COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) Instruction for Use

REF **Cat: GCCOV-402a**

IVD ***In Vitro* Diagnostic Medical Device**

For Emergency Authorization Use (EUA) only
For *in vitro* diagnostic use only
For prescription use only

INTENDED USE

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood, plasma from anticoagulated blood (Li+ heparin, K2EDTA and sodium citrate), or serum. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate or high complexity tests.

Results are for the detection of SARS CoV-2 antibodies. IgM and 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 positive results to the appropriate public health authorities.

The sensitivity of COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) early after infection in 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 COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 or IgM assay.

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is only for use under the Food and Drug Administration's Emergency Use Authorization.

INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals.4 The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) - are zoonotic in origin and have been linked to sometimes fatal illness. IgG and IgM antibodies to 2019 Novel Coronavirus can be detected with 1-3 weeks after exposure. The seroconversion rate and the antibody levels increased rapidly during the first two weeks.

PRINCIPLE

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The test uses anti-human IgM antibody (test line IgM) , anti-human IgG (test line IgG) and rabbit IgG (control line C) immobilized on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens (SARS-CoV-2 Spike S1 antigen) conjugated with colloid gold (COVID-19 conjugates). When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making an antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anti-human IgG) the complex is trapped forming a burgundy colored band which confirms a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result.

To serve as a procedural control, a colored line will always change from blue to red in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED

25 sealed pouches each containing a test cassette, a dropper and a desiccant
1 Buffer
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Centrifuge (for plasma only)
3. Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Use of this product is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests.
3. This test should be performed at 15 to 30℃. If stored refrigerated, ensure that the pouch and buffer are brought to operating temperature before performing testing.
4. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
5. Do not use it if the tube/pouch is damaged or broken.
6. Test is for single use only. Do not re-use under any circumstances.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
9. Humidity and temperature can adversely affect results (especially with an RH over 80%). Testing must be performed within one hour after opening the pouch .
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.
11. Practice a few times the use of the mini dropper prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by pipette capable to deliver 5 µL of volume.

12. This test has not been FDA cleared or approved.

13. This test has been authorized by FDA under an EUA for use by authorized laboratories.

14. This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

15. This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

SPECIMEN COLLECTION

1. COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using either venous whole blood, serum or plasma.

2. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) test has not been evaluated with fingerstick specimens. Use of this test with fingerstick blood is not recommended.

3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C for up to one month. Whole blood specimens must be stored at 2-8˚C if not tested immediately and tested within 24 hours of collection. Do not freeze whole blood specimens.

5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens cannot be frozen and thawed more than 3 times.

6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Results must be obtained within one hour.

2. Place the test device on a clean and level surface.

For Serum or Plasma Specimens:

With a 5 µL mini plastic dropper provided, draw serum/plasma specimen to exceed the specimen line as showed in the following image and then transfer drawn serum/plasma specimen into the sample well (S). Then add 2 drops (about 80 µL) of sample buffer to the buffer well (B) immediately. Avoid air bubbles.

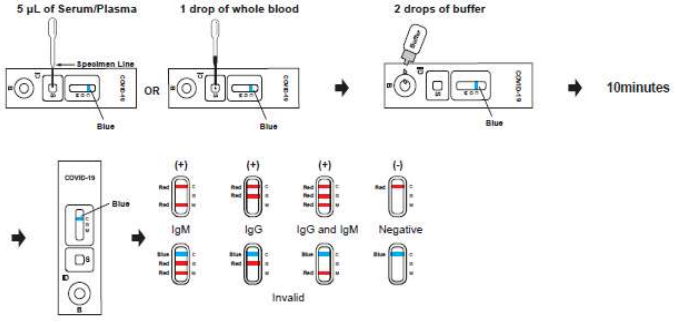
Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by pipette capable to deliver 5 µL of volume.

For Venous Whole Blood Specimen:

Hold the 5 µL mini plastic dropper vertically and transfer 1 drop of whole blood (about 10 µL) to the specimen well (S) of the test device, then add 2 drops (about 80 µL) of sample buffer to the buffer well (B) immediately. Avoid air bubbles.

3. Wait for the colored line(s) to appear. After 2 minutes, if the red color has not moved across the test window or if blood is still present in the specimen well (S), add 1 additional drop of the sample buffer to the buffer well (B).

