2019-nCoV Antigen Device (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADCOV4	20 Tests

Intended Use:
The 2019-nCoV Antigen Device is a rapid chromatographic immunoassay for the qualitative detection of antigens of SARS-CoV-2, a new strain of coronavirus (nCoV), in nasopharyngeal swab samples. For *in vitro* diagnostic use by trained professionals only.

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 nasopharyngeal swab extract 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 Buffer
Extraction tubes
Swabs
Instructions for Use sheet

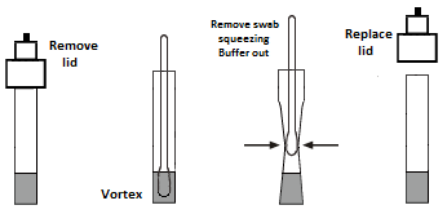
Materials not provided: Timer

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.
IMPORTANT: Viral Transport Media (VTM) can interfere in the test results. Do not store swab samples in VTM containing guanidine. Samples treated for extraction for RT-PCR must not be used in 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.

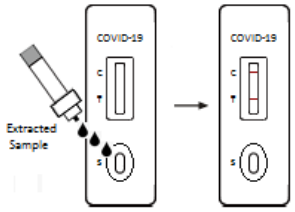
Sample Collection and Storage:
The 2019-nCoV Antigen Device test is performed using an extracted nasopharyngeal swab sample.
Collection: Insert the swab into the nasal cavity of the subject and push to the back of the nasopharynx. Wipe the swab over the posterior nasopharynx then withdraw the swab slowly whilst rotating it.
Transport and storage: Samples should be used in the test as soon as possible. If not tested Immediately, the swabs should be tightly sealed in a dry specimen container, under which conditions they may be stored up to 8 hours at room temperature (15 – 30°C) or 24 hours at 2 - 8°C.

Sample Preparation:
- Use the Extraction Tubes and Extraction Buffer supplied in the kit.
- Line up Extraction Tubes in the test tube rack and add 350 µl Extraction Buffer. Insert the dry 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.
- 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.

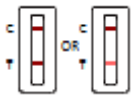


- Fit the lid of the Extraction Tube securely.
- The extracted sample is stable for 2 hours at room temperature (15 – 30°C) or 24 hours at 2 - 8°C.

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 (but no later than one hour after opening).
- Tip up the Extraction Tube and dispense 3 drops of extracted sample (approximately 100 µl) into the Sample Well (S). Start the timer.
- Wait for coloured lines to appear. Read the results at 15 minutes. Do not interpret any result after 20 minutes.



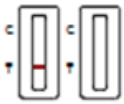
Interpretation of Results:



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 subjects. In particular, the correct procedure for collection of swab 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 nasopharyngeal 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 a subject experiences 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 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 testing samples from individuals displaying and not displaying symptoms. 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	80	1	
	Negative	3	120	
Total Results		83	121	204

Sensitivity: 96.4% (95% CI*: 89.8% - 99.2%) *Confidence Intervals
Specificity: 99.2% (95% CI*: 95.5% - 99.9%)
Accuracy: 98.0% (95%CI*: 95.1% - 99.5%)

Precision
Three levels of SARS-CoV-2 standard material including a Negative, a Weak SARS-CoV-2 antigen and a Strong SARS-CoV-2 antigen sample were used to determine Intra and Inter assay precision. Ten replicates of each level were tested each day on 3 consecutive days. Results for each replicate for each level were correct, according to the designated result for the standard sample, with more than 99% accuracy.

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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 via cross reactivity caused by other pathogenic organisms.

Specificity with a range of viruses

Virus	Dilution of virus in sample tested
Adenovirus type 3	3.16×10^4 TCID50/ml
Adenovirus type 7	1.58×10^5 TCID50/ml
Human Coronavirus OC43	2.45×10^6 LD50/ml
Influenza A H1N1	3.16×10^5 TCID50/ml
Influenza A H3N2	1×10^5 TCID50/ml
Influenza B	3.16×10^6 TCID50/ml
Human Rhinovirus 2	2.81×10^4 TCID50/ml
Human Rhinovirus 14	1.58×10^6 TCID50/ml
Human Rhinovirus 16	8.89×10^6 TCID50/ml
Measles	1.58×10^4 TCID50/ml
Mumps	1.58×10^4 TCID50/ml
Parainfluenza virus 2	1.58×10^7 TCID50/ml
Parainfluenza virus 3	1.58×10^8 TCID50/ml
Respiratory syncytial virus	8.89×10^4 TCID50/ml

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

Cross reactivity with other pathogenic organisms
A range of bacterial and fungal pathogens were tested as samples at 1×10^8 organisms/ml in the 2019-nCoV Antigen Device.

Arcanobacterium	Pseudomonas aeruginosa
Candida albicans	Staphylococcus aureus subspaureus
Corynebacterium	Streptococcus pneumoniae
Escherichia coli	Streptococcus epidermidis
Moraxella catarrhalis	Streptococcus pygenes
Niesseria lactamica	Streptococcus salivarius
Neisseria subflava	Streptococcus sp group F

None of the organisms caused any trace of colour line development at the test line region indicating no cross reactivity of these 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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