

# SGTi-flex COVID-19 IgG



COGT025E, COGT005E



For *in-vitro* diagnostic use only.  
For prescription use only.  
For Emergency Use Authorization only.

## ► INTENDED USE

The SGTi-flex COVID-19 IgG is a lateral flow immunoassay intended for qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, venous whole blood (sodium heparin, lithium heparin, sodium citrate and tripotassium EDTA), plasma (sodium heparin, lithium heparin, sodium citrate and tripotassium EDTA), and fingerstick whole blood. The SGTi-flex COVID-19 IgG is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The SGTi-flex COVID-19 IgG should not be used to diagnose or exclude acute SARS-CoV-2 infection.

Testing of serum, plasma and venous blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform moderate or high complexity tests.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Samples should only be tested from individuals that are 15 days or more post symptom onset.

The sensitivity of SGTi-flex COVID-19 IgG early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for SGTi-flex COVID-19 IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG assay.

The SGTi-flex COVID-19 IgG is only for use under the

Food and Drug Administration's Emergency Use Authorization.

## ► 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  $\alpha$ -Coronaviruses and HKU1, OC43, SARS-CoV, MERS-CoV belonging to  $\beta$ -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 may cause lethargy, fever, dry cough, and dyspnea in infected individuals. It may also cause severe symptoms like sepsis, MOF (Multiple Organ Failure) and ARDS (Acute Respiratory Distress Syndrome) or death. It is likely more contagious than SARS-CoV-1 which caused more than 800 deaths and 8,000 infected patients. Moreover, it has an incubation period of about 2 days to up to 14 days. Infected individuals may shed the virus and infect others even during the incubation period.

## ► PRINCIPLE

SGTi-flex COVID-19 IgG is an immunoassay for the qualitative detection of IgG antibodies to SARS-CoV-2 in human venous whole blood, fingerstick whole 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 onto the sample well, the specific IgG antibodies to SARS-CoV-2 flow through the membrane and move to the test line area and are captured by antibodies immobilized on the membrane, respectively. The antigen (Recombinant SARS-CoV-2 Nucleocapsid and Spike RBD Protein) is conjugated to colloidal gold nanoparticles and the antigen-gold conjugate moves to the test line area and attaches to the specific IgG antibodies to SARS-CoV-2. This leads to the generation of a reddish colored band. The user interprets test results by eye, according to the instructions for use.

## ► MATERIALS SUPPLIED

### [COGT025E]

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

### [COGT005E]

- ✓ Test Cassette 5
- ✓ Safety Lancet 5
- ✓ Alcohol Swab 5
- ✓ pettyPip 5
- ✓ Sample Buffer 1 ( 1 mL/tube)
- ✓ Instructions for Use 1
- ✓ QRI 1

## ► MATERIALS REQUIRED BUT NOT SUPPLIED

- ✓ Micro Pipette(s)
- ✓ Single Use Disposable Pipette Tip
- ✓ Timer
- ✓ SGTi-flex COVID-19 IgG Control

## ► STORAGE AND STABILITY

- DO NOT FREEZE.
- The test is stable through the expiration date printed on the sealed pouch at 2~30°C (36~86°F). Do not use after the expiration date.
- SGTi-flex COVID-19 IgG Test Cassette and Sample Buffer should be brought to room temperature for 30 minutes 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

- ✓ Test cassettes are single use only. Do not reuse.
- ✓ For use under Emergency Use Authorization only. For IN VITRO Diagnostic use only.
- ✓ This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- ✓ This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.

- ✓ The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- ✓ Do not use tests after the expiration date.
- ✓ 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.
- ✓ Please be cautious when handling the test cassette and samples because of the use of clinical samples containing potential infectious sources. Dispose of the used samples and test cassettes properly in accordance with the relevant regulations.
- ✓ Smoking and eating are prohibited at test site when handling specimens or kit reagents.
- ✓ This product was tested on serum, venous whole blood (sodium heparin, lithium heparin, sodium citrate, and tripotassium EDTA), and plasma (sodium heparin, lithium heparin, sodium citrate, and tripotassium EDTA) as anticoagulants. Using other anticoagulants may produce different results.

