SARS-CoV-2 S Antibody Test (Fluorescence Immunochromatography)

【Instructions for Use】

For in vitro diagnostic use only
Store at 2°C-30°C

IVD

1. INTENDED USE

The SARS-CoV-2 S Antibody Test is a single-use rapid immunochromatographic test for the qualitative and semi-quantitative detection in human serum, heparin plasma, EDTA plasma, citrate plasma, and whole blood. The SARS-CoV-2 S Antibody Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The SARS-CoV-2 S Antibody Test should not be used to diagnose acute SARS-CoV-2 infection.

Results are for the detection of SARS-CoV-2 antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time 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 SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for SARS-CoV-2 S Antibody Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second assay.

The SARS-CoV-2 S Antibody Test is for in vitro diagnostic use only.

2. TEST PRINCIPLE

The SARS-CoV-2 S Antibody Test is based on the immunochromatographic method. The SARS-CoV-2 antibody in the sample forms a complex with SARS-CoV-2 S-RBD-specific recombinant antigen labeled with fluorescent particles. This complex migrates along the membrane and reaches the test region (T-line) on which the antigen against the SARS-CoV-2 S antibody is applied. Unbound fluorescent particles migrate along the membrane to the control region (C-line) and are bound by the control region antibody. The fluorescence signal intensity can be detected and analyzed by BOH-180 Fluorescent Immunoassay Analyzer. The analyzer converts the fluorescence signals into corresponding concentrations.

3. KIT COMPONENTS

#	Item	Description
1	Instructions for Use	1 piece
2	Test Cassette	25 cassettes
3	Buffer	25 vials (2 mL of buffer)
4	Dropper	25 droppers with line
5	Safety Lancet	25 pieces
6	Alcohol pad	26 pieces

4. WARNINGS AND PRECAUTIONS

4.1. Samples for human serum, plasma or whole blood should be considered as potentially infectious. Operators should wear protective clothing, masks, gloves and take other appropriate safety precautions to avoid or reduce the risk of infection.

4.2. This test should be performed at 18 to 30°C (64 to 86°F). If stored refrigerated, ensure that the pouch and buffer are brought to operating temperature before performing testing.

4.3. Follow the instructions for use carefully. Reliability of assay results cannot be guaranteed if there is any deviation from the instructions in this package insert.

4.4. Professionals must handle the potentially contaminated materials safely according to local requirements.

4.5. Do not smoke, drink, eat, or use cosmetics in the working area. Wear Personal Protective Equipment (PPE) and disposable gloves when working with samples and reagents. Wash hands after operations.

4.6. Wipe and wash any splashed sample with highly effective disinfectant. Avoid splashing and the formation of aerosols.

4.7. Use a new clean disposable sample dispensing plastic dropper or tip for every sample to avoid cross contamination.

4.8. Decontaminate and dispose of all samples, reaction kits, and potentially contaminated materials as if they were infectious waste, in a biohazard waste container.

4.9. Use the unpacked Cassette as soon as possible to avoid being humidified. The Cassette is sensitive to humidity as well as to heat.

4.10. Do not use the Cassette beyond the labelled expiry date indicated on the outer container.

4.11. Do not use the Cassette if the pouch is damaged or the seal is broken.

4.12. The Cassette cannot be reused.

5. STORAGE CONDITIONS AND SHELF LIFE

The test card is stored at 2°C-30°C and the shelf life is 18 months. The test card sealed inside the aluminium foil bag shall be used within 1 hour after opening.

6. APPLICABLE INSTRUMENT

BOH-180 Fluorescent Immunoassay Analyzer produced by Biohit Healthcare (Hefei) Co., Ltd.

7. SAMPLE REQUIREMENTS

7.1. Applicable to human serum, heparin plasma, EDTA plasma, citrate plasma, and whole blood samples.

7.2. For whole blood sampling, it is recommended to use a safety lancet for pricking a fingertip. After puncturing the skin, use a clean gauze to wipe away the first drop of blood to avoid specimen dilution with interstitial fluid. With the patient's hand pointing downward, firmly grasp the finger towards the base with your thumb placed along the length of the patient's finger. Gently massage along the length of the finger towards the tip, using a light squeeze-and-release motion to allow large droplets of blood to form and encourage continuous blood flow. If using a capillary tube or pipette, allow a large drop of blood to form, position the device horizontally, and lightly touch the drop of blood (avoid touching the skin); allow the blood drop to be drawn into the collection vessel by capillary action (avoid air bubbles).

