2019-nCoV Neutralising Antibody Device (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADCOV8	25 Tests

Intended Use:
The 2019-nCoV Neutralising Antibody Device is a rapid chromatographic immunoassay intended for the qualitative detection of neutralising antibodies against SARS-CoV-2 spike protein receptor binding domain. It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2. 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 and are zoonotic. Reports of a novel coronavirus began in China in December 2019 and rapidly spread creating a worldwide pandemic. The development of vaccines was initiated early and, with accelerated clinical evaluation, different types of vaccine against the SARS-CoV-2 virus were approved for use from the beginning of 2021 and vaccination programmes began. The SARS-CoV-2 virus enters human cells via a receptor binding domain on the spike protein (S-RBD) which attaches to the ACE-2 receptor on the human cell. Pre-infection with SARS-CoV-2 and vaccines induce production of neutralising antibodies which bind to the RBD and block the entry of the virus into cells and hence reduce viral replication.

Test Principle:
The 2019-nCoV Neutralising Antibody Device test operates as a double antigen sandwich immunoassay. SARS-CoV-2 S-RBD protein is immobilized on the membrane at the test line. Tracer particles conjugated to recombinant SARS-CoV-2 S-RBD are coated on the membrane near the sample well. When sample is added to the sample well and begins to migrate, neutralising antibodies, if present in the sample, will bind to the labelled S-RBD. The immunocomplexes formed migrate up the membrane and bind to the S-RBD protein at the test line forming a coloured line indicating that the sample is positive. The control line, which should appear in every test, acts as a procedural control indicating that proper volume of sample has been added and capillary action along the membrane has occurred.

Materials provided:
Test cassettes, droppers, buffer, lancets, alcohol swabs, Instructions For Use sheet

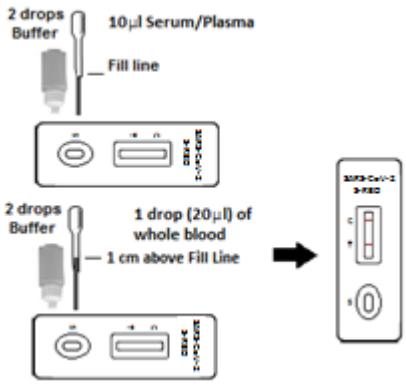
Materials not provided:
Timer, pipette

Precautions:
This Instructions For Use must be read completely before performing the test. Failure to follow the test procedure as described may yield inaccurate test results.
For professional in vitro diagnostic use only.
Do not use after the expiry date.
Do not eat, drink, or smoke in the area where the samples or kits are handled.
Do not use the test if the pouch is damaged.
Handle all samples and kit components as if potentially infectious. Follow Good Laboratory Practice procedures where samples and kits are handled and follow local regulations for correct disposal of samples and kit components.
Wear protective clothing including laboratory coat, disposable gloves and eye protection.
Wash hands thoroughly after testing.
The used test should be discarded according to local regulations.
Humidity and temperature can adversely affect results.

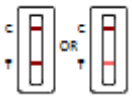
Storage and Stability:
Store the kit as packaged at room temperature or refrigerated (2 - 30°C). The test is stable until the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiry date.

Sample Collection and Preparation:
The SARS-CoV-2 Neutralising Antibody Device can be performed using serum, plasma and venous or finger prick whole blood.
Testing should ideally be performed immediately after the samples have been collected. Do not leave samples at room temperature for prolonged periods. Serum and plasma samples may be used in the test up to 7 days when stored at 2 - 8°C. For longer term storage freeze below -20°C. Whole blood samples can be tested up to 48 hours if stored at 2 - 8°C. Do not freeze whole blood samples.
Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Avoid repeated freeze/thawing.
If samples are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
EDTA-K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for plasma.

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 (but no later than one hour after opening).
- For serum and plasma
  Using the dropper take up sample to the top of the thin portion of the dropper (approximately 10 µl) and transfer it to the sample well. Add 2 drops of buffer to the sample well (approximately 80 µl) and start the timer. See illustration
  Using a pipette transfer 10 µl of serum or plasma to the sample well. Add 2 drops of buffer to the sample well (approximately 80 µl) and start the timer.
  - For venous whole blood
  Using the dropper take in whole blood to about 1 cm above the thin portion of the dropper and dispense 1 full drop (approximately 20 µl) to the sample well. Add 2 drops of buffer (approximately 80 µl) and start the timer.
  Using a pipette transfer 20 µl of whole blood to the sample well. Add 2 drops of buffer (approximately 80 µl) and start the timer.
  - For finger prick whole blood
  Clean an area of the patient's fingertip with the alcohol swab. Allow to dry. Squeeze the hand gently to encourage blood flow to the finger. Pierce the skin with the 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. Draw up the blood into the dropper up to about 1 cm above the thin portion of the dropper and dispense 1 full drop (approximately 20 µl) to the sample well. Add 2 drops of buffer (approximately 80 µl) and start the timer. Do not freeze whole blood samples. Whole blood collected by finger prick must be tested immediately.
- Wait for the coloured line(s) to appear. Read results at 10 minutes. Do not interpret any result after 20 minutes.