4. The result should be read in 10 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

NEGATIVE:

The colored line in the control line region (C) changes from blue to red. No line appears in the test line regions M or G. The result is negative.

IgM POSITIVE:

The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region M. The test result indicates the presence of IgM anti-SARS-Cov-2 antibodies.

IgG POSITIVE:

The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region G. The test result indicates the presence of IgG anti-SARS-CoV-2 antibodies

IgG and IgM POSITIVE:

The colored line in the control line region (C) changes from blue to red, and two colored lines appear in test line regions M and G. The test results indicate the presence of IgM and IgG anti-SARS-CoV-2 antibodies.

INVALID:

Control line is partially red, and fails to completely change from blue to red. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Additional controls may be required according to guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations.

LIMITATIONS

For use under an Emergency Use Authorization only.

1. Use of COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is limited to laboratory personnel who have been trained. Not for home use.

2. This product is only used for testing of individual serum, plasma (Li+ heparin, K_2EDTA and sodium citrate), and venous whole blood. Other specimen types have not been evaluated and should not be used with this assay.

3. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particles that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult.

4. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.

5. Reading test results earlier than 10 minutes after the addition of Buffer may yield erroneous results. Do not interpret the result after 15 minutes.

6. This test detects the presence of SARS-CoV-2 IgM/IgG in the specimen and should not be used to diagnose or exclude SARS-CoV-2 infection. Testing with

a molecular diagnostic must be performed to evaluate for active infection in symptomatic individuals.

7. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.

8. 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 adaptive immune response.

9. A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) early after infection is unknown. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.

10. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

11. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is limited to the qualitative detection of antibodies specific for the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen. Neither the quantitative value nor the rate anti-SARS-CoV-2 IgM/IgG concentration can be determined by this qualitative test.

12. The sensitivity of the test is impacted after being open for two hours—the density of T line becomes weak. Testing must be performed within one hour after opening the pouch.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) 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/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

Authorized laboratories using the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) ("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 will include with result reports of your product, 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 will use your product as outlined in the Instructions for Use. 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 will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

5. Authorized laboratories will 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 Healgen Scientific LLC (info@healgen.us) any suspected occurrence of false reactive or false non-reactive 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 immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your 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. Authorized distributors, and authorized laboratories using your product will 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, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests" as "authorized laboratories."

PERFORMANCE CHARACTERISTICS

1. Assay Clinical Performance

Study 1: Healgen Clinical Agreement Validation

The clinical performance of the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was evaluated by testing a total of 191 plasma (K2EDTA) clinical samples—90 positive samples and 101 negative samples) from individual patients exhibiting pneumonia, respiratory symptoms and fever etc. Testing was performed at two sites in China from January to mid-March 2020. COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) results for IgM and IgG detection were compared to the results of RT-PCR assays for SARS-CoV-2 from oropharyngeal swabs (Site #1) and sputum (Site #2). At Site #1, 61 retrospective specimens and 4 prospective specimens were included in the study. At Site #2, 95 retrospective specimens and 31 prospective specimens were included in the study. The time from RT-PCR result to collection of specimens (plasma) ranged from 15-45 days (Site #1) and 0-38 days (Site #2). The time from collection of specimens (plasma) from each individual to testing ranged from 12-23 days (Site #1) and 3-29 days (Site #2). Overall study results are shown in below (**Table 1**).

Table 1: Assay Clinical Study Results

Method			RT-PCR		Subtotal
			Positive	Negative	
COVID-19 IgG/IgM Rapid Test Cassette	Positive	IgG+/IgM+	78	0	78
		IgG-/IgM+	0	1	1
		IgG+/IgM-	9	2	11
	Negative	IgG-/IgM-	3	98	101
Subtotal			90	101	191

IgG

Positive Percent agreement (PPA): 96.7% (87/90) (95%CI: 90.7% ~ 98.9%)
Negative Percent agreement (NPA): 98.0% (99/101) (95%CI: 93.1%~99.5%)

IgM

Positive Percent agreement (PPA): 86.7% (78/90) (95%CI: 78.1%~92.2%)
Negative Percent agreement (NPA): 99.0% (100/101) (95%CI: 94.6%~99.8%)

Overall (either IgG+ or IgM+)

Positive Percent agreement (PPA): 96.7% (87/90) (95%CI: 90.7% ~ 98.9%)

Negative Percent agreement (NPA): 97.0% (98/101) (95%CI: 91.6% ~ 99.0%)

Study 2: Independent Clinical Agreement Validation

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 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 COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma). 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 one lot of the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma). Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).

