CE

COVID-19 Neutralizing Antibody Rapid Test Kit (Whole Blood/Serum/Plasma) Package Insert

For Medical professional in vitro diagnostic use only.

INTENDED USE

COVID-19 Neutralizing Antibody Rapid Test Kit(Whole Blood/Serum/Plasma) is a lateral flow immunoassay intended for qualitative detection of Neutralizing Antibody in whole blood/serum/plasma specimens from individuals suspected of COVID-19 who have recovered from infection or vaccined.
Results are for the identification of COVID-19 Neutralizing Antibody. Antibody is generally detectable in whole blood/serum/plasma during the acute phase of recovery or after vaccined. Positive results indicate the presence of Neutralizing Antibody.

COVID-19 Neutralizing Antibody Rapid Test Kit(Whole Blood/Serum/Plasma) is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests.

PRINCIPLE

COVID-19 Neutralizing Antibody Rapid Test Kit(Whole Blood/Serum/Plasma) is an immunochromatographic membrane assay that uses recombinant antigen to detect COVID-19 Neutralizing Antibody from whole blood/serum/plasma specimens.
COVID-19 recombinant antigen are immobilized onto the test region of the membrane and combined with other reagents/pads to construct a test strip.
During testing, the specimen reacts with COVID-19 recombinant antigen conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the reagents in test line region. Therefore, if the specimen contains Neutralizing Antibody, a colored line will appear in test line. If the specimen does not contain Neutralizing Antibody, no colored line will appear in the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appeared in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions
Lancet	For fingerstick blood specimens collection
Alcohol pad	For finger disinfection
Dropper	For specimens collection
Sample Solution	Phosphate buffered saline and preservative
Package insert	For operation instruction

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimens collection containerns
- Centrifuge
- Timer

WARNINGS AND PRECAUTIONS

- Do not use after expiration date. Do not use if pouch is damaged or open. Do not reuse the tests.
- Do not mix components from different kit lots. Avoid cross-contamination of specimens by using a new specimens collection container for each specimens obtained.
- 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.
- Humidity and temperature can adversely affect results.
- The sample solution contains a salt solution if the solution contacts the skin or eyes, flush with copious amounts of water.
- Discard the using testing materials in accordance with local regulations.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

Store unused test devices unopened at 4°C-30°C. If stored at 4°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

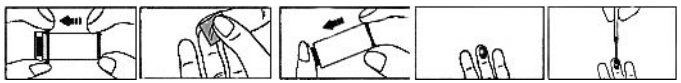
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Venous blood:
Collect venous blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer) by veinpuncture.

Plasma
Collect venous blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer) by veinpuncture. Separate the plasma by centrifuge. Carefully withdraw the plasma into new pre-labeled tube.

Serum
Collect venous blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer) by veinpuncture. Allow the blood to clot. Separate the serum by centrifuge. Carefully withdraw the serum into a new pre-labeled tube.

Fingerstick blood:
Wash hands with soap, disinfect the finger tip with alcohol pad, then dip the finger tip with lancet,collect blood specimen with the dropper.

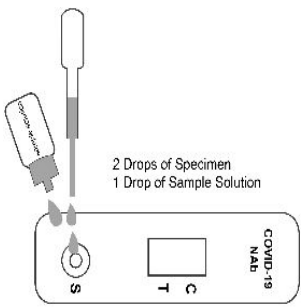


Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately up to 5 days. The specimens should be frozen at -20°C for longer storage except whole blood specimen.
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifuge before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

ASSAY PROCEDURE

- Bring the specimen and test components to room temperature. Mix the specimen well prior to assay once thawed. Place the test device on a clean, flat surface.
- Fill the dropper with the specimen then vertically add 2 drops (about 25 µL) of specimen into the sample well. Then add 1 drop (about 30 µL) of sample solution immediately into the sample well. Making sure that there are no air bubbles.
- Set up a timer. Read the result at 10 minutes.

Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.



INTERPRETATION OF ASSAY RESULT

POSITIVE RESULT:

A colored line appears in the control line region (C) and a colored line appears in test line region(T).

***NOTE:** The intensity of the color in the test line region will vary depending on the concentration of COVID-19 Neutralizing Antibody in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE RESULT:

A colored line appears in the control line region (C) and no line appears in test line region(T).

INVALID RESULT:

No line appears in control line region(C). Insufficient volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C band. The C line develops after adding sample solution. Otherwise, review the whole procedure and repeat test with a new device.
2. **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative to assure the proper performing of the assay.