## ► SAMPLE COLLECTION AND PREPARATION

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

1. Venous whole blood
  - 1) The anticoagulants sodium heparin, lithium heparin, sodium citrate, and tripotassium EDTA have been tested and may be used with this assay. The correct specimen type must be used in the assay.
  - 2) If venipuncture whole blood is not tested immediately, store at 2-8°C for up to 5 days.
2. Serum and Plasma
  - 1) Serum : Collect the blood specimen obtained by venipuncture into a tube without anticoagulant and allow to clot for about 30 minutes. Separate serum from the supernatant by centrifugation.
  - 2) Plasma : Collect the blood specimen obtained by venipuncture into a tube containing anticoagulant (sodium heparin, lithium heparin, sodium citrate and

tripotassium EDTA), and separate plasma from the supernatant by centrifugation.

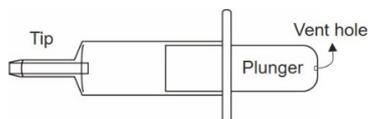
### 3) Serum and Plasma Stability

If specimens are not tested immediately, store at 2-8°C for up to 5 days.

For serum and plasma, the specimens should be frozen at -70°C for longer storage. For frozen samples, avoid repeated freezing/thawing cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently.

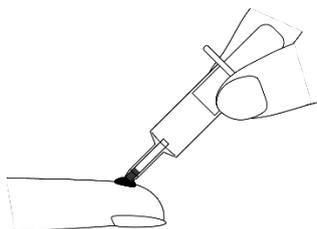
### 3. Fingertick whole blood

- 1) Before fingertick, lower the arm to allow for better blood circulation to the finger.
- 2) Use the alcohol swab to clean the puncture site. Allow to dry.
- 3) Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- 4) Carefully remove the protective cap of the sterile lancet by turning it clockwise. Never pluck away the protective cap
- 5) Push the sterile lancet firmly against the puncture site.
- 6) Whole blood collection using pettyPip: Place your fingers under the wing of the pettyPip and hold it horizontally. Take care not to cover the vent hole of the Plunger.

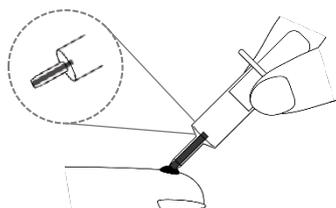


ⓘ Do not press plunger before use !

- 7) Make the blood drop form at the fingertip, then while holding the pettyPip tilted at an angle, touch the blood drop with the tip of pettyPip. When the Tip touches a blood drop, the pettyPip fills itself with blood.



- 8) Please wait until the Tip is completely filled with blood.



## ► TEST PROCEDURE

### ✓ Preparation before Test

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

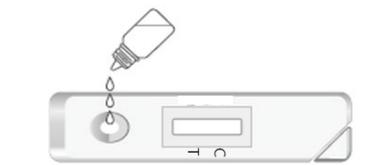
### [Test Procedure]

#### ✓ Venous whole blood, Serum and Plasma

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



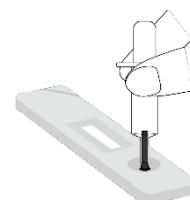
3. Add **3 drops** of sample buffer (approximately 90 µL) into the sample well on the cassette.



4. Read the result **after 10 minutes**. Results should not be read after 30 minutes, as the result after 30 minutes is invalid.

#### ✓ Fingertick whole blood

1. Place the Test Cassette on a flat surface.
2. Grip the pettyPip vertical to the sample well with the end of Tip touching the surface of sample well. When the end of the Tip touches the surface, blood begins to be absorbed into the sample well.



If blood remains in the Tip, push the plunger slowly so that all blood is completely absorbed.

3. After blood is added, immediately add 3 drops of buffer onto the sample well of the Test Cassette.

- ※ Squeeze the tube lightly to allow the drops to come out.



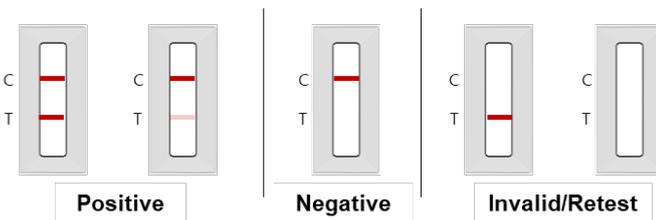
4. Read the results after 10 minutes.

The results are invalid after 30 minutes.



