SsmarTest COVID19 neutralizing Ab Test

INTENDEN USE

SsmarTest COVID19 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.

PRINCIPLES

SsmarTest COVID19 neutralizing Ab Test is a qualitative membrane based immunoassay for the detection of neutralizing antibodies to SARS-CoV-2 in whole blood, serum or plasma. The membrane is pre-coated with Angiotensin I Converting Enzyme 2 (ACE2) on the test line region of the strip. During testing, the neutralizing antibody in specimen reacts with S-RBD conjugated colloid gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with ACE2 on the membrane and generate a colored line. Presence of this colored line indicates a negative result, while its absence indicates a positive result.

SPECIMEN COLLECTION

SsmarTest COVID19 neutralizing Ab Test can be performed using whole blood, serum, or plasma. Whole blood or plasma could be collected with tube containing Heparin or Citrate.

TESTING PROCEDURE

1. Allow the test Device, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.
2. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it within one hour. Place the test Device on a clean and level surface.
3. For Serum or Plasma:
   Hold the dropper vertically and transfer 1 drop of serum/plasma (approximately 25µl) to the specimen well (S) of the test Device, then add 1 drop of buffer (approximately 40µl) and start the timer.
   For Whole Blood Specimens:
   Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50µl) to the specimen well (S) of the test Device, then add 1 drop of buffer (approximately 40µl) and start the timer.
4. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after.

INTERPRETATION OF RESULT

NEGATIVE:

The colored line in the control line region (C) appears and other colored lines should appear in test line region (T).

POSITIVE:

The colored line in the control line region (C) changes appears. No line appears in test line region (T).

INVALID:

Control line (C) fails to completely colored line. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure.

ANALYTICAL PERFORMANCE

Cross reactivity

A total of 96 samples of 17 pathogens without anti-SARS-CoV-2 were tested to evaluate cross-reactivity.

These results are confirming that there are no false negative or false positive results and no crossreactivity between antibody of 17 pathogens and neutralizing antibody to SARS-CoV-2.

List of pathogens samples from patient serum or plasma

No	Name of cross reactants	Number of sample
1	Human Immunodeficiency Virus 1/2	10 serums
2	Hepatitis B Virus	10 serums
3	Hepatitis C Virus	10 serums
4	Influenza A Virus	5 serums
5	Influenza B Virus	5 serums
6	Parainfluenza 1-4	10 serums
7	Enterovirus 71	5 serums
8	Chlamydia pneumonia	5 serums
9	Respiratory syncytial virus	5 serums
10	MERS	2 serums
11	Coronavirus HKU1	3 serums
12	Coronavirus OC43	3 serums
13	Antinuclear antibodies (ANA)	5 serums
14	Haemophilus influenza	1 serums , 2 plasmas
15	Rhinovivirus	5 serums
16	Rheumatoid Arthritis	5 serums
17	human metapneumovirus	5 serums

Interference

Ten types of interfering substances were prepared using stock solution, and then diluted to the negative and positive standard materials with their respective test concentrations to prepare working test materials. No substances showed any interference with the test. There were no differences observed between the results at 10 minutes.

Preparing the interfering substance

No	Interfering substances	Usage concentration	Stock Solution
1	Human serum albumin	60 ㎎/㎖	30% albumin solution
2	Bilirubin conjugated	0.4 ㎎/㎖	50 ㎎/㎖ stock
3	EDTA	1 ㎎/㎗	0.1 ㎎/㎖ stock
4	Human IgM	800 ㎎/㎗	2 ㎎/㎖ stock
5	Human IgG	200 ㎎/㎗	80 ㎎/㎖ stock
6	Cholesterol	4 ㎎/㎖	52.1 ㎎/㎖ stock
7	Histamine hydrochloride	4 ㎎/L	1g/㎖ stock
8	Hemoglobin	10 ㎎/㎖	20 ㎎/㎖ stock
9	Human Anti-mouse Antibody (HAMA)	800 ng/㎖	600 ng/㎖
10	Rheumatoid factor	2000 IU/㎖	20,000 IU/㎖ stock

CLINICAL PERFORMANCE

Thirty-three samples confirmed positive for neutralization antibody with Plaque Reduction Neutralizing antibody Assay (PRNT assay) from convalescent patients were evaluated with the SsmarTest COVID19 Neutralizing Antibody Test. Forty samples confirmed negative for neutralization antibody with RT-PCR Assay from the healthy population were evaluated with the SsmarTest COVID19 Neutralizing Antibody Test. Seventy-three samples in total were performed SsmarTest COVID19 Neutralizing Antibody Test, the relative sensitivity is 91.0 % and the relative specificity is about 100.0 %.

SsmarTest COVID-19 Neutralizing Ab Test	Comparator(Plaque reduction Neutralizing antibody Assay)		
	Positive	Negative	Total
Positive	30	0	30
Negative	3	40	43
Sub Total	33	40	73
Positive Percent Agreement (PPA)	91.0% (95% CI: 75.67 % –98.08 %)		
Negative Percent greement (NPA)	100% (95% CI: 89.42 % – 100%)		