SARS-CoV-2 (COVID-19) Neutralizing Antibody Test

(Serum/Plasma/Whole Blood) Format: Strip
Instructions for Use Catalog Number: B250S

INTENDED USE

Biocan Tell Me Fast SARS-CoV-2 (COVID-19) Neutralizing Antibody Rapid Test is a rapid in vitro semi-quantitative, membrane based immunochromatographic assay intended for detection neutralizing antibodies to SARS-CoV-2 in human serum, plasma (EDTA, citrate, Heparin) or venipuncture whole blood specimens (including finger prick) by a healthcare provider, laboratories, point of care and self-testing. The novel coronavirus neutralizing antibodies are protective antibody produced by the human body after inoculation with novel coronavirus vaccine or infection with novel coronavirus. This test is used as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection and to monitor the presence of neutralizing antibodies in subjects vaccinated with the novel coronavirus vaccine or in people infected with the novel coronavirus. It can be used to evaluate the immune effect after vaccination or whether neutralizing antibodies are produced in human body after infection with novel coronavirus. Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time neutralizing antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion. Negative results do not preclude acute SARS-CoV-2 infection.

SUMMARY

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, or 2019-nCoV) is an enveloped non-segmented positive-sense RNA virus. It is the causative agent of coronavirus disease 2019 (COVID-19), which is contagious in humans. SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N). The spike protein (S) contains a receptor-binding domain (RBD), which is responsible for recognizing the cell surface receptor, angiotensin converting enzyme-2 (ACE2). It is found that the RBD of the SARS-CoV-2 S protein strongly interacts with the human ACE2 receptor leading to endocytosis into the host cells of the deep lung and viral replication. Infection with SARS-CoV-2 initiates an immune response, which includes the production of antibodies, or binding antibodies, in the blood. Not all binding antibodies can block cellular infiltration and replication of the SARS-CoV-2 virus. The subpopulation of the binding antibodies that can block cellular infiltration and replication of the virus are named neutralizing antibodies. It is unknown how long it takes for neutralizing antibodies to be produced, and if they are always produced after SARS-CoV-2 infection or vaccination. While individuals infected with SARSCoV-2 develop binding antibodies to the virus, not all of them develop neutralizing antibodies to SARS-CoV-2. The Tell Me Fast SARS-CoV-2 (COVOD19) Neutralizing Antibody Detection Kit is specific to SARS-CoV-2 neutralizing antibodies and is a robust serological test to detect neutralizing antibodies to SARS-CoV-2 which is urgently needed to determine not only the infection rate, herd immunity and predicted humoral protection, but also vaccine efficacy during clinical trials and after large-scale-vaccination.

PRINCIPLE OF THE TEST

Biocan Tell Me Fast SARS-CoV-2 (COVID-19) Neutralizing Antibody Rapid Test is a lateral flow chromatographic immunoassay for the semi-quantitative detection of SARS-CoV-2 neutralizing Antibody after vaccination or after infection with SARS-CoV-2 virus in human serum, plasma and whole blood. The test strip consists of a strip which consists of a burgundy-colored conjugate pad containing SARS-COV-2 S-RBD antigen conjugated with colloidal gold (SARS CoV-2 conjugates) and mouse IgG-gold conjugates and a nitrocellulose membrane strip containing one test band (T) and a control band (C band). The test band is pre-coated with SARS-COV-2 ACE2 antigen for competitively binding to RBD with neutralizing antibody, to detect the neutralizing antibody in serum, plasma and whole blood. The C band is pre-coated with goat anti mouse IgG. When an adequate volume of test specimen is dispensed into the sample pad of the test strip, the specimen migrates by capillary action across the strip. If there is antibody produced after vaccine, the RBD antibody will be conjugated with RBD antigen, thus the ACE2 antigen can not bind to RBD antigen, so the test line will not be colored, and its intensity will be lower than that of the C band indicating a positive result. If no antibodies are produced, the ACE2 antigen will bind to RBD antigen, the test line will be colored with same or higher intensity than the C band indicating a negative result.

PRECAUTIONS

- Specimen processing should be performed in accordance with pertaining national biological safety regulations and following the recommended WHO guidelines on biosafety and biosecurity. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed

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pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

MATERIALS

MATERIALS PROVIDED

- Test strips in desiccated vail/bottle (50 tests per vail).
- Sample Diluent buffer Bottle (10ml)
- Instructions for use (which includes color chart)
- Negative control (0.1ml) The controls should be run with each new lot when patient testing is conducted to confirm the test performance

Also available in single test packing containing one test strip, alcohol swab, pipette, buffer and IFU.

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Timer
- Pipette
- Lancet. Alcohol Swab & Pipette provided on request for each test

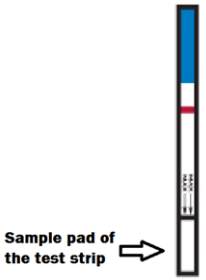
SPECIMEN COLLECTION AND PREPARATION

- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, serum & plasma specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for the transportation of etiologic agents. The test can be performed using serum, plasma or whole Blood (including finger prick) specimen, including plasma or whole blood samples prepared from commonly used anticoagulants (EDTA, heparin, sodium citrate).

DIRECTIONS FOR USE

Allow the tests and controls to reach to room temperature (15-30ºC) prior to testing. Do not open the package until ready to perform the assay.