- ※ Do not move the Test Cassette before 10 minutes.
- ※ Do not read before 10 minutes.
- ※ Do not read after 30 minutes.

#### [Interpretation of Results]



##### 1. Positive

Test line (T) and Control line (C) appear in the result window: Positive for IgG antibody to SARS-CoV-2

The color intensity in the test line will vary. Any faint colored line in the test line should be considered as positive.

##### 2. Negative

If only Control line (C) appears in the result window: Negative for IgG antibody to SARS-CoV-2

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.

Control Materials are available for purchase from Sugentech Inc. (Cat no: COVC0001E) and are not supplied with this kit. However, external positive and negative controls should be tested to ensure the proper performance of the assay, particularly under the following circumstances:

- A new operator uses the kit;
- A new lot of test kits is used;
- A new shipment of kits is used;
- To investigate the cause of repeated invalid results;
- The temperature used during storage of the kit falls outside of 2-30°C

#### ► LIMITATIONS OF THE SYSTEM

##### For use under an Emergency Use Authorization Only

1. This test is not for home use.
2. The test is for qualitative detection of anti-SARS-CoV-2 IgG antibody in human whole blood, serum or plasma and does not indicate the quantity of the antibodies. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
3. Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.
4. The test results should be interpreted between 10 and 30 minutes after addition of buffer. The test results should not be interpreted after 30 minutes.
5. The test is for in vitro diagnostic use only.
6. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. The sensitivity of the SGTi-flex COVID-19 IgG early after infection is unknown. False positive results for IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
7. A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or if the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody used in the test.
8. Testing with a molecular diagnostic should be performed to evaluate symptomatic patients for acute SARS-CoV-2 infection, particularly in those who have been in contact with the virus.
9. Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
10. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including

clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response. 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.

11. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.
12. Not for the screening of donated blood.
13. SARS-CoV-2 antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 15 days.
14. Testing must be performed immediately after opening the pouch.
15. The performance of this device has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this assay should not be interpreted as an indication or degree of protection from infection after vaccination.
16. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected from the United States between February 2020 and June 2020 for serum, venous whole blood (sodium heparin, lithium heparin, sodium citrate and tripotassium EDTA), and plasma (sodium heparin, lithium heparin, sodium citrate and tripotassium EDTA) and between November 2020 and January 2021 for fingerstick whole blood. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

## ► CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The SGTi-flex COVID-19 IgG Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>

Authorized laboratories using the SGTi-flex COVID-19 IgG Letter of Authorization (“your product” in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories\* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Sugentech Inc. (email: [info@sugentech.com](mailto:info@sugentech.com)) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in immunochromatographic techniques and use appropriate laboratory and personal protective equipment when handling this kit and use this product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Sugentech Inc., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

\*The letter of authorization refers to “authorized laboratories” as the following:

Testing of serum, venous whole blood and plasma is

limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation."

## ► PERFORMANCE CHARACTERISTICS

### 1. Cross-Reactivity

SGTi-flex COVID-19 IgG was evaluated with a total of 57 other viruses, bacteria or autoantibodies (246 samples total). The results show that the SGTi-flex COVID-19 IgG has no cross-reactivity with samples containing antibodies to other viruses, bacteria as well as autoantibodies.

31	Enterovirus group A IgM	5
32	Enterovirus group A IgG	5
33	Respiratory syncytial virus IgM	5
34	Respiratory syncytial virus IgG	5
35	Rhinovirus group A IgM	5
36	Rhinovirus group A IgG	5
37	<i>Haemophilus Influenzae</i> IgG	5
38	<i>Mycoplasma</i> IgM	1
39	<i>Mycoplasma</i> IgG	1
40	Rotavirus IgM	5
41	Rotavirus IgG	5
42	Cytomegalovirus IgM	1
43	Cytomegalovirus IgG	1
44	Varicella Zoster Virus (VZV) IgM/IgG	5
45	Mumps IgM	5
46	Mumps IgG	5
47	Measles IgM	5
48	Measles IgG	5
49	anti-HIV-I Virus Type 1	5
50	anti-HBs positive	5
51	anti-HCV	3
52	ds-DNA	5
53	Autoimmune Control	3
54	Rheumatoid Arthritis	2
55	Dengue IgM	5
56	<i>Chlamydia</i> IgM	1
57	<i>Chlamydia</i> IgG	1

