SGTi-flex

COVID-19 IgM/IgG

INTENDED USE

SGTi-flex COVID-19 IgM/IgG Test is an immunoassay for qualitative detection of IgM or IgG antibodies to COVID-19 in human whole blood, serum or plasma. The test is useful as a screening test for COVID-19.

SUMMARY AND EXPLANATION

The novel coronavirus (SARS-CoV-2) was identified in December 2019, and in February 2020, the World Health Organization (WHO) officially named the disease caused by SARS-CoV-2 as COVID-19. Belonging to the family Coronaviridae, it has a positive-sense single-stranded RNA and can be transmitted between people. The coronaviruses identified for human infection include 229E, NL63 belonging to α-Coronaviruses and HKU1, OC43, SARS-CoV, MERS-CoV belonging to β- Coronaviruses.

The new coronavirus was published under the name of SARS-CoV-2, with 80% of genetic similarity to SARS-CoV by ICTV (International Committee on Taxonomy of Viruses).

COVID-19 spreads mainly through respiratory droplets, which cause lethargy, fever, dry cough, and dyspnea when infected. It can be even led to death with its severe symptoms like sepsis, MOF (Multiple Organ Failure) and ARDS (Acute Respiratory Distress Syndrome). It is more contagious than SARS which caused more than 800 deaths and 8,000 infected patients. Moreover, it has an incubation period of about 3 days to up to 16 days and becomes a big threat as infectivity appears even during the incubation period. There is currently no specific treatment for COVID-19, and rapid and accurate diagnosis is an important issue for isolation of patients with symptoms of suspected COVID-19.

PRINCIPLE

SGTi-flex COVID-19 IgM/IgG is an immunoassay for the qualitative detection of IgM and IgG antibodies to COVID-19 in human blood, serum or plasma. The cassette contains a test strip which is located inside a plastic housing. When the sample and sample buffer are loaded to the sample well, the specific IgM or IgG antibodies to COVID-19 flow through the membrane, and move to the test line area and are accumulated by each capture antibody immobilized on the membrane, respectively. The antigen-gold conjugate move to the test line area and attach to the specific IgM or IgG antibodies to COVID-19. This leads to the generation of a reddish colored band. The intensity of the band depends on quantity of specific antibodies (IgM or IgG) to COVID-19 and the test results are interpreted by user's eye according to the instructions for use.

MATERIALS SUPPLIED

- Test Cassette 25
- Sample Buffer Tube ..... 1 (4.5 mL/tube)
- Instructions for Use 1

MATERIALS REQUIRED BUT NOT SUPPLIED

- Micro Pipette(s)
- Single Use Disposable Pipette Tip

STORAGE AND STABILITY

- Store SGTi-flex COVID-19 IgM/IgG Test Cassette and Sample Buffer at 2~30℃ (36~86℉). It is available to use until the expiration date printed on the package.
- If SGTi-flex COVID-19 IgM/IgG Test Cassette and Sample Buffer are stored in cold storage, allow them for 30 minutes to return to room temperature before testing.
- Do not open the pouch of Test Cassette until ready to use. After opening aluminum pouch, Test Cassette should be used immediately.
- Keep away from direct sunlight.

WARNING AND PRECAUTIONS

- For *in-vitro* diagnostic use only.
- Clinical diagnosis should be made through a comprehensive review of the specialist ba[illegible] other test methods and clinical symptoms.
- Please read the instructions carefully before you begin the test and follow the proc[illegible] correctly.
- It is prohibited to reuse Test cassettes because they are single use only.
- The test result after the expiry date is not reliable.
- Test Cassette should remain in the sealed pouch until use because it is sensitive to moisture. Use Test Cassette immediately after opening the pouch.
- Do not use the Test Cassette if it is broken or the pouch is not stored in sealed.
- Samples and Test Cassette must be at room temperature before testing.
- It is an in-vitro diagnostic product and the risk of infection is low because there is no direct contact with the body. However please be cautious when handling test cassette and samples because of the use of clinical samples containing potential infectious sources. Dispose of the used samples, test cassettes, sample extracts and sample collecting swabs properly in accordance with the relevant regulations.
- Smoking and eating are prohibited at test site when handing specimens or kit reagents.

SAMPLE COLLECTION AND PREPARATION

SGTi-flex COVID-19 IgM/IgG can be performed with whole blood, plasma or serum.