7.3. For serum and heparin plasma, EDTA plasma, or Citrate plasma samples, the samples should be tested immediately after collection. Serum and heparin plasma, EDTA plasma or Citrate plasma samples can be stored for 5 days at 2-8°C. If long-term storage is required, it should be stored at -20°C (It has been confirmed that the sample can be stored for 3 months at -20°C). Serum or plasma specimens can be subjected to a maximum of 3 freezing/ thawing cycles.

7.4. Let the samples reach room temperature and mix well before testing. When there are visible particles in the sample, it should be centrifuged before the test to remove the precipitate.

7.5. If there is a lot of lipid (Triglyceride concentration over 37 mmol/L), hemolysis or turbidity in the sample, please do not use the sample to avoid affecting the result interpretation.

8. MATERIALS REQUIRED BUT NOT PROVIDED

- 10-100 µL Pipette and Tips
- Test Tubes
- Sample Collection Tubes
- Timer
- Quality Control

9. TEST PROCEDURES

Step 1: Tear the aluminium foil bag to open, take out the test cassette and place it on the horizontal surface.

Step 2: For serum or plasma specimen, pipette 10 µL to the buffer vial pre-filled with 2 ml buffer; for fingertip blood, collect fingerstick whole blood specimen to the indicated fill line and squeeze the dropper to transfer 1 drop (20 µL) to the buffer vial.

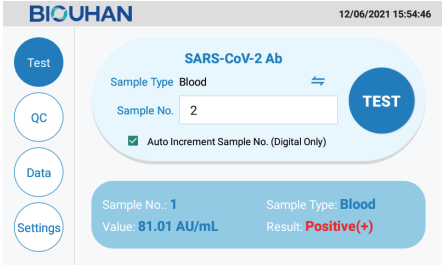
Step 3: Mix the specimen in the buffer thoroughly and then apply 2 drops of the solution to the sample well on the side near the result window.

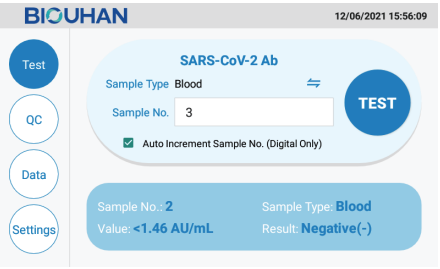
Step 4: After 15 minutes, insert the test cassette into the cassette slot of BOH-180. Press Test, and BOH-180 will automatically run test and generate test results.

10. INTERPRETATION OF THE RESULTS

10.1. The analyzer converts the fluorescence signals into corresponding concentrations. Concentration higher than or equal to 1.46 AU/mL indicates SARS-CoV-2 S antibody positive while concentration lower than 1.46 AU/mL indicates SARS-CoV-2 S antibody negative. If the chromatography is not successful and the analyzer gives "Result: Failure", it indicates that the test fails and the sample needs to be retested with a new test cassette.

10.2. Due to the complex structure of bioactive substances in samples and the difference of antigen antibody specificity, the possibility of false positive results cannot be completely ruled out when using this kit. If the test results are inconsistent with the clinical indications, other appropriate test methods should be used for confirmation.





11. LIMITATION OF THE PROCEDURES

11.1. This test can only be used for the analysis of serum, heparin plasma, EDTA plasma, citrate plasma, and whole blood samples.

11.2. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. the sensitivity of the SARS-CoV-2 S Antibody Test early after infection is unknown. False positive results for antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

11.3. A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or if the virus has undergone minor amino acid mutation (s) in the epitope recognized by the antibody used in the test.

11.4. 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 an alternative serology test to confirm an immune response.

11.5. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

11.6. This test is not to be used for screening donated blood.

12. PERFORMANCE CHARACTERISTICS

Limit of Blank

Test five serum samples in 4 replicates for each, and the LOB is 0.67 AU/mL.

Limit of Detection

Test samples of 1-5×LoB in 4 replicates, and the LoD is 1.46 AU/mL.

Linear range

In the concentration range of 1.46 AU/mL-367.75 AU/mL, the correlation coefficient (r) is not less than 0.990.

Accuracy

Recovery test is used to evaluate the accuracy of the kit. The recovery rate is in the range of 85.0%～115.0%.

Precision

CVs of intra-assay, inter-assay, intra-day, inter-day, different operators and different labs variation studies are not higher than 15%.

Cross-reactivity

Cross-reactivity was evaluated by testing possible cross-reacting substances as listed in below table. Potential cross-reacting substances were tested. None of the substances tested interfered with SARS-CoV-2 S Antibody Test performance by generating false positive results.