Table 1. Cross-reactive substances

No	Analytical reactive substances	Number of Samples
1	Coronavirus 229E IgG	5
2	Coronavirus NL63 IgG	5
3	Coronavirus OC43 IgM	5
4	Coronavirus OC43 IgG	5
5	Coronavirus HKU1 IgM	5
6	Coronavirus HKU1 IgG	5
7	Parainfluenzae 1 IgM	5
8	Parainfluenzae 1 IgG	5
9	Parainfluenzae 2 IgM	5
10	Parainfluenzae 2 IgG	5
11	Parainfluenzae 3 IgM	5
12	Parainfluenzae 3 IgG	5
13	Parainfluenza virus IgM	5
14	Parainfluenza virus IgG	5
15	Human Metapneumovirus IgM	5
16	Human Metapneumovirus IgG	5
17	Epstein-Barr Virus IgM	5
18	Epstein-Barr Virus IgG	5
19	Epstein-Barr Virus (EBV) VCA IgM	1
20	Epstein-Barr Virus (EBV) VCA IgG	1
21	<i>Plasmodium falciparum</i> IgM	5
22	<i>Plasmodium falciparum</i> IgG	5
23	SARS-CoV	5
24	MERS-CoV	5
25	Adenovirus type 1 IgM	5
26	Adenovirus type 1 IgG	5
27	Influenza A virus (H1N1+H3N2) IgM	5
28	Influenza A virus (H1N1+H3N2) IgG	5
29	Influenza B virus (Yamagata+Victoria) IgM	5
30	Influenza B virus (Yamagata+Victoria) IgG	5

### 2. Clinical Agreement Study

#### A. Sugentech, Inc. Clinical Agreement Study

Comparison studies between the test device (SGTi-flex COVID-19 IgG) and an EUA authorized PCR-based test were conducted by lab professionals, using total 419 specimens. The sensitivity and specificity (positive and negative percent agreements) were 92.43% and 99.15%, respectively.

Table 2. Clinical Performance analysis

		Reference method		
		Positive	Negative	Total
Test device	Positive	171	2	173
	Negative	14	232	246
	Total	185	234	419

(1) Sensitivity (Positive percent agreement): 92.43% (171/185, 95% CI: 87.70%~95.44%)

(2) Specificity (Negative percent agreement): 99.15% (232/234, 95% CI: 96.94%~99.77%)

When estimating the sensitivity of IgG over time from symptom onset for all positive samples, the proportion of IgG positive patients reached 98.6% approximately 15 days after symptom onset.

Table 3. The sensitivity estimates for IgG over time

Days after symptom onset (days)	IgG Positive
0~7	41.2 % (7/17) (95% CI: 21.61~63.99 %)
8~14	91.7 % (22/24)

	(95% CI: 74.15~97.68 %)
≥15	98.6 % (142/144) (95% CI: 95.08~99.62 %)

### B. Fingerstick Whole Blood Clinical Performance

The fingerstick whole blood clinical study was conducted in point-of-care (POC) sites. A total of 75 fingerstick whole blood samples (42 RT-PCR positive and 33 RT-PCR negative) were included in this study. A total of 42 symptomatic subjects were studied who had positive PCR results; all of these subjects also tested positive for IgG with the SGTi-flex COVID-19 IgG test. A total of thirty-three (33) subjects were studied who had negative PCR results within one week of test; all of these subjects also tested negative with the SGTi-flex COVID-19 IgG test. The results are presented below.

#### IgG PPA for the SGTi-flex COVID-19 IgG

Days after symptom onset (days)	IgG Positive
≥15	100 % (42/42) (95% CI: 91.62% - 100 %)

#### IgG NPA for the SGTi-flex COVID-19 IgG

# PCR Negative	IgG Negative
33	100 % (33/33) (95% CI: 89.57% - 100 %)

### C. Independent Clinical Agreement Validation Study

The SGTi-flex COVID-19 IgG was tested on August 19, 2020 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and anticoagulant citrate dextrose (ACD) plasma samples. Each of the 30 antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the SGTi-flex COVID-19 IgG. The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers.

All antibody-negative samples were collected prior to 2020 and include i) seventy (70) samples selected without regard to clinical status, "Negatives" and ii) ten (10) samples selected from banked serum from HIV+ patients, "HIV+". Testing was performed by one operator using 1 lot of SGTi-flex COVID-19 IgG. Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).