1. Whole blood

1) Collect the blood specimen obtained by venipuncture into a tube containing anticoagulant or use fingertip blood. After disinfecting the fingers with alcohol swabs, use a lancet to puncture the fingertips and collect blood with a pipette or capillary.

2) Collected whole blood should be used immediately or stored at 4℃.

2. Plasma

1) Collect the blood specimen obtained by venipuncture into a tube containing anticoagulant, and separate plasma from the supernatant by centrifugation.

2) For accurate results, samples should be used within 24 hours before testing.

3. Serum

1) Collect the blood specimen obtained by venipuncture into a tube without anticoagulant and allowed to be agglutinated for about 30 minutes. And separate serum from the supernatant by centrifugation.

TEST PROCEDURE

Preparation before Test

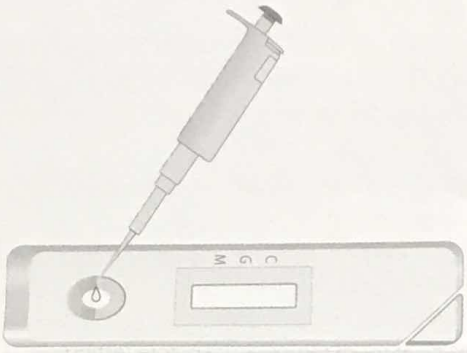
1. All samples and reagents should be stored at room temperature and stayed homogenous 15~30 minutes prior to testing.
2. Test cassette is moisture sensitive so should be used **immediately** after opening.

Test Procedure

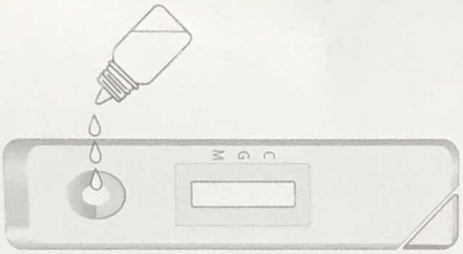
1. All samples and reagents should be stored at room temperature and stayed homogenous 15~30 minutes prior to testing.
2. Remove the test cassette from the foil pouch and place it on a clean and flat surface.

IVD CE

3. Using a pipette, add **10 µL** of the specimen (whole blood, plasma or serum) into the sample well on the cassette.

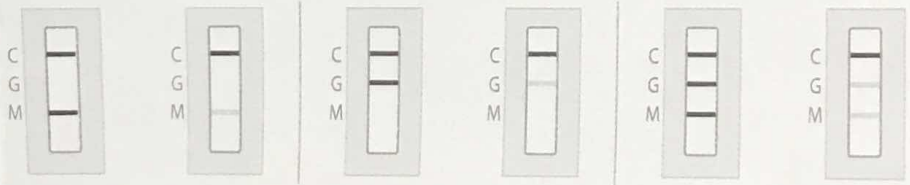


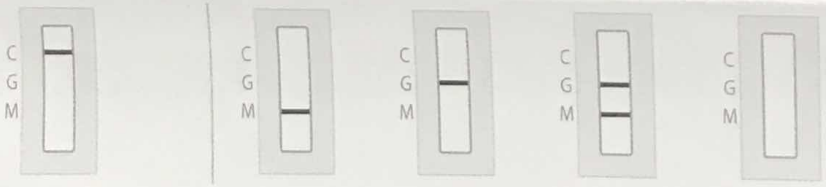
4. Add **3 drops** of sample buffer (Approximately 90 µL) into the sample well on the cassette.



5. Read the result **after 10-15 minutes**. The result after 30 minutes is invalid.

INTERPRETATION OF RESULTS





1. Positive

- Test line (G) and Control line (C) are appeared in the result window: Positive for IgG antibody to COVID-19
- Test line (M) and Control line (C) are appeared in the result window: Positive for IgM antibody to COVID-19
- Test line (G), Test line (M) and Control line (C) are appeared in the result window: Positive for both IgM, IgG antibody to COVID-19

2. Negative

If only Control line (C) appears in the result window: Negative for both IgM, IgG antibody to COVID-19

3. Invalid/Retesting

If control line fails to appear, the result is invalid and retest with a new test cassette.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS OF THE SYSTEM

1. The test is for qualitative detection of anti-COVID-19 antibody in human whole blood, serum or plasma and does not indicate the quantity of the antibodies.
2. The test is for in-vitro diagnostic use only.
3. This test has not been reviewed by the FDA.
4. 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.
5. 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.
6. 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.
7. Not for the screening of donated blood.

