SCREEN®

SCREEN TEST COVID-19 NT (Whole Blood/Serum/Plasma) Package Insert

REF: SC-1569-20	English

A rapid test for the qualitative detection of SARS-CoV-2 Neutralization Antibody in human whole blood, serum or plasma specimens.
For professional in vitro diagnostic use only.

INTENDED USE

The SARS-CoV-2 Neutralization Antibody Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay intended for the qualitative detection of neutralization antibodies against SARS-CoV-2 that block the interaction between the receptor binding domain of the viral spike glycoprotein (RBD) with the cell surface receptor ACE2 in human whole blood, serum or plasma. It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2.
Results are for the detection of SARS-CoV-2 neutralization antibodies. Positive results indicate the presence of neutralization antibodies to SARS-CoV-2.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.
All coronaviruses share similarities in the organization and expression of their genome, in which 16 nonstructural proteins (nsp1 through nsp16), encoded by open reading frame (ORF) 1a/b at the 5' end, are followed by the structural proteins spike (S), envelope (E), membrane (M), and nucleocapsid (N), which are encoded by other ORFs at the 3' end.[1]
The virus gains entry to the host cell through binding of the S protein receptor-binding domain (RBD) to the angiotensin-converting enzyme 2 (ACE2) receptor on target cells, particularly respiratory epithelial cells of the host. Upon infection with SARS-CoV-2, the host usually mounts an immune response against the virus by producing different types of antibodies in the blood. A subset of these antibodies, which reduce viral infectivity by binding to the surface epitopes of viral particles and thereby blocking the entry of the virus to an infected cell, are defined as neutralizing antibodies (NAbs).

PRINCIPLE

This test contains two key components: the recombinant SARS-CoV-2 RBD fragment, labeled by colloidal gold, as tracers; and the human ACE2 receptor protein (hACE2), coated with cellulose nitrate membrane. When specimens are added to the sample pad, neutralizing antibodies, if present in the specimen, will bind to the RBD labeled colloidal gold and block the protein-protein interaction between RBD and hACE2. The unbound RBD labeled colloidal gold as well as any RBD labeled colloidal gold bound to non-neutralizing antibody will be captured on the test line. The control line acts as a procedural quality control.

REAGENTS

The test contains recombinant SARS-CoV-2 RBD fragment coated particles as a detection reagent and human ACE2 receptor protein coated with cellulose nitrate membrane as a capture reagent.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
2. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use the test if the pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the collection, handling, storage and disposal of patient samples and the disposal of used kit contents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Wash hands thoroughly after testing.
8. Please ensure that appropriate amounts of samples are used for testing. Too much or too little may lead to deviation of results.
9. The used test should be discarded according to local regulations.
10. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable until the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The SARS-CoV-2 Neutralization Antibody Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma specimen.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 7 days. For long term storage, they should be kept below -20°C. Whole blood specimens should be stored at 2-8°C if the test is to be run within 2 days after collection. Do not freeze whole blood specimens.
- 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 local regulations covering the transportation of etiologic agents.
- EDTA-K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

MATERIALS

Materials Provided

• Test cassettes • Droppers • Buffer • Package Insert

Materials required but not provided

• Centrifuge • Timer
• Specimen collection containers • Pipette

DIRECTIONS FOR USE

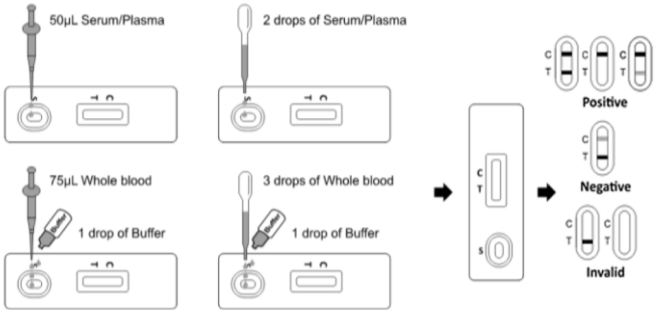
Allow the test, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Take out the test from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test on a flat and clean surface.