For the evaluation of cross-reactivity with HIV+, it was determined whether an increased false positive rate among antibody-negative samples with HIV was

statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown in the tables below.

#### Summary Results

	Comparator Method			Collected pre-2020		Total
	Antibody Positive			Antibody Negative		
SGTi-flex COVID-19 IgG	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Neg.	HIV +	
IgG+	29					29
IgG-	1			70	10	81
Total	30			70	10	110

#### Summary Statistics

Measure	Estimate	Confidence Interval
IgG Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
IgG Specificity	100% (80/80)	(95.4%; 100%)
PPV for prevalence = 5.0%	100%	(48.9%; 72.9%)
NPV for prevalence = 5.0%	99.8%	(99.1%; 100%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

#### Important limitations:

1. Samples were not randomly selected, and sensitivity and specificity estimates may not be indicative of the real-world performance of the device
  2. These results are based on serum and ACD plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.
  3. The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.
3. Antibody Class Specificity

SGTi-flex COVID-19 IgG showed 100% agreement with expected result before and after competitive treatment with capture IgG and IgM antibodies to establish antibody class specificity.

#### 4. Matrix Equivalency

Matrix equivalency studies with the test device (SGTi-flex COVID-19 IgG) in the claimed matrices were conducted by lab professionals. Five (5) matched sets of samples from individual donors, comprised of serum, plasma (sodium heparin, lithium heparin, sodium citrate and tripotassium EDTA), and whole blood (sodium heparin, lithium heparin, sodium citrate and tripotassium EDTA)

were evaluated. A negative, low positive, and moderate positive sample was evaluated using each matrix. Results of the study demonstrate that performance is equivalent for all matrices tested.

	Manufacturer
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► 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

► INQUIRIES AND GENERAL INFORMATION

Please visit website [www.sugentech.com](http://www.sugentech.com) or  
Contact Sugentech via email: [info@sugentech.com](mailto:info@sugentech.com)



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Rev.No. IS220E-03/2021.10.05

► EXPLANATION OF SYMBOLS USED ON PACKAGE

	<i>In vitro</i> diagnostic medical device
	Contains sufficient for 25 tests
	Do not reuse
	Consult instructions for use.
	Store between 2°C and 30°C
	Caution, consult accompanying documents
	Batch code
	Use by
	Catalogue number

# Quick Reference Instructions of SGTi-flex COVID-19 IgG

IVD

- ✓ For use under an Emergency Use Authorization Only.
- ✓ For prescription use only.

- ✓ For in vitro diagnostic use only.
- ✓ This is for fingerstick whole blood.

1. This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
2. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
3. The user should be trained in the procedure. Wear appropriate protective attire for your safety when handling patient samples.
4. Read the complete Quick Reference Instructions before performing the test. For technical assistances, please call 1-646-930-7373, Ext. (751).
5. Due to the risk of false positive result, confirmation of positive result should be considered using a second, different serology test.

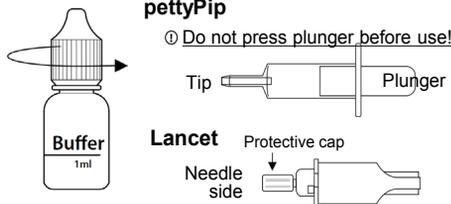
## Preparation before Test

- Test components should be brought to room temperature for 30 minutes before testing.
- Test should not be used beyond its expiration date.

- 1 Carefully read the Quick Reference Instructions for using SGTi-flex COVID-19 IgG.
- 2 Open the cassette pouch and place on the flat surface. Use the test cassette immediately after opening the pouch.



- 3 Remove cap of buffer bottle and set it aside. Prepare a lancet, alcohol swab, pettyPip.



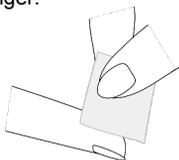
## Test Procedure

- 4 Before fingerstick, lower the arm to allow for better blood circulation to the finger.

