SGTi-flex

COVID-19 IgM/IgG

IVD REF COVT005E CE

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 5
- Alcohol Swab 5
- Sample Buffer Tube ..... 1 (1 mL/tube)
- Safety Lancet 5
- pettyPip 5
- Instructions for Use 1

MATERIALS REQUIRED BUT NOT SUPPLIED

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

STORAGE AND STABILITY

- Store all kit components 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 based on other test methods and clinical symptoms.
- Please read the instructions carefully before you begin the test and follow the procedure correctly.
- It is prohibited to reuse Test cassettes, Safety Lancet, Alcohol Swab and pettyPip, 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 all kit components and samples because of the use of clinical samples containing potential infectious sources. Dispose of the used samples, test cassettes, safety lancet, alcohol swab and pettyPip properly in accordance with the relevant regulations.
- Smoking and eating are prohibited at test site when handing specimens or kit reagents.
- If the safety lancet is damaged, please discard it and use other lancet.
- Dispose of the safety lancet past the expiration date immediately.

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(Na-heparin) 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) If venipuncture whole blood is not tested immediately, store at 2-8℃ for up to 5 days.

2. Serum and Plasma

1) Serum : 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

2) Plasma : Collect the blood specimen obtained by venipuncture into a tube containing anticoagulant (Na-heparin, Li-heparin and Na-Citrate), and separate plasma from the supernatant by centrifugation.

3) Serum and Plasma Stability

If specimens are not tested immediately, store at 2-8℃ for up to 5 days. The specimens should be frozen at -70℃ for longer storage

For frozen samples, avoid more than 4 freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently.

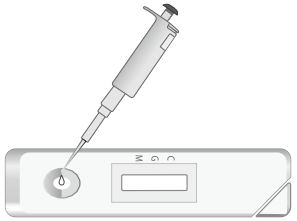
TEST PROCEDURE

Preparation before Test

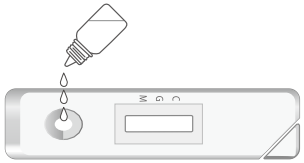
1. All samples and reagents should be stored at room temperature and stayed homogenous 15~30 minutes prior to testing.
2. Test cassette is moisture sensitive so should be used **immediately** after opening.

Test Procedure

1. Remove the test cassette from the foil pouch and place it on a clean and flat surface.
2. Using a pipette or pettyPip, add **10 µL** of the specimen (whole blood, plasma or serum) into the sample well on the cassette.

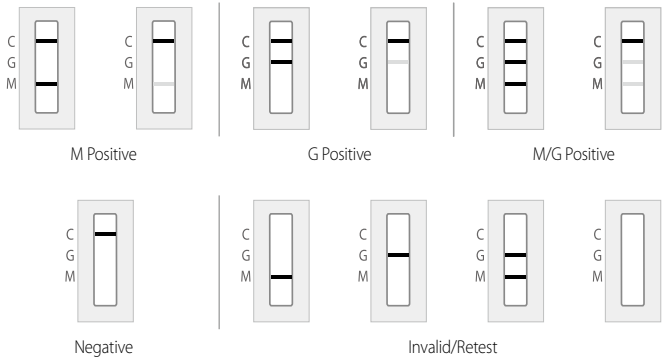


3. Add **3 drops** of sample buffer (Approximately 90 µL) into the sample well on the cassette.



4. 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. 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.
4. 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.
5. 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.
6. 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 143 other virus, bacteria or autoantiboies. 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 as well as autoantiboies.

Table 1. Cross-reactive substances

No	Analytical reactive substances	Number of Samples	No	Analytical reactive substances	Number of Samples
1	Adenovirus IgM	6	21	Anti-HCV	3
2	Adenovirus IgG	6	22	VZV IgM/IgG Positive	3
3	Enterovirus	1	23	anti-HBs positive (total)	5
4	Measles IgM	6	24	anti-HIV-I Virus Type 1	5
5	Measles IgG	6	25	Influenza A virus (H1N1+H3N2) IgM	5
6	Mumps IgM	5	26	Influenza A virus (H1N1+H3N2) IgG	5
7	Mumps IgG	6	27	Influenza B virus (Yamagata+Victoria) IgM	5
8	Parainfluenza	1	28	Influenza B virus (Yamagata+Victoria) IgG	5
9	Epstein-Barr Virus (EBV) VCA IgM	1	29	Enterovirus group A IgM	5
10	Epstein-Barr Virus (EBV) VCA IgG	1	30	Enterovirus group A IgG	5
11	Cytomegalovirus IgM Antibody	1	31	ds-DNA	5
12	Cytomegalovirus IgG Antibody	1	32	Parainfluenza virus IgM	5
13	Varicella Zoster Virus (VZV) IgM Antibody	1	33	Parainfluenza virus IgG	5
14	Varicella Zoster Virus (VZV) IgG Antibody	1	34	Respiratory syncytial virus IgM	5
15	Mycoplasma IgM Antibody	1	35	Respiratory syncytial virus IgG	5
16	Mycoplasma IgG Antibody	1	36	Rotavirus IgM	5
17	Chlamydia IgM Antibody	1	37	Rotavirus IgG	5
18	Chlamydia IgG Antibody	1	38	Rhinovirus group A IgM	5
19	Rheumatoid Arthritis	2	39	Rhinovirus group A IgG	5
20	Autoimmune Control	3			

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 prescription/OTC drugs, and elevated levels of chemical and biological analytes.