No.	Potential interferent
1	Anti-influenza A (IgG and IgM)
2	Anti- influenza B (IgG and IgM)
3	Anti-HCV
4	Anti-HBV (Anti-HBs, Anti-HBe, Anti-HBc)
5	ANA

6	Anti-respiratory syncytial virus (IgG and IgM)
7	Anti-Haemophilus influenzae (IgG and IgM)
8	Anti-229E (alpha coronavirus) IgG
9	Anti-NL63 (alpha coronavirus) IgG
10	Anti-OC43 (beta coronavirus) IgG
11	Anti-HKU1 (beta coronavirus) IgG
12	Anti-acute bacterial pneumonia (IgG and IgM)

Endogenous/exogenous interference

Sample diluent, SARS-CoV-2 S antibody positive serum, plasma and whole blood samples and SARS-CoV-2 S antibody negative serum, plasma and whole blood samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positive or false negative result was found with the following.

Purified mucin	60 g/L
Bilirubin	342 μmol/L
Triglyceride	37 mmol/L
Hemoglobin	2 g/L
Rheumatoid factor	30 IU/mL
HAMA	25 mg/mL
α - interferon	40 ng/mL
Zanamivir	10 μg/L
Ribavirin	20 mg/mL
Oseltamivir	250 μg/L
Peramivir	30 mg/L
Lopinavir	12 mg/L
Ritonavir	12.5 mg/L
Abidor	10 μg/mL
Levofloxacin	25 mg/L
Azithromycin	25 mg/mL
Ceftriaxone	10 μg/mL
Meropenem	3.3 mg/mL
Tobramycin	125 mg/L
Histamine hydrochloride	50 mg/L
acetylsalicylic acid	50 mg/L
Paracetamol	20 mg/L
Ibuprofen	40 mg/L

Hook Effect

No high dose Hook effect was observed when tested with Anti-SARS-CoV-2 S antibody sample at a concentration of 1000 AU /mL.

Clinical Evaluation

The clinical performance of the SARS-CoV-2 S Antibody Test was evaluated in a retrospective study testing 309 samples collected from SARS-CoV-2 RT-PCR positive and negative individuals as indicated below. All samples were randomized. A sensitivity of 96.33% and a specificity of 99.50% were determined for the SARS-CoV-2 S Antibody Test.

Positive Percent Agreement (PPA) The PPA was determined by testing 109 subjects hospitalized for COVID-19 infection or suspected of COVID-19 and confirmed positive in a SARS-CoV-2 RT-PCR test. All samples were collected from symptoms onset ⩾15 days.

Negative Percent Agreement (NPA) The NPA was determined by testing 200 subjects who were SARS-CoV-2 negative based on a RT-PCR test.

		PCR results	
		Positive	Negative
SARS-CoV-2 S Antibody Test	Positive	105	1
	Negative	4	199
	Total	109	200
Sensitivity		96.33% (95CI:90.87%-98.99%)	
Specificity		99.50% (95CI: 97.25%-99.99%)	

13. PROCEDURAL NOTES

13.1. Read this manual carefully before using this test.
13.2. This test needs to be conducted in a laboratory under proper testing conditions. All samples and materials in the testing process should be handled according to the operational specifications of an infectious disease laboratory.
13.3. Protect the test cassette from moisture.
13.4. All reagents and samples should reach room temperature (18-30°C) before use.
13.5. Do not use lipemic samples.
13.6. Do not use hemolytic samples.
13.7. Do not use turbid or contaminated samples.
13.8. Do not dilute the sample before testing.
13.9. Do not store this kit in a frozen condition.
13.10. The interpretation of the test results must be carried out in strict accordance with this manual.
13.11. Use of this test kit is limited to qualitative and semi-quantitative detection of SARS-CoV-2 antibody in human serum, heparin plasma, EDTA plasma, Citrate plasma or whole blood.
13.12. False negative results will be caused when the antibody titer in the sample is lower than the minimum detection limit of the test or when the antibody does not appear at the time of sample collection.

14. DATE OF ISSUE

SARS-CoV-2 S antibody Test (Fluorescence Immunochromatography) insert.
Version 1.2, December 10, 2021

15. EXPLANATION OF THE SYMBOLS USED

IVD	For in vitro Diagnostic Use
REF	Catalogue Number
LOT	Batch Code
	Manufacturer
	Date of Manufacture
	Use by
	Do Not Use if Package is Damaged
	Consult Instruction for Use
2°C 30°C	Temperature Limit at 2°C~30°C
Σ	Sufficient for use
	Do Not Re-use
	Caution
	Keep Dry

16. GENERAL INFORMATION

Manufacturer

Biohit Healthcare (Hefei) Co., Ltd.
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