PERFORMANCE CHARACTERISTICS

1. Precision

Within-run, Between-run, Batch-to-batch performance results meet 100% of the acceptance criteria.

2. Cross-Reactivity

SGTi-flex COVID-19 IgM/IgG was evaluated with a total of 18 commercial plasma. The results show that the SGTi-flex COVID-19 IgM/IgG has no cross-reactivity with samples containing IgM or IgG antibodies to other viruses, bacteria.

No.	Analytical reactive substances	No.	Analytical reactive substances
1	Adenovirus IgM plasma	10	Epstein-Barr Virus (EBV) VCA IgG Positive Plasma
2	Adenovirus IgG plasma	11	Cytomegalovirus IgM Antibody Positive Plasma
3	Enterovirus positive plasma	12	Cytomegalovirus IgG Antibody Positive Plasma
4	Measles IgM plasma	13	Varicella Zoster Virus (VZV) IgM Antibody Positive Plasma
5	Measles IgG plasma	14	Varicella Zoster Virus (VZV) IgG Antibody Positive Plasma
6	Mumps IgM plasma	15	Mycoplasma IgM Antibody Positive Plasma
7	Mumps IgG plasma	16	Mycoplasma IgG Antibody Positive Plasma
8	Parainfluenza positive plasma	17	Chlamydia IgM Antibody Positive Plasma
9	Epstein-Barr Virus (EBV) VCA IgM Positive Plasma	18	Chlamydia IgG Antibody Positive Plasma

3. Analytical Specificity – Interference test

Various concentrations of potential interfering substances were prepared in negative and positive sample. The results show that the SGTi-flex COVID-19 IgM/IgG has no interferences by the potential interfering substances below which may exist in specimen, such as biological analytes.

No.	Interfering substance	Concentration
1	Albumin	150 mg/ml
2	Glucose	1.2 mg/ml
3	Hemoglobin	160 mg/ml
4	Bilirubin	0.02 mg/ml
5	HAMA	46 ng/mL

4. Class Specificity

SGTi-flex COVID19 IgM/IgG showed no cross-reactivity with cross-reactive substances such as anti-human IgG, IgM, IgA and IgE. There was no cross-reactivity to anti-human IgM, IgA and IgE in Test line (G) and no cross-reactivity to anti-human IgG, IgA and IgE in Test line (M).

5. Clinical Agreement Study

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 250 specimens.

The results showed the accuracy (overall percent agreement) was 94.40%. The sensitivity and specificity (positive and negative agreements) were 91.00% and 96.67%, respectively

		Reference method		
		Positive	Negative	Total
Test device (SGTi-flex COVID-19 IgM/IgG)	Positive	91	5	96
	Negative	9	145	154
	Total	100	150	250

REFERENCES

1. WHO, Coronavirus disease 2019 (COVID-19) Situation report
2. Emerging Infectious Diseases (www.cdc.gov/eid) Vol. 13, No. 10, (Oct, 2007), Duration of Antibody Response after Severe Acute Respiratory Syndrome, Li-Pin Wu, et, al.
3. Scientific Report, 9, 1390 (Feb, 2019) Development and Evaluation of a Multiplexed Immunoassay for Simultaneous Detection of Serum IgG Antibodies to Six Human coronaviruses Suvang U. Trivedi. et,al.
4. J.virol. Methods. 2008, 152(1-2): 77-84, A rapid point of care immunoswab assay for SARS-CoV detection
5. Clinical and Diagnostics laboratory immunology, 2004, vol.11(4) : 792-794, kinetics of Severe acute respiratory syndrome(SARS) coronavirus specific antibodies in 271 Laboratory-confirmed cases of SARS

EXPLANATION OF SYMBOLS USED ON PACKAGE

IVD	*In-vitro* diagnostic medical device	Σ 25	Contains sufficient for 25 tests
	Consult instructions for use.	30°C 2°C	Store between 2°C and 30°C
LOT	Batch code		Use by
	Manufacturer	EC REP	Authorized representative in the European community
	Do not reuse	REF	Catalogue number
	Caution, consult accompanying documents	CE	The device conforms to EU-regulations.

SUGENTECH, INC.

721-26, Jeongjungyeonje-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea

Made in Korea

www.sugentech.com

EC REP

MT Promedt Consulting GmbH

Altenhofstr. 80, 66386 St. Ingbert, Germany

Rev.No. IS209E-03/2020.03.27