

ABFIND™

By Meril

POST VACCINATION NEUTRALIZING ANTIBODY TEST



USER GUIDE

WHAT'S IN THE BOX?



1 Test device



1 Assay buffer



1 Capillary tube



1 Alcohol swab



1 Lancet



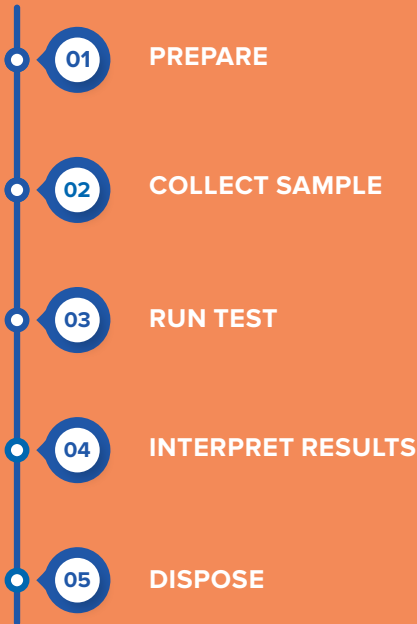
1 Disposal bag



1 User guide

HOW TO USE?

TAKE THE TEST IN 5 EASY STEPS:



STEP 1: PREPARE

- 1** Wash your hands. Make sure they are dry before starting the test.



- 2** Remove the test components from the box and place them on a flat surface.



- 3** Remove the test device from the pouch and keep it ready.



- 4** Peel the aluminium foil from the pre-filled buffer tube and secure the cap on top of the buffer tube.



- 5** Push the buffer tube on to the perforated circle of the box.



STEP 2: COLLECT SAMPLE

- 1** Choose your ring or the middle finger and clean the tip of the finger with the alcohol swab and let it dry for 5 -7 seconds.



- 2** Twist & pull the tip of the Lancet.



- 3** Position the lancet over your finger tip and push it against the skin until you hear a click.



- 4** Wait for a good size of a drop of blood to form. If it doesn't, squeeze the sides of the finger for it to form.



- 5** Squeezing the top of the capillary tube, bring the capillary tip in contact with the blood drop and release the top of the capillary tube, allowing blood to flow into the tube.



- 1** Squeeze the top of the capillary tube to transfer the blood into the sample well of the test device.



Add 3 drops of the buffer on to the sample well of the test device.



- 3** Wait for 15-20 mins to interpret the test results. Results post 20 mins should not be considered valid.



20 min

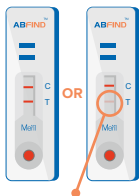
Neutralizing Antibody Negative result

If only the control (C) band is developed, the test indicates that the result is negative.



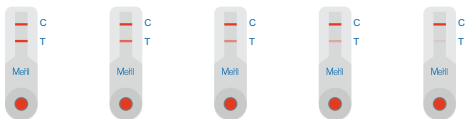
Neutralizing Antibody Positive result

If control (C) and test (T) bands are developed, the test indicates for the presence of COVID-19 Neutralizing antibody in the sample. The result is positive.



Different possibilities of Positive result

Look very closely!
Even a faint line
at "T" indicates
a positive result.



Invalid result

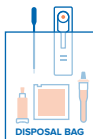
If no control (C) band is developed, then the assay is invalid regardless of colour development on test (T) band as indicated below. Repeat the assay with a new device.

If none of the bands are developed, then the assay is invalid. Repeat the assay with a new device.



STEP 5: DISPOSE

Place used lancet, alcohol swab, capillary tube, assay buffer tube and test device into the disposal bag. Seal the disposal bag and dispose the bag in a waste bin.



All the used materials should be put inside the waste disposal bag and thrown in the household waste.



Disinfect all surfaces that the specimen may have touched and wash your hands after disposal.



THE DO'S

- Store the test device at 2°C- 30° C.
- Check the expiry date printed on the kit packaging.
- Stand up so that your hand is below your heart level. This will also help your blood flow better.
- Follow standard local procedure and guidelines for handling and disposal of used kits.

THE DONT'S

- Do not refrigerate.
- Do not use if expiry date has passed.
- Do not interpret the result after 30 minutes. (Interpret the results after 20 minutes of test.)
- Do not dispose the used material anywhere except the disposal bag.

FAQS

How does Neutralizing Antibody Test work?