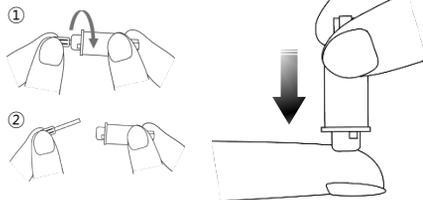


## Test Procedure

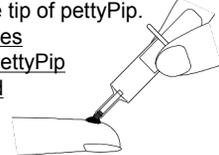
- 5 Use the alcohol swab to clean the puncture site. Allow to dry.  
Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.



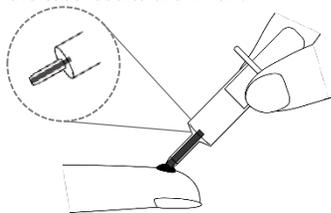
- 6 Turn the protective cap clockwise to remove it. **Never pluck away the protective cap.** Push the sterile lancet firmly against the puncture site.



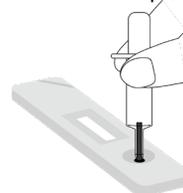
- 7 Place your fingers under the wing of the pettyPip and hold it horizontally. Take care not to cover the vent hole of the Plunger. Make the blood drop form at the fingertip, then while holding the pettyPip tilted at an angle, touch the blood drop with the tip of pettyPip. **When the tip touches a blood drop, the pettyPip fills itself with blood.**



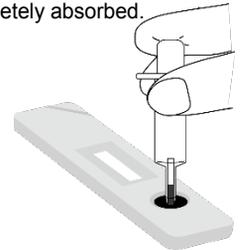
- 8 Please wait until the tip is completely filled with blood.  
⊗ If the blood is not completely filled, the test results are invalid.



- 9 Grip the pettyPip vertical to the sample well with the end of tip touching the surface of sample well. When the end of the tip touches the surface, blood begins to be absorbed into the sample well.



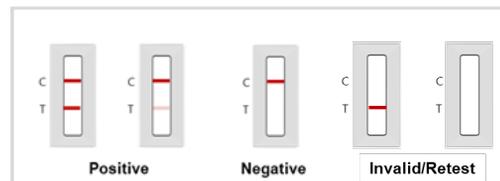
- 10 If blood remains in the tip, push the plunger slowly so that all blood is completely absorbed.



- 11 When blood is added, immediately add 3 drops of buffer onto the sample well of the Test Cassette. Squeeze the tube lightly to allow the drops to come out.



- 12 Read the results after 10 min. The results are invalid after 30 min.  
⊗ Do not read before 10 min.  
⊗ Do not read after 30 min.



- ⊗ The color intensity in the test line will vary. Any faint colored line in the test line should be considered as positive.
- ⊗ If control line fails to appear, the result is invalid and retest with a new Test Cassette.

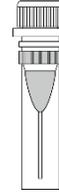
# Quick Reference Instructions of SGTi-flex COVID-19 IgG Control

## Preparation before Test

– Test components should be brought to room temperature for 30 minutes before testing

- 1 Carefully read the Quick Reference Instructions for using SGTi-flex COVID-19 IgG Control.
  - SGTi-flex COVID-19 IgG Positive control
  - SGTi-flex COVID-19 IgG Negative control

- 2 Allow this product to reach room temperature.  
Gently mix by tapping the tube before use.

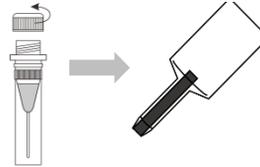


## Test Procedure

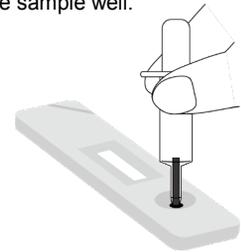
- 3 Open the cassette pouch and place on the flat surface. Use the test cassette immediately after opening the pouch.  
Remove cap of buffer bottle and set it aside.



- 4 Remove cap of positive control or negative control and set it aside. While holding the pettyPip tilted at an angle, touch the control solution with the tip of pettyPip. When the tip touches the control solution, the pettyPip is filled with the control solution.



- 5 Grip the pettyPip vertical to the sample well with the end of tip touching the surface of sample well. When the end of the tip touches the surface, control solution begins to be absorbed into the sample well.



- 6 Immediately add 3 drops of buffer onto the sample well of the Test Cassette. Squeeze the tube lightly to allow the drops to come out.