For evaluation of cross-reactivity with HIV+, it was evaluated 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.

Table 2. Summary Results

	Comparator Method	

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)		Positive (IgM/IgG) +	Negative (IgM/IgG)-	Negative, HIV+	Total
Positive	IgM +/ IgG+	29	0	0	29
	IgM+, IgG-	1	0	0	1
	IgM-, IgG+	0	2	0	2
Negative	IgM- / IgG)-	0	68	10	78
Total (n=110)		30	70	10	110

Table 3. Summary Statistics

Measure	Estimate	Confidence Interval
IgM Sensitivity	100% (30/30)	(88.7%; 100%)
IgG Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
(IgM+ or IgG+; Total) Sensitivity (PPA)	100% (30/30)	(88.7%; 100%)
(IgM-/IgG-; Total) Specificity (NPA)	97.5% (78/80)	(91.3%; 99.3%)
Cross-reactivity with HIV+	0% (0/10) not detected	

Limitations of Study 2

- Samples were not randomly selected, and sensitivity and specificity estimates may not be indicative of the real-world performance of the device.
- These results are based on serum and plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.
- Information about anticoagulants used is not known.
- 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.

2. Assay Cross Reactivity

Cross-reactivity of the COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) was evaluated using serum samples which contain antibodies to the pathogens listed below. A total of 120 specimens from 24 different categories were tested. No false Positives were found with the following (**Table 4**):

Table 4: Assay Cross Reactivity Results

Sample Categories	Tested Sample Number
Influenza A virus IgG	5
Influenza B virus IgG	5
Respiratory syncytial virus IgG	5
Adenovirus IgG	5
Rhinovirus IgG	5
Human metapneumovirus IgG	5
Mycoplasma pneumoniae IgG	5
Chlamydia pneumoniae IgG	5
HCV IgG	5
Haemophilus influenza IgG	5
HBV core antibody IgG	5
Bacterial pneumonia	5
Influenza A virus IgM	5
Influenza B virus IgM	5
Respiratory syncytial virus IgM	5
Adenovirus IgM	5
Rhinovirus IgM	5
Human metapneumovirus IgM	5
Mycoplasma pneumoniae IgM	5
Chlamydia pneumoniae IgM	5
HCV IgM	5
Haemophilus influenza IgM	5
HBV core antibody IgM	5
Antinuclear antibodies (ANA)	5

3. Potentially Endogenous Interfering Substances

Low titer COVID-19 antibody positive serum samples and COVID-19 antibody negative serum samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false Positives or false Negatives were found with the following (**Table 5**).

Table 5: Assay Interfering Substance Results

Name of Substances	Concentration
Ascorbic Acid	20 mg/dL
Hemoglobin	1000 mg/dL
Bilirubin	10 mg/dL
Albumin	2000 mg/dL
Triglyceride	500 mg/dL

4. Class Specificity

A Class Specificity Study was conducted to determine the impact of DTT treatment on the detection of IgM and/or IgG positive samples by the COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma). IgM samples treated with DTT showed no visible IgM line with the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma), whereas the IgG samples were not affected by DTT treatment. Test results with IgM positive samples after DTT treatment showed 100% agreement to the expected results. Test results with IgG positive samples after DTT treatment showed 100% agreement to the expected results. The results observed confirm the class specificity of the test.

5. Study of: Venous Whole Blood and Plasma Specimens with Anticoagulants

To evaluate if various anticoagulants have an effect on the results of the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma), negative plasma specimens and positive plasma specimens (with 2 different low positive IgG and IgM concentrations) were mixed with three different anticoagulants (lithium heparin, EDTA, sodium citrate) in separate tubes and tested in triplicate in plasma only or spiked into venous whole blood. IgG and IgM were correctly identified in all spiked whole blood specimens by the test, similar to results obtained with the plasma only specimens. There was a 100% concordance rate with expected results when IgM or IgG positive venous whole blood specimens or plasma specimens were tested with anticoagulants.

REFERENCE:

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81: 85-164.
2. Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013: 825-58.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24: 490-502.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.

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	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C~30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#