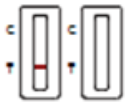
Interpretation of Results



POSITIVE: One coloured line appears in the control region (C) and one coloured line appears at the test line (T). Positive result indicates the detection of neutralising antibodies against SARS-CoV-2 in the sample.

* NOTE: The intensity of colour development at the test line will vary depending on the concentration of antibody 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) and no line in the test region. Negative result indicates that neutralising antibody against SARS-CoV-2 was not detected.



INVALID: A Control line fails to appear. Insufficient sample or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Limitations of the Test:
The test procedure and the interpretation of test result must be followed closely when testing for the presence of neutralising antibodies. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
The 2019-nCoV Neutralising Antibody Device is for in vitro diagnostic use only.
The test is only to be used for detection of neutralising antibodies against SARS-CoV-2 in human whole blood, serum, or plasma samples. Neither a quantitative concentration nor the rate of increase in concentration of neutralising antibodies against SARS-CoV-2 can be determined by this qualitative test.
Haematocrit level of whole blood can affect the test results. Haematocrit level needs to be between 25% and 65% for accurate results.
A negative result is only indicative of a titre of the neutralising antibodies in the sample lower than the minimum detection limit of the test, or that neutralising antibody against SARS-CoV-2 has not appeared at the time of sample collection. Results from immunosuppressed patients should be interpreted with caution.
Repeated positive or negative results for antibodies against SARS-CoV-2 S-RBD cannot be used to determine the efficacy of a certain therapy and results should only be used in conjunction with other diagnostic procedures and clinical findings for diagnostic purposes.
Positive results may be due to previous or current infection with other coronaviruses.

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Performance Characteristics:

The 2019-nCoV Neutralising Antibody Device has been evaluated in clinical trials by comparing results obtained using the kit against a commercial neutralising antibody ELISA. The results are summarised below.

Method		ELISA		Total Results
SARS -CoV-2 Neutralising Antibody Device	Results	Positive	Negative	
	Positive	87	2	89
	Negative	2	128	130
Total Results		89	130	219

Relative Sensitivity: 97.8% (95%CI*: 92.1%-99.7%) *Confidence Interval Relative
Specificity: 98.5% (95%CI*: 94.6%-99.8%)
Accuracy: 98.2% (95%CI*: 95.4%-99.5%)

Precision
Intra-Assay precision was determined using 3 replicates each of a negative sample, two different IgG positive samples and an IgM positive sample in 2019-nCoV Neutralising Antibody Device tests. The negative and positive results were correctly recorded with an accuracy of > 99%.

Inter-Assay precision was determined using a negative sample, two different IgG positive samples and an IgM positive sample in three separate assays on 3 lots of 2019-nCoV Neutralising Antibody Device over 3 days. The negative and positive results were correctly recorded with an accuracy of > 99%.

Interfering Substances
Preparations of the following endogenous blood constituents at the concentrations given below were tested as samples in 2019-nCoV Neutralising Antibody Device tests. Triglyceride: 100 mg/dl, ascorbic acid: 20 mg/dl, haemoglobin: 1000 mg/dl, bilirubin: 60 mg/dl and total cholesterol: 15 mmol/l. No interference was observed.

Cross-reactivity
The 2019-nCoV Neutralising Antibody Device was tested using samples positive for other viruses including anti-Influenza A virus, anti-Influenza B virus, anti-RSV, anti-adenovirus, anti-Measles, anti-EV71, anti-Parainfluenza virus, anti-Syphilis, anti-H Pylori, anti-HIV and anti-HCV and HAMA, RF, non-specific IgG, non-specific IgM and HBsAg. None of the samples showed cross-reactivity in the 2019-nCoV Neutralising Antibody Device tests.

References:
Nature Reviews Immunology. COVID-19 vaccines: modes of immune activation and future challenges. https://doi.org/10.1038/s41577-021-00526-x.

Glossary of Symbols:

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

CE

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