2019-nCoV Antigen Device (Anterior Nasal Swab) (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADCOV6-20T	20 Tests
RADCOV6-05T	5 Tests
RADCOV6-02T	2 Tests

Intended Use:
The 2019-nCoV Antigen Device (Anterior Nasal Swab) is a rapid chromatographic immunoassay for the qualitative detection of antigens of SARS-CoV-2 in anterior nasal swab samples.

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 China in December 2019 and in January 2020 the World Health Organisation designated the new strain 2019-nCoV (later SARS-CoV-2). 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 operates as a double antibody immunoassay. Anti-SARS-CoV-2 antibody is immobilized on the membrane in the test zone. Particles conjugated with anti-SARS-CoV-2 antibody are coated on the membrane near the sample well. During the test extracted nasal swab sample is added to the sample well where it interacts with the antibody coated particles and SARS-CoV-2 antigens present in the sample will bind to the antibody. The antigen-particle complexes migrate up the membrane by capillary action where they interact with the anti-SARS-CoV-2 antibody at the test line and are captured. A positive result is indicated when a coloured line forms at the 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-SARS-CoV-2 antibody.

Materials Provided
Individually pouched test devices
Extraction tubes containing Extraction Buffer
Swabs
Instructions for Use sheet

Materials not provided: Timer

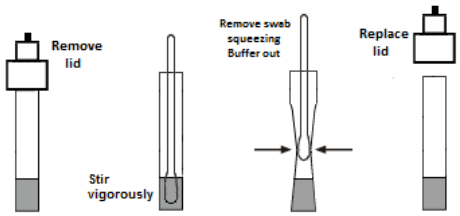
Precautions:
Do not touch the nasal swab head, hold only by the shaft and never touch the test result window of the cassette.
Humidity and temperature can adversely affect results. Conduct the test in a well ventilated room.
Follow local guidelines for correct disposal of samples.

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.

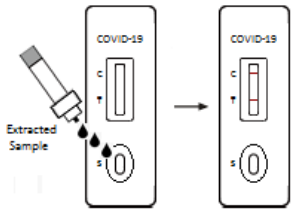
Sample Collection and Storage:
The 2019-nCoV Antigen Device test is performed using an extracted anterior nasal swab sample.
Collection: Insert the swab into the left nasal cavity of the subject to a depth of 2 cm and then rotate gently 5 times. Withdraw the swab then insert it into the right nasal cavity to a depth of 2 cm, rotate it gently 5 times then withdraw the swab and immerse it in the Extraction Buffer inside the Extraction Tube.
Transport and storage: Ideally samples should be used in the test straight away. If testing cannot be performed immediately, the swabs should be put into the Extraction Tubes, and may be stored and transported in this condition for up to 4 hours at 2 – 8°C.

Sample Preparation:
- For samples tested immediately, open the cap of the Extraction Tubes already containing the buffer. Insert the nasal swab sample into the buffer and, holding the swab head below the surface of the buffer, stir the swab vigorously in the liquid to release antigens into the Extraction Buffer. Leave for one minute.
- For all swabs to remove, press the swab against the wall of the tube then lift out the swab while squeezing the sides of the tube around it to release as much buffer as possible from the swab head. See illustration below.
- Fit the dropper lid on the Extraction Tube securely.
- The extracted sample is stable up to 1 hour at room temperature (15 – 30°C) or 4 hours at 2 - 8°C.

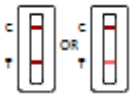
Assay



Procedure:
- Bring the device, samples 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.
- Invert the Extraction Tube and dispense 3 drops of extracted sample (approximately 100 µl) into the Sample Well. Start the timer.
- Wait for coloured lines to appear. Read the results at 15 minutes. Do not interpret any result after 20 minutes.



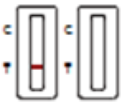
Interpretation of Results:



Positive: Two clear coloured lines appear. One band appears at the Control line (C) and one band develops at the Test line (T). This result indicates detection of SARS-CoV-2 antigens.

* NOTE: The intensity of colour development at the test line will vary depending on the concentration of antigens present in the sample. Therefore, any shade of colour developing at the test line should be considered positive.

Negative: One coloured line appears at the control line (C). No visible coloured line appears in the test zone.



