2019-nCoV Antigen Device (Saliva) (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADCOV7-20T	20 Tests
RADCOV7-05T	5 Tests
RADCOV7-02T	2 Tests

Intended Use:
The 2019-nCoV Antigen Device is a rapid chromatographic immunoassay for the qualitative detection of antigens of SARS-CoV-2 in saliva 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 saliva 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
Saliva collection bags
Transfer pipettes
Instructions for Use sheet

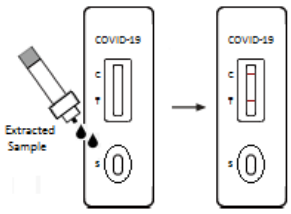
Materials not provided: Timer

Precautions:
When handling saliva and the test cassette, treat these as if potentially infectious. Avoid contact with saliva samples 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.
If the humidity in the environment of kit use is greater than 60% the device cassette must be used immediately.

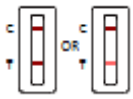
Sample Collection, Preparation and Storage:
The 2019-nCoV Antigen Device test is performed using an extracted saliva sample. Ensure the subject has not eaten or drunk anything or smoked for at least 10 minutes before collection.
Collection: Once the subject, with no swallowing, has collected a pool of saliva within the buccal cavity, this should be spat into a saliva collecting bag. Approximately 1 ml saliva should be collected. Fill the transfer pipette until saliva is three quarters of the way up the stem of the pipette (0.3 ml saliva) and dispense the saliva into the extraction tube.
Transport and storage: Samples should be used in the test as soon as possible. If not tested immediately, the saliva samples in the extraction tubes may be transported and stored up to 1 hour at room temperature (15 – 30°C) or 4 hours at 2 - 8°C.

Assay Procedure:
- Bring the device and samples 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.
- Vigorously shake the extraction tube containing the saliva to extract viral antigens then fix the dropper cap onto the tube.
- Invert the Extraction Tube and dispense 2 drops of extracted sample into the Sample Well. 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.

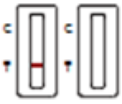
Interpretation of Results:



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 apparent 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 subjects. In particular, the correct procedure for collection and preparation of the saliva sample is essential. Failure to follow the procedure may give inaccurate results.
The 2019-nCoV Antigen Device is limited to the qualitative detection of antigens of SARS-CoV-2 in extracted saliva 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.
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.
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.

Performance Characteristics:
The 2019-nCoV Antigen Device has been evaluated in clinical trials using saliva 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	104	2	
	Negative	6	218	
Total Results		110	220	330

Sensitivity: 94.6% (95% CI*: 88.5% - 98.0%) *Confidence Intervals
Specificity: 99.1% (95% CI*: 96.8% - 99.9%)
Accuracy: 97.6% (95%CI*: 95.3% - 99.0%)

Limit of Detection
The Limit of Detection was determined by making serial dilutions of inactivated SARS-CoV-2 virus in a matrix of pooled extracted negative saliva samples and using the preparations as samples in 2019-nCoV Antigen Device tests according to the IFU. The Limit of Detection was determined as 30 $TCID_{50}$/ml.

Interference
The 2019-nCoV Antigen Device has been assessed for interfering substances by testing various compounds diluted in sample matrix to the concentrations shown as samples in 2019-nCoV Antigen Device (Saliva) tests.

Haemoglobin	1.2% (v/v)	Tobramycin	4 µg/ml
Mucin	2% (v/v)	Benzocaine	0.15% (v/v)
Fluticasone propionate	0.3 ng/ml	Oseltamivir Phosphate	1.3 mg/ml
Oxymetazoline	12% (v/v)	Ribavirin	12.9 mg/ml
Saline Nasal Spray	5% (v/v)		

None of the substances caused any trace of colour line development at the test line region indicating no interference of these substances in the 2019-nCoV Antigen Device.

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Cross Reactivity

The 2019-nCoV Antigen Device has been assessed for cross reactivity by testing a range of viruses associated with fever, cough and other respiratory symptoms and other pathogenic organisms at the concentration given below in sample matrix either with or without inactivated SARS-CoV-2 virus (1.5×10^2 $TCID_{50}$/ml).

Microorganism	Concentration of organism	Test Result – Cross Reactivity	Test Result - Interference
Adenovirus type 3	1×10^5 $TCID_{50}$/ml	Negative	Positive
Measles virus	1×10^5 $TCID_{50}$/ml	Negative	Positive
Mumps virus	1×10^5 $TCID_{50}$/ml	Negative	Positive
Human Coronavirus 229E	1×10^5 $TCID_{50}$/ml	Negative	Positive
Human Coronavirus OC43	1×10^5 $TCID_{50}$/ml	Negative	Positive
Human Coronavirus NL63	1×10^5 $TCID_{50}$/ml	Negative	Positive
MERS Coronavirus	1×10^5 $TCID_{50}$/ml	Negative	Positive
Influenza A (H1N1, 2009)	1×10^5 $TCID_{50}$/ml	Negative	Positive
Influenza A (H3N2)	1×10^5 $TCID_{50}$/ml	Negative	Positive
Influenza B (Victoria Strain)	1×10^5 $TCID_{50}$/ml	Negative	Positive
Influenza B (Y Strain)	1×10^5 $TCID_{50}$/ml	Negative	Positive
Respiratory Syncytial Virus A	1×10^5 $TCID_{50}$/ml	Negative	Positive
Human Rhinovirus	1×10^5 $TCID_{50}$/ml	Negative	Positive
Avian Influenza Virus (H7N9)	1×10^5 $TCID_{50}$/ml	Negative	Positive
Enterovirus (CA16)	1×10^5 $TCID_{50}$/ml	Negative	Positive
Chlamydia pneumoniae	1×10^6 PFU/ml	Negative	Positive
Streptococcus pneumoniae	1×10^6 PFU/ml	Negative	Positive
Staphylococcus aureus	1×10^6 PFU/ml	Negative	Positive
Mycoplasma pneumoniae	1×10^6 PFU/ml	Negative	Positive
Bordetella parapertussis	1×10^6 PFU/ml	Negative	Positive

None of the virus samples and none of the pathogenic organisms in negative matrix 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.
None of the virus samples and none of the pathogenic organisms in matrix also containing inactivated SARS-CoV-2 virus caused failure of colour line development at the test line region indicating no interference of these pathogenic organisms in the 2019-nCoV Antigen Device using SARS-CoV-2 antigen positive samples.

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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