Also, SGTi-flex COVID19 IgM/IgG showed no cross-reactivity with cross-reactive substances such as anti-human IgG, IgM, IgA and IgE.

Table 2. Potential interfering substances

No.	Interfering substance	Concentration	No.	Interfering substance	Concentration
1	Albumin	150 mg/ml	8	Acetylsalicylic acid	0.7 mg/mL
2	Glucose	1.2 mg/ml	9	Caffeine	0.1 mg/mL
3	Hemoglobin	20 mg/ml	10	Ascorbic acid	0.2 mg/mL
4	Bilirubin	0.02 mg/ml	11	human IgG	5.5 mg/mL
5	HAMA	46 ng/mL	12	human IgM	1.2 mg/mL
6	Triglyceride	10 mg/mL	13	human IgA	1.1 mg/mL
7	Acetaminophen	0.2 mg/mL	14	Immunoglobulin E (IgE)	13.3 IU/mL

4. Class Specificity

SGTi-flex COVID19 IgM/IgG showed 100% agreement with expected result to establish antibody class specificity.

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 523 specimens.

The results showed the accuracy (overall percent agreement) was 97.13%. The sensitivity and specificity (positive and negative agreements) were 94.48% and 98.33%, respectively.

Table 3. Total Clinical Performance analysis (Combined)

		Reference method		
		Positive	Negative	Total
Test device (SGTi-flex COVID-19 IgM/IgG)	Positive	154	6	160
	Negative	9	354	363
	Total	163	360	523

(1) Accuracy (Overall percent agreement) : 97.13% (508/523, 95% CI: 95.32%~98.25%)

(2) Sensitivity (Positive percent agreement) : 94.48% (154/163, 95% CI: 89.84%~97.07%)

(3) Specificity (Negative percent agreement) : 98.33% (354/360, 95% CI: 96.41%~99.23%)

Table 4. Total Clinical Performance analysis for IgM

		Reference method		
		Positive	Negative	Total
Test device IgM result	Positive	148	6	154
	Negative	15	354	369
	Total	163	360	523

(1) Accuracy (Overall percent agreement) : 95.98% (502/523, 95% CI: 93.94%~97.36%)

(2) Sensitivity (Positive percent agreement) : 90.80% (148/163, 95% CI: 85.37%~94.34%)

(3) Specificity (Negative percent agreement) : 98.33% (354/360, 95% CI: 96.41%~99.23%)

Table 5. Total Clinical Performance analysis for IgG

		Reference method		
		Positive	Negative	Total
Test device IgG result	Positive	147	0	147
	Negative	16	360	376
	Total	163	360	523

(1) Accuracy (Overall percent agreement) : 96.94% (507/523, 95% CI: 95.09%~98.11%)

(2) Sensitivity (Positive percent agreement) : 90.18% (147/163, 95% CI: 84.65%~93.87%)

(3) Specificity (Negative percent agreement) : 100.00% (360/360, 95% CI: 98.94%~100.00%)

When estimating the sensitivity of IgM and IgG over time from symptom onset for all positive samples, the proportion of IgM positive patients reached a peak of 100.0% approximately 15-21 days after symptom onset, whereas the proportion of IgG positive patients reached 100% approximately 22 days after symptom onset.

Table 6. The sensitivity estimates for IgM/IgG combined over time

Days after symptom onset (days)	Combined Positive
≤7	83.8% (31/37) (95% CI: 68.86~92.35 %)
8~14	93.8 % (45/48) (95% CI: 83.16~97.85 %)
15~21	100.0 % (45/45) (95% CI: 92.13~100.00 %)
≥22	100.0 % (33/33) (95% CI: 89.57~100.00 %)

REFERENCES

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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 5	Contains sufficient for 5 tests
	Do not reuse		Consult instructions for use.
2°C 30°C	Store between 2℃ and 30℃		Caution, consult accompanying documents
LOT	Batch code		Use by
REF	Catalogue number	STERILE R	Method of sterilization using irradiation
	Manufacturer	EC REP	Authorized representative in the European community
CE	The device conforms to EU-regulations.		

Safety Lancet

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