SAS™ COVID-19 TOTAL ANTIBODY DETECTION TEST

A Rapid Visual Assay for the Qualitative Detection of antibodies against SARS-CoV-2 in human whole blood, serum or plasma

For *In-Vitro* Diagnostic Use

Store at 15º to 30ºC

For Technical Assistance Call 800-272-2710
Outside the USA Call 1-210-699-8800

SA Scientific, Ltd.
4919 Golden Quail
San Antonio, TX 78240 USA

READ ALL INSTRUCTIONS BEFORE BEGINNING THE ASSAY

INTENDED USE
SAS™ COVID-19 Total Antibody Detection Test is a rapid visual assay for the presumptive qualitative detection of total antibodies (including IgG, IgM and IgA) against SARS-CoV-2 from human whole blood, serum or plasma.

BACKGROUND
COVID-19 is an infectious disease caused by the novel SARS-CoV-2 strain of coronavirus that was first found in Wuhan, China in patients suffering from viral pneumonia. Patients showed clinical symptoms of fever, fatigue, cough that developed into severe pneumonia, septic shock and multiple organ failure. Most patients show symptoms 4-5 days after exposure, though the incubation period can range from 2-14 days after exposure.

PRINCIPLE OF THE TEST
The SAS™ COVID-19 Total Antibody Detection Test utilizes an immunochromatographic sandwich assay to detect anti-SARS-CoV-2 antibodies in patient samples. The reaction between antibodies in the positive sample and the colored particle-conjugated with SARS-CoV-2 antigen forms a complex that migrates along the membrane. If anti-SARS-CoV-2 antibodies are present in the sample, a complex will be formed and captured by SARS-CoV-2 antigen on the membrane, forming a red S line indicating a positive result for SARS-CoV-2 antibody. An internal control line C (control) area is built-in to assure that the test has been carried out correctly.

MATERIALS & REAGENTS PROVIDED
1. Test devices
2. Running buffer
3. Package insert

PRECAUTIONS
1. For in vitro diagnostic use only.
2. In accordance with the principles of Good Laboratory Practice it is strongly recommended that all specimens be treated as potentially infectious and handled with all necessary precautions.
3. Discard all used devices into a biohazard container.
4. Do not use kits after the stated expiration date, and do not mix kit components from different lots.
5. Users are cautioned against over reading of membrane immunoassays. Only clearly visible line in the C area should be considered a positive result.
6. Follow test procedure for each specimen type as written.

STORAGE CONDITIONS
SAS™ COVID-19 Total Antibody Detection Test devices should be kept at room temperature (15-30°C) in the sealed pouches. Do not freeze the test kit or kit reagents.

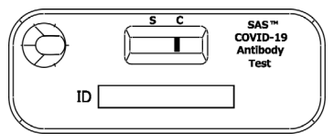
SPECIMEN COLLECTION, STORAGE AND TRANSPORTATION
Acceptable specimens for evaluation with the SAS™ COVID-19 Total Antibody Detection Test include human whole blood, serum or plasma. Samples should be tested as soon as possible after collection.

TEST PROCEDURE FOR SPECIMENS

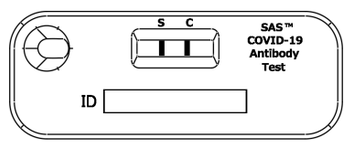
Procedure for use with human whole blood or serum:
1. Open test cassette pouch and lay on a flat surface
2. Label device with specimen type and ID
3. For blood samples: drop 40uL of whole blood into the testing well and wait 30 seconds
   For serum/plasma samples: drop 20uL of serum/plasma into the testing well and wait 30 seconds
4. Dispense 3 drops of buffer into the testing well and start a timer
5. Read results between 10 and 15 minutes. DO NOT interpret results after 15 minutes

INTERPRETATION OF RESULTS

Negative Results
The test is negative if a colored line appears only in the C area (control).



Positive Result
The test is positive for SARS-CoV-2 antibody if a colored line appears in the S area (sample).



Invalid Results
The test is invalid if no colored line appears in the C area even if a colored line appears in the S area. Colored lines that appear after 15 minutes are invalid and should be ignored.

PERFORMANCE CHARCTERISTICS

Clinical Performance

	PCR Positive	Negative
Reactive	46	1
Non-Reactive	1	159
Total	47	160
	PPA	98%
	NPA	99%

Positive samples have been confirmed COVID-19 positive by PCR. 30 negative samples have been confirmed COVID-19 negative by PCR and remaining 130 samples were drawn prior to 2019.

TEST LIMITATIONS

- This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.
- Laboratories and healthcare providers must include this information in their patient test report as provided by the FDA guidance:
  - This test has not been reviewed by FDA
  - Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow up testing with a molecular diagnostic should be considered to rule out infection in these individuals
  - 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.
  - Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E
  - Not for the screening of donated blood

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