2019-nCoV IgG/IgM Device (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADCOV1	20 Tests

Intended Use:
The 2019-nCoV IgG/IgM 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, serum and plasma specimen.

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, serum or plasma 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 Rapid Test.

Materials Provided
Individually pouched test devices
Droppers
Buffer
Instructions for Use sheet

Materials not provided: Timer, specimen collection container, centrifuge

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.

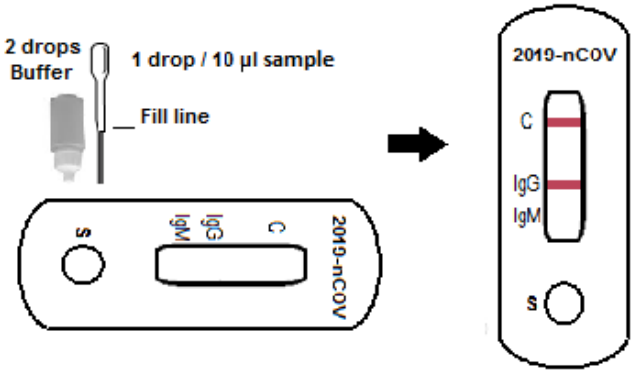
Storage and Stability:
The kit can be stored at room temperature or refrigerated (2 - 30°C). The test device is stable up to the expiry date printed on the sealed pouch. The device must remain in the sealed pouch until use. Do Not Freeze. Do not use after the expiry date. The stability of the buffer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

Sample Collection and Preparation:
The 2019-nCoV IgG/IgM Device test can be performed using whole blood, serum, or plasma.
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 hand again then 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.
Venepuncture Whole Blood samples: Collect blood by standard venepuncture technique. The whole blood may be used in the test up to 48 hours after collection if stored at 2 - 8°C.
Serum and Plasma samples: Separate serum and plasma from red blood cells as soon as possible to avoid haemolysis. Use only clear, non-haemolysed samples. EDTA, Heparin citrate and potassium oxalate anticoagulants can be used. Serum and plasma samples may be stored at 2 - 8°C for up to 3 days. For long term storage, samples should be frozen below -20°C. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be repeatedly thawed and re-frozen. If samples are to be shipped, they should be packed in compliance with local regulations for transportation of etiologic agents.

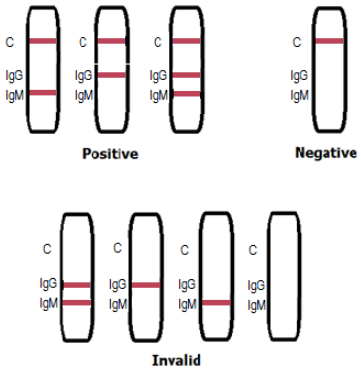
Assay Procedure:
Bring the device, samples, buffer and controls fully to room temperature (15 - 30°C) before starting any testing. Remove the test device from the sealed pouch, place it on a clean and level surface and use it immediately.

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 below.
Using a pipette, transfer 10 µl of whole blood, serum or plasma to the sample well, add 2 drops of buffer (approximately 80 µl) and start the timer.

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-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, serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
The 2019-nCoV IgG/IgM Device is limited to the qualitative detection of anti-2019-nCoV IgG and IgM antibodies in the sample types mentioned. 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 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 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%)

Prestige Diagnostics UK Ltd, 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 25642100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

V3: rev May 2020

IgM Results

Method		EIA		Total Results
2019-nCoV IgG/IgM 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%)

Cross-reactivity
The 2019-nCoV IgG/IgM 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 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

CE

Prestige Diagnostics UK Ltd, 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 25642100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

V3: rev May 2020