



SsmarTest

COVID19 Neutralizing Ab Test

Catalogue number: SLS-006

Panel: Immunology

1. About SsmarTest COVID19 Neutralizing Ab Test

1 What is SsmarTest COVID19 Neutralizing Ab Test?

SsmarTestCOVID19 Neutralizing Ab Test is a rapid chromatographic immunoassay for the qualitative detection of neutralizing antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of the presence of neutralizing antibodies.

2 Specification

Detection Target	Specific antibodies to SARS-CoV-2 S Protein
Detection Technology	Antibody test with immunochromatography assay (ICA)
Specimen Type	Human blood (serum, plasma or whole blood)
Test Time	10 to 15 minutes

3 Highlights

- Test the presence of SARS-CoV-2 S protein antibodies after 2 weeks from vaccination.
- Simple and easy test procedure.
- Test result within 15 minutes.

4 Kit Contents

- [1] Test Device
- [2] Spit
- [3] Running Solution
- [4] Information for Use

5 Clinical and analytical performance

Sensitivity/Specificity (after 2 weeks from vaccination)

Sensitivity: 93.94 % (95% CI of 80.39-98.32%)

Specificity: 96.67 % (95% CI of 83.33-99.41%)

Cross reactivity

As a result of testing with serum and plasma samples containing the pathogens (HIV, HBV, HCV, RSV, influenza A/B, enterovirus 71), no false negative or false positive results were found.

Interference

There were no false-negative or false-positive results in the tests using the following substances: hemoglobin, EDTA, HAMA, human IgG, human IgM, HSA)



[4]



[2]



[3]



[1]



2. Specimen Collection Procedure

Sample Collection

Blood collection; must use sterile vacutainer or syringe needle.

Place blood immediately in blood collection tube and invert for the anticoagulants mixing.

Transport

If specimen cannot be shipped within 24 hours of collection, separate serum or plasma and store at 4°C or below.

Analysis

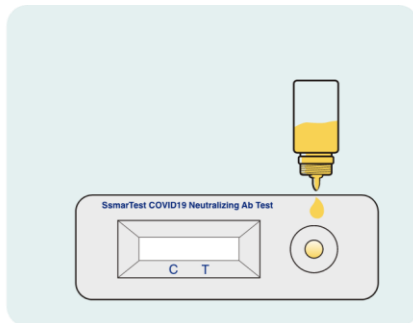
Use by doctor, nurse or medical laboratory technician.
Test with the user manual.

Interpretation

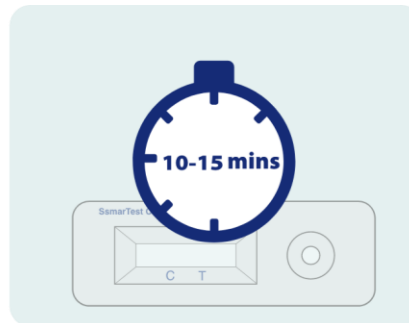
The test results must be interpreted with the user manual.
The test results are used in conjunction with other laboratory tests.

3. Reference Negative Sample Preparation

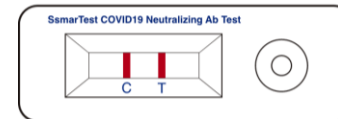
1) Add 2 drops of running solution



2) Reference line appears in 10~15 minutes

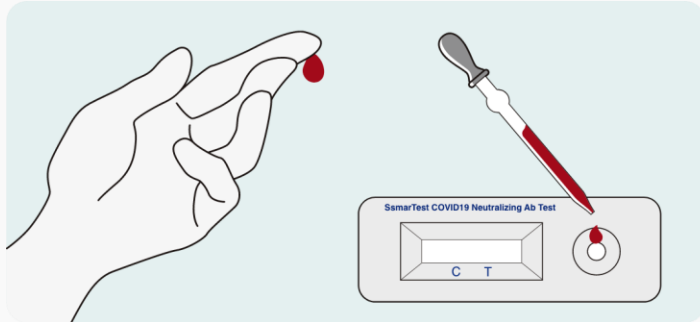


3) Reference line after 10~15 minutes

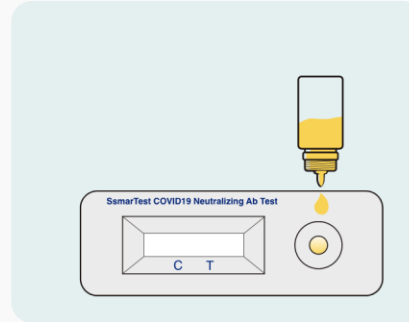


4. Test Method

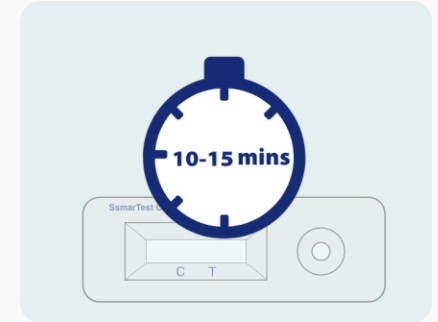
1) Add 1 drop of specimen (whole blood, serum or plasma)



2) Add 1 drop of running solution



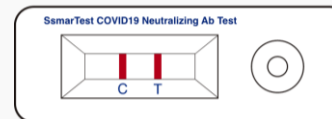
3) Read results in 15 minutes and it should not exceed 20 minutes.



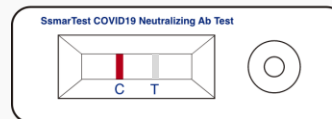
5. Result Interpretation

- 1) The test results should be read and interpreted between 10 to 15 minutes after the sample application and it should not exceed 20 minutes.
- 2) A clear red line must appear on the control line (C) in all tests. If not, re-inspection shall be performed.
- 3) Compared to the Reference Negative Sample T-line, the lighter T-line interpreted as positive. The same or less pink T-line interpreted as negative.
- 4) Positive means Neutralizing Antibody detected in the body.

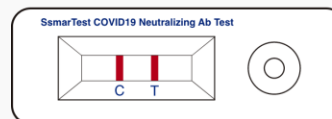
Reference Negative Sample



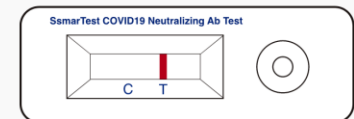
Positive



Negative



Invalid 1



Invalid 2