For **Serum or Plasma** specimen:
- Use a dropper: Hold the dropper vertically and transfer **2 drops of serum or plasma** (approximately 50μL) to the specimen well (S). Start the timer.
- Use a pipette: Transfer **50μL of serum or plasma** to the specimen well(S), then start the timer.

For **Whole Blood** specimen:
- Use a dropper: Hold the dropper vertically and transfer **3 drops of whole blood** (approximately 75μL) to the specimen well (S). Then add **1 drop of buffer** (approximately 40μL) and start the timer.
- Use a pipette: Transfer **75μL of whole blood** to the specimen well(S), then add **1 drop of buffer** (approximately 40μL) and start the timer.

3. Wait for the colored line(s) to appear. **Read results at 10 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE: One colored line appears in the control region (C) or two colored lines appear, color intensity of test region (T) is equal or weaker than line in control region (C). Positive result indicates the detection of neutralization antibodies against SARS-CoV-2 in the sample.
NEGATIVE: Two colored lines appear. **One colored line should be in the control region (C) and another colored line in the test region (T). The color intensity of test region (T) is stronger than control region (C).**
Negative result indicates the neutralization antibody against SARS-CoV-2 was not in the sample.
INVALID: Control line fails to appear. Insufficient specimen or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The test procedure and the interpretation of test result must be followed closely when testing for the presence of neutralization antibodies against SARS-CoV-2 in human whole blood, serum, or plasma. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The performance of the SARS-CoV-2 Neutralization Antibody Rapid Test (Whole Blood/Serum/Plasma) was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
3. The SARS-CoV-2 Neutralization Antibody Rapid Test (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for detection of neutralization antibodies against SARS-CoV-2 in human whole blood, serum, or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of neutralization antibodies against SARS-CoV-2 can be determined by this qualitative test.
4. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.
5. The test will show negative results under the following conditions: The titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the neutralization antibody against SARS-CoV-2 has not appeared at the time of sample collection.
6. Results from immunosuppressed patients should be interpreted with caution.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The SARS-CoV-2 Neutralization Antibody Rapid Test (Whole Blood/Serum/Plasma) was compared with a leading commercial ELISA; the results were tabulated as below.

Method		ELISA		Total Results
SARS-CoV-2 Neutralization Antibody Rapid Test	Results	Positive	Negative	
	Positive	86	2	88
	Negative	3	128	131
Total Results		89	130	219

Relative Sensitivity: 96.6% (95%CI*: 90.5%-99.3%) *Confidence Interval
Relative Specificity: 98.5% (95%CI*: 94.6%-99.8%)
Accuracy: 97.7% (95%CI*: 94.8%-99.3%)

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of three specimens: negative, 500ng/ml and 1000ng/ml. The negative, 500ng/ml and 1000ng/ml values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same three specimens: negative, 500ng/ml and 1000ng/ml. Three different lots of the SARS-CoV-2 Neutralization Antibody Rapid Test (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, 500ng/ml and 1000ng/ml specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The SARS-CoV-2 Neutralization Antibody Rapid Test (Whole Blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, Anti-Measles, HAMA, RF, non-specific IgG, non-specific IgM, anti-EV71, anti-Parainfluenza virus, HBsAg, anti-Syphilis, anti-H.Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the SARS-CoV-2 Neutralization Antibody Rapid Test (Whole Blood/Serum/Plasma) and no interference was observed.

Triglyceride: 100 mg/dL Ascorbic Acid: 20mg/dL Hemoglobin: 1000mg/dL
Bilirubin: 60mg/dL Total cholesterol: 15mmol/L

BIBLIOGRAPHY

1. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502. PMID:27012512 DOI: 10. 1016/ j. tim. 2016. 03. 003.

INDEX OF SYMBOLS

IVD	For *in vitro* diagnostic use only	Σ	Tests per kit	EC REP	Authorized Representative
2°C 30°C	Store between 2-30°C		Use by		Do not reuse
	Do not use if package is damaged	LOT	Lot Number	REF	Catalog #
	Manufacturer		Consult Instructions For Use		

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