antigen and goat anti-mouse IgG on the membrane of the 2019-nCoV IgG/IgM WB Device.

Materials Provided

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

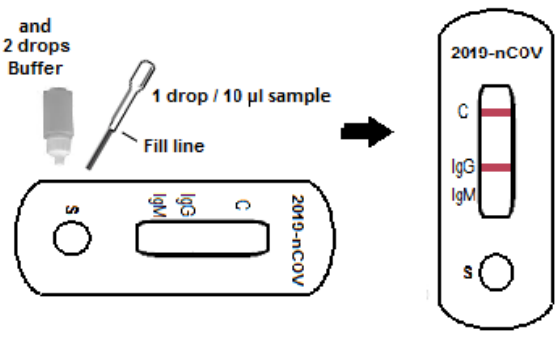
Materials not provided: Timer

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.
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 an alcohol 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 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.

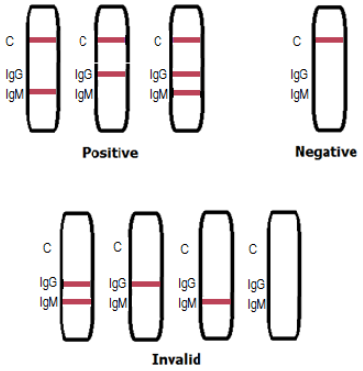
Assay Procedure:
Bring the device, samples, buffer and controls fully to room temperature (15 - 30°C) before starting any testing. Remove the test device from the sealed pouch, place it on a clean and level surface and use it immediately.



Using the dropper take up sample into the tip of the dropper and dispense a small drop into the sample well (approximately 10 µl). Add 2 drops of buffer to the sample well (approximately 80 µl) and start the timer. See illustration.

Wait for coloured lines to appear. Read the results between 10 and 15 minutes. Do not interpret any result after 15 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-SARS-CoV-2 IgG or anti-SARS-CoV-2 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 SARS-CoV-2 in whole blood, serum or plasma 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-SARS-CoV-2 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-SARS-CoV-2 IgG and anti-SARS-CoV-2 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 SARS-CoV-2 virus.
The results obtained with this test should not be used as the sole criterion for diagnosis of SARS-CoV-2 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 EIA test the results indicating high specificity and sensitivity.
IgG Results

Method		EIA		Total Results
2019-nCoV IgG/IgM WB Device	Results	Positive	Negative	
	Positive	101	9	
	Negative	9	241	
Total Results		110	250	360

Relative Sensitivity: 91.8% (95% CI*: 74.5% - 98.9%) *Confidence Intervals
Relative Specificity: 96.4% (95% CI*: 93.1% - 98.6%)
Accuracy: 95.0% (95%CI*: 93.5% - 97.0%)

IgM Results

Method		EIA		Total Results
2019-nCoV IgG/IgM WB Device	Results	Positive	Negative	
	Positive	111	6	
	Negative	5	214	
Total Results		116	220	336

Relative Sensitivity: 95.7% (95%CI*: 90.3% - 97.9%)
Relative Specificity: 97.3% (95% CI*: 94.9% - 98.6%)
Accuracy: 96.7% (95% CI*: 93.1% - 98.6%)

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Cross-reactivity

The 2019-nCoV IgG/IgM WB Device has been tested using samples positive for other diseases associated with fever, cough and other respiratory symptoms including anti-Influenza A virus, anti-Mycoplasma pneumoniae, anti-Streptococcus pneumoniae and anti-HCV. These samples, positive for their respective disease, showed no cross-reactivity in the 2019-nCoV IgG/IgM WB Device test.

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:

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by date
	Manufacturer		Do not reuse

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