SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood)

Package Insert

For Self-testing

REF ICSG-402H	English

【INTENDED USE】

The SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood) is a rapid chromatographic immunoassay intended for the qualitative detection of IgG antibodies to SARS-CoV-2 spike (S) protein receptor binding domain (RBD) in human Fingerstick Whole Blood approximately 10 days after vaccination. 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 S-RBD IgG antibodies. Positive results indicate the presence of IgG antibodies to SARS-CoV-2.

【MATERIALS PROVIDED】

- Test Cassette（Each test cassette is sealed in foil pouch with a desiccant）
- Package Insert
- Buffer
- Alcohol Pad
- Sterile Lancet
- Dropper
- Biosafety bag (Optional)

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Timer

【STORAGE】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). **DO NOT FREEZE.**

Do not use the kit after expiration date printed on the test pouch.

Do not open the foil pouch until you are ready to use the test.

Test cassette should be used within 1 hour after opening.

【TESTING】

Before testing:

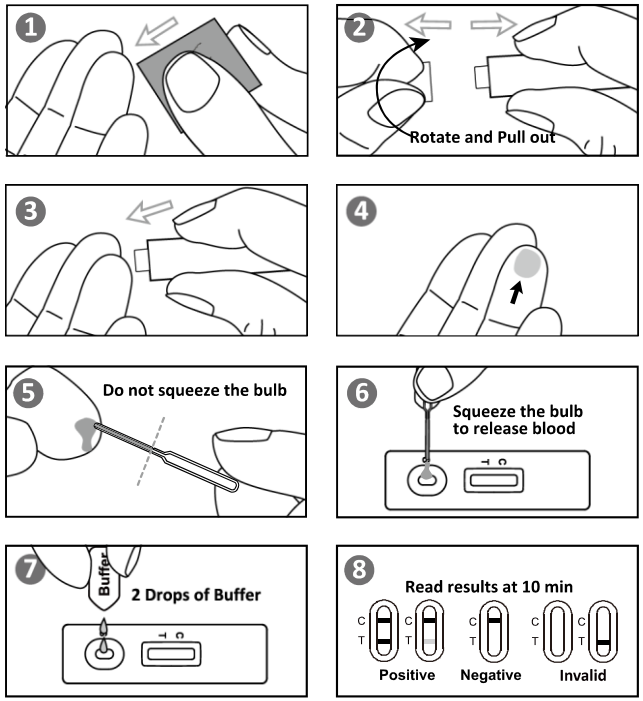
Allow the test and buffer to room temperature (15-30°C) before testing.

Wash hands thoroughly in warm water and dry.

Take out the test cassette from the foil pouch and use it within 1 hour. Do not touch the test reaction area (strip area beside to C, T, S) of the test strip. Best results will be obtained if the assay is performed immediately after opening.

Place the test on a flat and clean surface.

1. Use alcohol pad to clean the fingertip of the middle finger or ring finger as the puncture site. Let it dry for 10 seconds.
2. Carefully rotate and pull off the lancet cap. Only open the lancet before testing.
3. Press the sterile lancet firmly against the fingertip of the middle finger or ring finger.
4. To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site.
5. Without squeezing the capillary dropper bulb, put it in contact with the blood. The blood migrates into the capillary dropper to the line indicated on the capillary dropper.
   You may massage again your finger to obtain more blood if the line is not reached.
   Avoid air bubbles, discard the blood into a plastic bag (e.g., biosafety bag) if air bubbles happen, and repeat above collecting steps.
6. Squeeze the dropper bulb to release the blood to the specimen well(S) immediately after collection.
7. Add **2 drops of buffer** to the Specimen well(S) and start the timer. Do not move the test during test developing.
8. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.

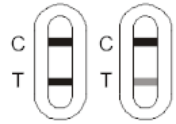


Note: After test is completed, thoroughly clean the surface of testing.

Do not reuse any used components of the kit.

