SA Scientific™
Texas, USA

SAS™ IgM/IgG COVID-19 Antibody Detection Test

A Rapid Visual Assay for the Qualitative Detection of IgM and IgG antibodies of COVID-19 in human whole blood, serum or plasma

CLINICAL PERFORMANCE REPORT

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1. 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.

2. PRINCIPLE OF THE TEST

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

3. INTENDED USE

SAS™ COVID-19 IgM/IgG Antibody Detection Test is a rapid visual assay for the presumptive qualitative detection of IgM and IgG antibodies against SARS-CoV-2 from human whole blood, serum or plasma

4. TEST CHARACTERISTICS

4.1 Storage Conditions

SAS™ COVID-19 IgM/IgG 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.

4.2 Specimen Collection, Storage and Transportation

Acceptable specimens for evaluation with the SAS™ COVID-19 IgM/IgG Antibody Detection Test include human whole blood, serum or plasma. Samples should be tested as soon as possible after collection.

4.3 Stability

The SAS™ COVID-19 IgM/IgG Antibody Detection Test is stable for one year if stored and used according to package insert. The test kit must be stored at room temperature (15-30°C) with devices in the sealed pouch.

5. CLINICAL PERFORMANCE

5.1 Clinical Performance-Method

The clinical performance of the SAS™ COVID-19 IgM/IgG Antibody Detection Test was evaluated using retrospectively collected samples. All samples were collected from patients in the United States and PCR was used as the comparator to determine if samples were COVID-19 positive. 30 of the negative samples were confirmed negative by PCR and the remaining 135 were drawn prior to 2019.

5.2 Clinical Performance-Result's

Positive Percent Agreement: 47 samples that were verified to be COVID-19 positive through PCR were tested, 44 of which tested positive for IgM, IgG or both.

Negative Percent Agreement: 165 negative samples were also tested on the SAS™ COVID-19 IgM/IgG Antibody Detection Test. Of the 165 samples tested, 161 tested negative. Tables below show the PPA/NPA for IgM/IgG, IgM, and IgG

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Table 1. Clinical performance -overall

	PCR Positive	Negative
SAS IgM and IgG Positive	44	3
SAS IgM and IgG Negative	3	161
Total	47	165
	PPA	94%
	NPA	98%

PPA: 44/47 = 94% NPA: 161/165 = 98%

Table 2. Clinical performance- IgM

	PCR Positive	Negative
SAS IgM Positive	44	3
SAS IgM Negative	3	162
Total	47	165
	PPA	94%
	NPA	98%

PPA: 44/47 = 94%; NPA: 162/165 = 98%

Table 3. Clinical performance- IgG

	PCR Positive	Negative
SAS IgG Positive	43	2
SAS IgG Negative	4	163
Total	47	165
	PPA	91%
	NPA	99%

PPA: 43/47 = 91%; NPA: 163/165 = 99%