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Clinical evaluation study report

Product : SGTi-flex COVID-19 IgM/IgG

Keimyung University Dongsan Hospital

Dept. of Laboratory Medicine, Sunggyun Park

Daejeon Eulji Medical Center, Eulji University

Dept. of Laboratory Medicine, Chunhwa Ihm

Sugentech, Inc.

CEO, Mi-Jin Sohn

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Purpose

To evaluate the performance of SGTi-flex COVID-19 IgM/IgG for qualitative detection of IgM or IgG antibodies to coronavirus disease 2019 (COVID-19) in human whole blood, serum or plasma

Test Device

SGTi-flex COVID-19 IgM/IgG, Lot: COVT20901, Exp. Date: Feb. 2021

Test Samples (Specimens)

(1) Positive samples

- A total of 150 specimens were collected from patients who were positively confirmed by the real time RT-PCR with nasopharyngeal swab, oropharyngeal swab or sputum specimens at Keimyung University's Daegu Dongsan Hospital and Keimyung University Dongsan Hospital or Daejeon Eulji Medical Center, Eulji University.
- The specimens (plasma or serum) were paired samples obtained from the same subjects who provided nasopharyngeal swab, oropharyngeal swab or sputum samples which were used in the real time RT-PCR as confirmative diagnosis for COVID-19.

(2) Negative samples

- A total of 200 specimens were collected from 100 clinically non-infected healthy individuals and 100 patients with respiratory symptoms.
- The specimens of patients were paired samples obtained from who were negatively confirmed by the COVID-19 real-time RT-PCR test conducted by Keimyung University Dongsan Hospital during the same period.

Method

SGTi-flex COVID-19 IgM/IgG were evaluated with the 350 blood samples obtained from patients with respiratory symptoms or healthy individuals. The study subjects were selected by examining the medical records of the COVID-19 confirmers and dividing them before and after 10 days of symptom onset, and the comparative group was also selected by reviewing the medical records of patients.

The experiment was carried out according to the instructions suggested by the manufacturer using the serum samples selected, and each antibody is qualitatively judged by visual inspection.

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Results

The test results are summarized as follows.

1) Test result 1

SGTi-flex COVID-19 IgM&IgG		RT-PCR		
		Positive	Negative	Total
Test device	Positive	48	1	49
	Negative	2	49	51
	Total	50	50	100

(1) Accuracy (Overall agreement) = 100 x (48+49) / 100 = 97.00%

(2) Sensitivity (Positive agreement) = 100 x 48 / 50= 96.00%

(3) Specificity (Negative agreement) = 100 x 49 / 50 = 98.00%

2) Test result 2

SGTi-flex COVID-19 IgM/IgG		RT-PCR		
		Positive	Negative	Total
Test device	Positive	45	1	46
	Negative	5	49	54
	Total	50	50	100

(1) Accuracy (Overall agreement) = 100 x (45+49) / 100 = 94.00%

(2) Sensitivity (Positive agreement) = 100 x 45 / 50= 90.00%

(3) Specificity (Negative agreement) = 100 x 49 / 50 = 98.00%

3) Test result 3

SGTi-flex COVID-19 IgM/IgG		RT-PCR		
		Positive	Negative	Total
Test device	Positive	46	4	50
	Negative	4	96	100
	Total	50	100	150

(1) Accuracy (Overall agreement) = 100 x (46+96) / 150 = 94.67%

(2) Sensitivity (Positive agreement) = 100 x 46 / 50= 92.00%

(3) Specificity (Negative agreement) = 100 x 96 / 100 = 96.00%

Conclusion

Comparison studies between the test device (SGT i-flex COVID19 IgM/IgG) and the predicate device (Reference method, real time RT-PCR) were conducted by lab professionals, using total 350 specimens.

Through three different tests, the results showed the accuracy (overall percent agreement) was 94.00~97.00%. The sensitivity and specificity (positive and negative agreements) were 90.00~96.00% and 96.00~98.00%, respectively.

In the case of real-time RT-PCR test, the virus is diagnosed just by being present in the specimen, and it can be confirmed from patients after the onset. The serology test seeks for the specific antibodies (IgM or IgG) toward COVID-19 virus.

SGTi-flex COVID-19 IgM/IgG is faster and easier to diagnose COVID-19 and it has good agreement with real-time RT-PCR test. Therefore, SGTi-flex COVID-19 IgM/IgG is a useful kit that can help in emergency situations where viral infections are expanding especially for community spread.