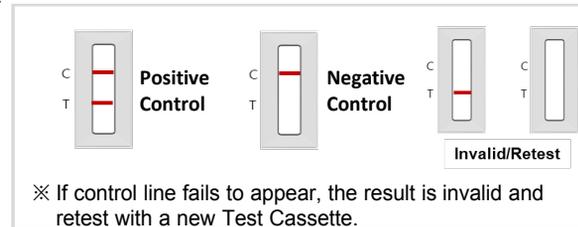


- 7 Read the results after 10 min. The results are invalid after 30 min.

※ Do not read before 10 min.  
※ Do not read after 30 min.



### Expected Results



# SGTi-flex COVID-19 IgG Control



Cat. No: COVC001E

## ▶ INTENDED USE

SGTi-flex COVID-19 IgG Control is intended to be used for *in vitro* diagnostic use in the quality control of SGTi-flex COVID-19 IgG kit. **For *in vitro* diagnostic use.**

## ▶ SUMMARY

The controls in this kit are to be used as quality control for SGTi-flex COVID-19 IgG assay. The purpose of quality control is to ensure proper performance of the SGTi-flex COVID-19 IgG test.

## ▶ SAFETY PRECAUTIONS AND WARNINGS

- √ For *in vitro* diagnostic use.
- √ For laboratory/ professional use only.
- √ For use under Emergency Use Authorization only.
- √ These controls are used with the SGTi-flex COVID-19 IgG. This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- √ This product is authorized for use with a test authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- √ The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- √ SGTi-flex COVID-19 IgG Control is only available for use with the SGTi-flex COVID-19 IgG Kit.
- √ This control is provided for quality assurance only and must not be used for calibration.
- √ This control should not be used past the expiration date.
- √ If microbial contamination or excessive turbidity is suspected, the control should be discarded, and a new control vial should be used.
- √ After use, any residual material should **not be returned** to the original control vial.
- √ Do not pipette by mouth. Wear protective clothing and gloves when handling this product.
- √ Caution should be used when handling this product to prevent splashing. Wear appropriate eye/face protection when using this product to protect from splashes.
- √ The preparation contains material of human origin. It has been tested and found negative for HBsAg, anti-HIV and HCV RNA. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health.
- √ It should be used and discarded according to your own laboratory's safety procedures.

## ▶ STORAGE AND STABILITY

- √ UNOPENED: Store at +2 to +8 °C. Stable until expiration date on the label.
- √ OPENED: Store at +2 to +8 °C. Once opened, SGTi-flex COVID-19 IgG Control is stable for 30 days when stored at +2 to +8 °C in the absence of contamination.

## ▶ MATERIALS SUPPLIED

**This control is prepared from processed human plasma or serum.**

- √ SGTi-flex COVID-19 IgG Positive control .... 1 x 0.1mL
- √ SGTi-flex COVID-19 IgG Negative control .. 1 x 0.1mL
- √ Instructions for Use ..... 1

## ▶ PREPARATION FOR USE

1. The controls are to be used according to the instruction for use for the SGTi-flex COVID-19 IgG test kit. Sample volumes and test procedures are as described in the instructions for use for the SGTi-flex COVID-19 IgG test kit.
2. Prior to use, allow this product to reach room temperature.
3. Mix contents by gentle vortex and spin down the control.
4. Avoid microbial contamination when opening and dispensing from the tube.
5. Dispense 10 uL of this product using a pipette or the full volume collected using the pettyPip from tube.
6. After each use, return this product to refrigerated (2 to 8°C) storage.

## ▶ EXPECTED RESULTS

- √ The result for the control should show the expected results when tested using SGTi-flex COVID-19 IgG. If they do not, the assay should be repeated using a new control or SGTi-flex COVID-19 IgG Kit.
- √ If test is invalid, both controls must be retested with another device.

	Expected results		
	C Line	T Line	Result
SGTi-flex COVID-19 IgG Negative control	+	-	Negative
SGTi-flex COVID-19 IgG Positive control	+	+	Positive

► EXPLANATION OF SYMBOLS USED ON PACKAGE

	<i>In vitro</i> diagnostic medical device
	Consult instructions for use.
	Store between 2°C and 8°C
	Caution, consult accompanying documents
	Batch code
	Use by
	Catalogue number
	Manufacturer
	Biological Risks

**Manufacturer:**

**SUGENTECH, INC.**

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

**Made in Korea**

Rev.No. IS310E-03/2021.10.29