COVID-19 Neutralizing Antibody Test detects the neutralizing antibodies to SARS-CoV-2 in human whole blood specimens. When the presence of neutralizing antibody in the blood specimens binds with the Spike-RBD Antigen coated on the device, the complexion will react and form a color band at test region, indicating a positive test.

What are the differences between COVID-19 Antigen Test, Antibody and NAB Test ?

COVID-19 Antigen Tests detects the coronavirus proteins. COVID-19 Antibody tests detect antibodies produced by your body's immune system in response to a previous COVID-19 infection. ABFIND COVID-19 Neutralizing Antibody Test is a NAB test. NAb tests are used to detect the immune system post COVID-19 infection or immune response to vaccination.

Who should have the COVID-19 (Coronavirus) NAB Test?

This can be used by individuals who want to find the presence of Neutralising Antibodies post vaccination or post SARS-CoV2 infection.

This kit should not be used by individuals with bleeding or clotting disorders, those taking anti-coagulants, or by patients taking immunosuppressive drugs or undergoing chemotherapy.

Why do we need NAb testing?

There are 2 main uses for Neutralizing Antibody (NAB) Tests:

1. Confirms if an individual has developed an immune response post SARS-CoV2 infection.
2. Confirms if an individual has developed an immune response post vaccination.

Does a positive antibody test mean I am immune?

There is not enough scientific evidence to confirm if having antibodies means you are definitely immune.

As per research, some human reinfections with SARS-CoV-2 have been confirmed in patients who had antibodies but this is extremely rare. This suggests the body usually develops significant immunity as antibody levels seem to rise in patients as viral counts drop and reinfections are very uncommon.

Research showed, following the 2002 SARS virus outbreak the responsible virus SARS-CoV, patients with antibodies were immune over a 3 year period. COVID-19 (SARS-CoV-2) is closely related to SARS-CoV, both viruses having originated in bats.

When to use antibody test?

It is recommended to use ABFIND Neutralizing Antibody Test 2 weeks after the Second dose of vaccine or 2 weeks after SARS-CoV-2 infection. It can also be used at regular intervals post vaccination or infection to check for the presence of neutralising antibodies.

Who can use antibody test?

Persons vaccinated against SARS-CoV-2 virus and persons infected by SARS-CoV-2 infection.

INTENDED USE AND TEST PRINCIPLE

Intended Use:

ABFIND COVID-19 Neutralizing Antibody Rapid Test is a qualitative in-vitro diagnostic immunochromatography assay. This test is designed for use to detect the circulating SARS-CoV-2 neutralizing antibodies in whole blood. This test is intended for use in any laboratory & non-laboratory setting to check immune response in subjects post COVID-19 vaccination & or infection with the SARS-CoV-2 initiated by the healthcare professional and individual's with self collected specimen.

Principle:

ABFIND COVID-19 Neutralizing Antibody Rapid Test is a qualitative membrane-based immunoassay for the detection of SARS- CoV-2 Neutralizing Antibody in whole blood. This test consists of two components, test region (T) coated with Recombinant Spike-RBD Antigen, and control region (C) coated with Goat Anti-Chicken IgY.

The Recombinant Spike-RBD Antigen and Goat Anti-Chicken IgY labeled by colloidal gold are as tracers.

When specimens are processed and added to the test device, neutralizing antibodies present in the specimen will bind to the colloidal gold labeled Spike-RBD Antigen, Antigen-Antibody complex further bind with coated Recombinant Spike-RBD Antigen test region, form a color band at test region (T).

The colloidal gold labeled Chicken IgY antibody is bound to the Goat Anti-Chicken IgY antibody coated on the control line (C), forms a color band. The control band is used for procedural control and should always appear if the test procedure is performed correctly.

Disclaimer:

Meril ABFIND detects IgG antibodies against the receptor binding domain (RBD) of the spike protein of SARS-CoV-2.

A positive result indicates anti-RBD IgG at or above the limit of detection of the test. A positive result indicates past SARS-CoV-2 infection and / or COVID-19 vaccination. Studies indicate that individuals with Anti-RBD IgG have a lower risk of future SARS-CoV-2 infection, symptomatic COVID-19 and severe COVID-19 compared to individuals without Anti-RBD IgG.

ABFIND may give negative result when an individual doesn't have Anti-RBD IgG or if the antibody titers are too low to be detected by the test. Some individuals who test negative may develop antibodies later or may have antibodies other than Anti-RBD IgG.

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POST VACCINATION NEUTRALIZING ANTIBODY TEST

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