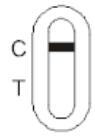
Place all the used components of the test kit into the plastic bag (e.g., biosafety bag) and tightly seal it., then dispose according to local regulation.

【READ RESULTS】



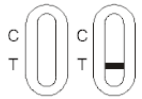
POSITIVE:* Two colored lines appear. One colored line in the control region (C) and another colored line in the test region (T). Positive result in the test region indicates there is SARS-CoV-2 S-RBD IgG detected in the sample.

***NOTE**: The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 S-RBD IgG present in the sample. So any shade of color in the test region (T) should be considered positive.



NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test line region (T).

Negative result means SARS-CoV-2 S-RBD IgG Antibody is not detected in the sample.



INVALID: Control line fails to appear. Insufficient specimen volume 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 with your healthcare provider.

【Q&A】

1. **How can I know my test is working well?**
   If your test is working well, you will see a line in the control line area(C) on the test cassette. If there is no line in the control line area, your test did not work and the test result is invalid.
2. **When is the best time to run the test?**
   Test can be done at any time of the day.
3. **How soon can I read my results?**
   You can read your results at 10 minutes after sample and buffer adding, do not read result after 20 minutes.
4. **Can the result be wrong? Are there any factors that can affect the test result?**
   The results will only give accurate results as far as the fresh fingerstick whole blood used and followed the instructions carefully. Nevertheless, the result can be incorrect. Non-SARS-CoV-2 coronavirus strains or other interference factors may cause a preliminary Positive Result.
5. **How to read the test if the color and the intensity of the lines are different?**
   The color and intensity of the lines have no importance for result interpretation. The test should be considered as Positive whatever the color intensity of the test line (T) is.
6. **What should I do if the test result is positive but I was not vaccinated?**
   If your test result is positive but you were not vaccinated, you should isolate yourself and contact with your local healthcare provider to perform PCR test in case of COVID-19.
7. **What should I do if the test result is negative but I was vaccinated?**
   If you were vaccinated and the test result is negative, it may because the antibody level is below the detection level or no SARS-CoV-2 S-RBD IgG antibody detected; it is recommended to run a new test several days later. If the test result is still negative, contact with your healthcare provider.

【PRINCIPLE】

The SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood) is a qualitative membrane-based immunoassay intended to detect IgG antibodies to SARS-CoV-2 spike (S) protein receptor binding domain (RBD) in fingerstick whole blood.

【REAGENTS】

The test contains recombinant SARS-CoV-2 RBD fragment and anti-human IgG antibodies.

【SUMMARY】

Coronaviruses infect many species of animals including humans, causing acute and chronic diseases.[1] 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.[2] 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.

【WARNINGS】

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 self-testing *in vitro* diagnostic use only.
3. Keep out the reach of children. Test for children and young people should be used with an adult.
4. Do not eat, drink or smoke in the area where the specimens or kits are handled.
5. Do not use the test if the pouch is damaged.
6. Wash hands thoroughly before testing.
7. Please ensure that appropriate amounts of samples are used for testing. Too much or too little may lead to deviation of results.
8. Do not touch the test reaction area of the test strip.
9. The used test should be disposed of according to local regulations. Do not reuse any components of the kit.
10. Do not drink the buffer in the kit. Handle the buffer carefully and avoid contact with skin or eyes; if in contact, rinse immediately with running water.
11. The SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood) is only used for people who had been COVID-19 vaccinated.