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. Quality Controls 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 antigens to SARS-CoV-2 in subjects. In particular, the correct procedure for collection of the anterior swab sample is essential, inadequate sample collection or improper sample handling may yield false negative results.
The 2019-nCoV Antigen Device is limited to the qualitative detection of antigens of SARS-CoV-2 in extracted anterior nasal swab samples. The intensity of the test band does not have linear correlation with the antigen concentration in the sample.
A negative result for an individual subject indicates absence of a detectable level of SARS-CoV-2 antigen. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19. If individuals experience continuing symptoms a repeat of the test with newly collected sample a few days later is recommended or testing by a molecular method.
If blood is present in the swab sample or excess mucus this can lead to false positive results and false negative results can be obtained following incorrect sample collection, extraction or storage.
The 2019-nCoV Antigen Device detects viable and non-viable virus. Test performance depends on the antigen load in the sample and may not correlate with cell culture tests performed on the same sample. A positive test result does not rule out the possibility that other pathogens may be present so results should be taken in consideration with clinical symptoms.
Children tend to shed virus for longer than adults which may result in differences in sensitivity between adults and children.
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.

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Performance Characteristics:
The 2019-nCoV Antigen Device has been evaluated in clinical trials using anterior swab samples. The reference method for the study was RT-PCR, the matched sample results for which were regarded as the definitive virus status, either positive or negative.

Method		PCR		Total Results
2019-nCoV Antigen Device	Results	Positive	Negative	
	Positive	286	2	
	Negative	11	400	
Total Results		297	402	699

Sensitivity: 96.3% (95% CI*: 94.2% - 97.1%) *Confidence Intervals
Specificity: 99.5% (95% CI*: 97.9% - 100%)
Accuracy: 98.1% (95%CI*: 97.3% - 98.5%)

Limit of Detection
The Limit of Detection was determined by testing serial dilutions of inactivated SARS-CoV-2 virus in Extraction Buffer (stock concentration 1 x 10^6 $TCID_{50}$/ml) as samples in 2019-nCoV Antigen Device tests.

Dilution	1/100	1/200	1/400	1/800	1/1600	1/3200
Concentration in diluted sample ($TCID_{50}$)	1 x 10^4	5 x 10^3	2.5 x 10^3	1.25 x 10^3	6.25 x 10^2	3.125 x 10^2
%CV	100	100	100	100	100	10

The Limit of Detection was defined as the lowest concentration of virus giving ≥ 95% positive results (≥19/20). The Limit of Detection was determined as 6.25 x 10^2 $TCID_{50}$/ml

Cross-reactivity
The 2019-nCoV Antigen Device has been assessed for cross reactivity by testing specificity with a range of viruses associated with fever, cough and other respiratory symptoms and for cross reactivity caused by other pathogenic organisms.

Microorganism	Concentration of organism	Result
Adenovirus type 1	1.5 x 10^6 $TCID_{50}$/ml	Negative
Adenovirus type 3	7.5 x 10^4 $TCID_{50}$/ml	Negative
Adenovirus type 5	4.5 x 10^5 $TCID_{50}$	Negative
Adenovirus type 7	1 x 10^6 $TCID_{50}$/ml	Negative
Human Coronavirus 229E	1.5 x 10^6 $TCID_{50}$/ml	Negative
Human Coronavirus OC43	1.5 x 10^6 $TCID_{50}$/ml	Negative
Human Coronavirus NL63	1.5 x 10^6 $TCID_{50}$/ml	Negative
Human Coronavirus HKU1	1.5 x 10^6 $TCID_{50}$/ml	Negative
MERS Coronavirus	72 µg/ml	Negative
Influenza A H1N1 WS/33	2 x 10^7 $TCID_{50}$/ml	Negative
Influenza A H3N2 A/Hong Kong/8/68	4.6 x 10^7 $TCID_{50}$/ml	Negative
Influenza B B/Lee/40	8.5 x 10^7 $TCID_{50}$/ml	Negative
Influenza B B/Taiwan/2/62	4 x 10^7 $TCID_{50}$/ml	Negative
Respiratory syncytial virus	2.5 x 10^6 $TCID_{50}$/ml	Negative
Human Rhinovirus 16	1.5 x 10^6 $TCID_{50}$/ml	Negative
Human Metapneumovirus 16 Type A1	1.5 x 10^6 $TCID_{50}$/ml	Negative
Human Metapneumovirus 3 Type B1	1.5 x 10^6 $TCID_{50}$/ml	Negative
Mycobacterium tuberculosis	1 x 10^5 PFU/ml	Negative
Streptococcus pneumoniae	1 x 10^5 PFU/ml	Negative
Streptococcus pyogenes	1 x 10^5 PFU/ml	Negative
Mycoplasma pneumoniae	1 x 10^5 PFU/ml	Negative
Legionella pneumophila	1 x 10^5 PFU/ml	Negative

None of the virus samples and none of the pathogenic organisms caused any trace of colour line development at the test line region indicating no cross reactivity of these pathogenic organisms in the 2019-nCoV Antigen Device.

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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