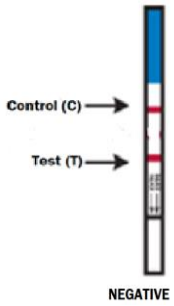
1. Place the test strip on a clean and level surface. Pipette 30µL of serum, plasma or whole blood (including finger prick) into the sample pad of the test strip.
2. Add 2 drops of diluent buffer to sample pad of the test strip.
3. Wait for the red lines to appear. The test result should be read between 10 and 15 minutes.



Note: Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

SARS-COV-2 Neutralizing Antibody Negative:

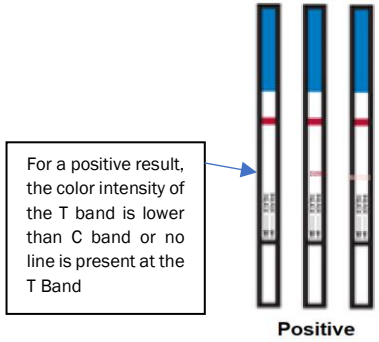


A colored band appears in the control band region (C) and in the in the Neutralizing Antibody test band region (T). The intensity of the T line is same or darker than the C (Control) line indicating a negative result.

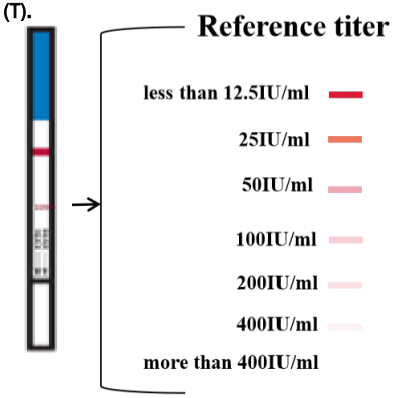
The negative result could mean:
The patient tested was not infected by SARS-COV-2 virus or the sample tested still does not have detectable level of SARS-CoV-2 Neutralizing Antibody after infection of SARS-CvV-2 or after vaccination (mRNA vaccine, adenovirus vector-based vaccine and inactivated virus vaccine)

Positive: SARS-COV-2 Neutralizing Antibody Positive:

A colored band appears in the control band region (C) and there is no colored test band (T) or lighter colored band (T) than C band intensity appearing in the test band region (T), the concentration of neutralizing antibody is more than 12.5IU/ml and test is positive.



NOTE: The intensity of the colored band appearing at test region (T) has to be lighter than the colored band appearing at control region (C) for the test to be positive. Please see the below color reference chat which will indicate the estimated approximate concentration of SARS-CoV-2 Neutralizing Antibodies detected as per the intensity of the color band at the Test Region (T).



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INVALID: Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of lines in the T region of the strip. Repeat the test using a new strip.

QUALITY CONTROL

Internal procedural controls are included in the test. A pink line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

PERFORMANCE

Clinical Performance

The evaluation of Tell Me Fast SARS-CoV-2 (COVID19) Neutralizing Antibody Test was conducted using 500 clinical samples from SARS-CoV-2 susceptible subjects. All patients were were test by Tell Me Fast SARS CoV-2 (COVID19) Neutralizing Antibody Rapid Test Kit (the cut-off is 12.5IU/ml) and by a reference US FDA EUA PCR and SARS-CoV-2 neutralizing antibody test (VNT). Comparison for all samples are showed in the following table:

	Biocan SARS CoV-2 (COVID19) Neutralizing Antibody Rapid Test		
Both PCR and VNT Results	Positive	Negative	Total
Positive	99	0	99
Negative	1	400	401
Total	100	400	500

Relative Sensitivity: 99%; Relative Specificity:100%; Overall agreement: 99.8%

Limit of Detection (LOD）

The limit of detection of the Tell Me Fast SARS CoV-2 (COVID19) Neutralizing Antibody Test was evaluated using WHO Reference Standard (NIBSC: 20/136) and was found to be 12.5IU/ml. To ensure reproducibility 20 tests at the LOD were performed and agreement rate was 100%.

Concentration	Positive Results	Agreement Rate
12.5IU/ml	20/20	100%

Cross Reactivity:

This test had no cross reactivity with HCoV-229E, HCoV-OC43, HCoV-NL63, SARS, HCoV-HKU1,MERS-CoV, Influenza(A/B), Adenovirus, Rotavirus, Parainfluenza virus, M.Pneumonia, Measles ,Streptococcus Pneumoniae, Staphylococcus aureus, EBV, Coxsachie virus, AIV H7N9, AIV H5N1 and HIV.

HOOK Effect:

Tell Me Fast SARS-CoV-2 (COVID19) Neutralizing Antibody Rapid Test was tested with RBD antibody at a concentration up to 1mg/ml RBD antibody, and no high-dose hook effect was observed.

Interference Specificity: This test had no interference with HAMA, Human serum Albumin, Antinuclear antibody, Antimitochondrial antibody, Cholesterol, Bilirubin conjugated, Lipids, Hemoglobin, Bilirubin unconjugated, Rheumatoid factor, etc.

LIMITATIONS

1. This test provides a preliminary diagnosis for SARS-CoV-2 Neutralizing Antibodies. A confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated and verified by other qualified assays.
2. A negative result may be obtained if the specimen is inadequate or SARS-CoV-2 neutralizing antibody concentration is below the limit of detection of the test. Therefore, it is recommended that all negative test results undergo confirmatory testing using other method and/or qualified assays.
3. This test is not intended for donor screening purposes.

CE

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	Storage temperature	LOT	Lot number
IVD	In vitro diagnostic device		Expiry date
	Read instruction before use		Manufacturer
	Protect from light and moisture		Do not reuse

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