【LIMITATIONS】

1. Failure to follow the testing steps may give inaccurate results.
2. The SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood) is for self-testing *in vitro* diagnostic use only. This test should be used for detection of IgG antibodies to SARS-CoV-2 spike (S) protein receptor binding domain (RBD) in fingerstick whole blood specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG antibodies to SARS-CoV-2 spike (S) protein receptor binding domain (RBD) can be determined by this test.
3. 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 novel coronavirus antibody has not appeared at the time of sample collection. It is recommended to retest with a new test a few days later.
4. Negative S-RBD IgG Antibody result does not mean no COVID-19 protection.
5. The continued presence or absence of antibodies cannot be used to determine the success or failure of a certain therapy.
6. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains or other interference factors and/ or past or present infection with SARS-CoV-2.
7. Not for the screening of donated blood.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

Study A: A clinical evaluation was conducted from vaccinated people, unvaccinated and uninfected people, comparing the results obtained using the SARS-CoV-2 S-RBD IgG Antibody Rapid Test with SARS-CoV-2 Antibody CLIA test results.

	CLIA confirmed sample number	Correct identified	Rate	95%CI (Confidence interval)
Positive sample	283	276	97.5% (Sensitivity)	95.0%-99.0%
Negative sample	154	153	99.4% (Specificity)	96.4%-99.9%
total	437	429	98.2% (Total Accuracy)	96.4%-99.2%

The clinical trial included 437 specimens. The results demonstrated 99.4% specificity and 97.5% sensitivity with an overall accuracy of 98.2%.

Study B: Clinical specificity was evaluated by testing 320 presumed SARS-CoV-2 negative samples from blood donors collected prior to the COVID-19 outbreak. The following table describes negative percent agreement (NPA).318 samples were negative. The NPA of the SARS-CoV-2 S-RBD IgG Antibody Rapid Test was 99.4%.

	Positive	Negative	NPA	95%CI (Confidence interval)
Apparently Healthy	2	318	99.4%	97.8%-99.9%

Cross-reactivity

The SARS-CoV-2 S-RBD IgG Antibody Rapid Test has been tested for anti-HCoV 229E, anti-HCoV NL63, anti-HCoV OC43, anti-HCoV HKU1, anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, Anti-Measles, HAMA, RF, non-specific IgG, anti-EV71, anti-Parainfluenza virus, HBsAg, anti-Syphilis, anti-H.Pylori, anti-HIV, anti-HCV and Anti-ANA positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the SARS-CoV-2 S-RBD IgG Antibody Rapid Test and no interference was observed.

Substance	Conc.	Substance	Conc.
Triglyceride	100mg/dL	HAMA	1mg/mL
Ascorbic Acid	20mg/dL	Ribavirin	40mg/L
Hemoglobin	1000mg/dL	Oseltamivir	30mg/L
Bilirubin	60mg/dL	Levofloxacin	200mg/L
Total cholesterol	15mmol/L	Azithromycin	100mg/L
Biotin	1000mg/dL	Cefuroxime axetil	250mg/L
Paracetamol	500mg/L	Ibuprofen	1.44mg/mL
Aspirin	500mg/L	Acarbose	300mg/L
Repaglinide	1mg/mL	Valsartan	90mg/L
Candesartan cilexetil	50mg/L	Ibuprofen and codeine	200mg/L
Total IgG	16g/L	Total IgM	2.3g/L
Total IgA	50g/L	Pregnant women blood	/

【REFERENCES】

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164. PMID:22094080 DOI:10.1016/B978-0-12-385885-6.00009-2
2. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology 2016; 24:490-502. PMID:27012512DOI:10.1016/j.tim. 2016.03.003

【INDEX OF SYMBOLS】

IVD	*In vitro* diagnostic medical device	Σ	Tests per kit	EC REP	Authorized Representative in EU
30°C 2°C	Temperature limit 2-30°C		Use by		Do not reuse
	Do not use if package is damaged	LOT	Batch code	REF	Catalog #
	Manufacturer		Consult Instructions For Use	CE 1434	CE mark

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street,
Hangzhou Economic & Technological Development Area,
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

EC REP
MedNet GmbH
Borkstrasse 10
48163 Muenster Germany

CE 1434

Number: 146555900
Effective date:

Statement: Information about manufacturer of lancet and alcohol pad is placed on the packaging.