PERFORMANCE CHARACTERISTICS

1. Clinical study: A side-by-side comparison was conducted (used sample matrix: whole blood/serum/plasma samples) using the research reagent and referencing reagent. Compare with LFIA:

		LFIA result		Total
		Positive	Negative	
Safecare Test	Positive	422	1	423
	Negative	3	412	415
Total		425	413	838
Relative Sensitivity		99.29% (97.95%～99.85%)		
Relative Specificity		99.76% (98.66%～99.99%)		
Overall Agreement		99.52% (98.78%～99.87%)		

2. Cross-reactivity: Cross-reactivity studies are performed to demonstrate that the test does not react with the following antibody to microorganisms in the table below.

Cross-Reactant	
Adenovirus	Candida albicans
Human metapneumovirus (hMPV)	Staphylococcus aureus
Rhinovirus	Mycobacterium tuberculosis
Enterovirus	Streptococcus pyogenes
Human coronavirus OC43	Streptococcus pneumoniae
Human coronavirus 229E	Mycoplasma pneumoniae
Human coronavirus NL63	Legionella pnuemophila
Human parainfluenza virus 1	Haemophilus influenzae
Human parainfluenza virus 2	Chlamydia pneumoniae
Human parainfluenza virus 3	Bordetella pertussis
Human parainfluenza virus 4	Respiratory Syncytial Virus
Influenza A	HCV
MERS	HBV
Influenza B	HIV

3. Interference: The following endogenous interference substances were evaluated at the concentrations listed and no effect was found.

Interfering substances	Concentration	Interfering substances	Concentration
Histamine hydrochloride	1µg/mL	Total IgM	50µg/mL
Cefatriaxone	1mg/mL	Purified mucin	1µg/mL
Meropenem	100mg/mL	Phenylephrine	1µg/mL
Sodium chloride (with preservative)	1mg/mL	Oxazole	1µg/mL
Dexamethasone	1.53µmolL	Beclomethasone	1µg/mL
Azithromycin	15.3µmolL	Fluorinone	1µg/mL
Tobramycin	25.7µmolL	Triamcinolone acetonide	1µg/mL
EDTA	3.4µmol/L	Budesonide	1µg/mL
citrate	1µg/mL	Amethasone	1µg/mL
heparin	3000U/L	Fluticasone	1µg/mL
Hemoglobin	2g/L	Lopinavir	1µg/mL
bilirubin	342µmol/L	Ritonavir	1µg/mL
proteins	60g/L	Zana Mi Vee	1µg/mL
triglycerides	37mmol/L	Ribavirin	1µg/mL
HAMA	10µg/mL	Osteltamivir	1µg/mL
Total IgG	50µg/mL	Pa Rami Vee	1µg/mL

LIMITATIONS OF TEST

1.For professional in vitro diagnostic use and should be only for the detection of COVID-19 neutralizing antibody. not for any other viruses or pathogens.
2. Test performance depends on the amount of antibody in the sample and may or may not correlate with viral culture results performed on the same sample.
3.The performance was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4.A negative test result may occur if the COVID-19 protective antibody titer in the sample is below the minimum detection limit of the kit, or the COVID-19 protective antibody has not appeared at the time of sample collection.
5.Negative results do not rule out SARS-COV-2 infection, particularly those who have been in contact with the virus. Direct testing with a molecular diagnostic should be performed to evaluate for acute SARS-CoV-2 infection in symptomatic individuals.
6.False negative results may occur if a specimen is improperly collected, transported, or handled.
7.Positive results may be due to current or past infection with non-SARS-COV-2 corona virus strains, such as HKU1, NL63, OC43, or 229E.
8.A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
9.Results from this test should not be used to diagnose or to exclude acute SARS-COV-2 infection or to inform infection status.
10.It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.

INDEX OF SYMBOLS

	Do not reuse	IVD	For in vitro diagnostic use only
4℃ 30℃	Stored between 4-30℃		Consult instruction for use
	Date of Manufacture	LOT	Lot number
	Use-by date	Σ	Contains sufficient for <n> tests
	Manufacturer	EC REP	Authorized Representative in the European Community

Safecare Biotech(Hangzhou) Co., Ltd.
Building 2/203, No.18 Haishu Rd, Cangqian
Sub-district, Yuhang District Hangzhou, 311121, China

EC REP NIC GmbH
Erlenweg 13, 49076 Osnabrück, Germany

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