HEALGEN®

COVID-19 IgG/IgM Rapid Test

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma.

Red Byrd
Laboratory Solutions

Red Byrd Laboratory Solutions
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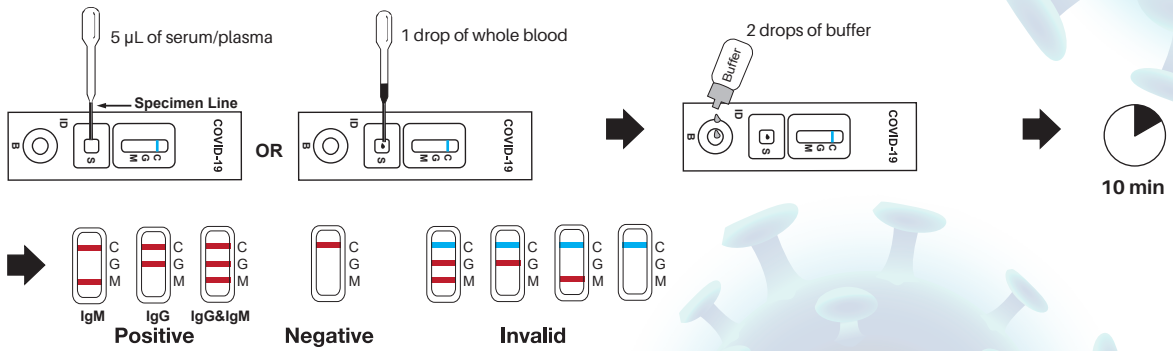
Key Facts of COVID-19

- The 2019 new coronavirus pneumonia(NCP), or"COVID-19", was discovered for the 2019 Wuhan Viral Pneumonia case in China and was named by the world Health Organization on January 12, 2020.
- For confirmed coronavirus disease 2019 (COVID-19) cases, reported illnesses have ranged from mild symptoms to severe illness and death. Symptoms can include:
  - Fever
  - Cough
  - Shortness of breath
- The virus is thought to spread mainly from person-to-person.
  - Between people who are in close contact with one another (within about 6 feet).
  - Via respiratory droplets produced when an infected person coughs or sneezes.
  - These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.

Features & Benefits

- Fast results as soon as 2-10 minutes
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- Little specimens, only 5 μL of serum/plasma or 10 μL of whole blood specimens
- All necessary reagents provided & no equipment needed
- High sensitivity and specificity

Test Procedure & Interpretation



Ordering Information

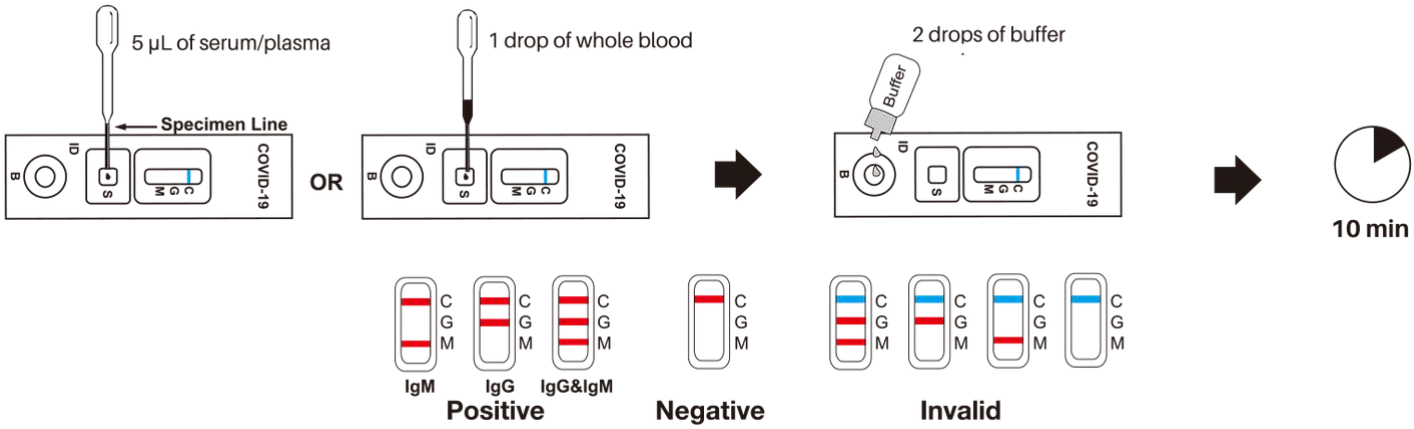
Product Description	Specimen	Catalog No.	Format	Kit Size
COVID-19 IgG/IgM Rapid Test	Whole Blood/Serum/Plasma	GCCOV-402a	Cassette	25 Tests/Kit

INSTRUCTIONS: Healgen COVID-19 IgG/IgM Rapid Test

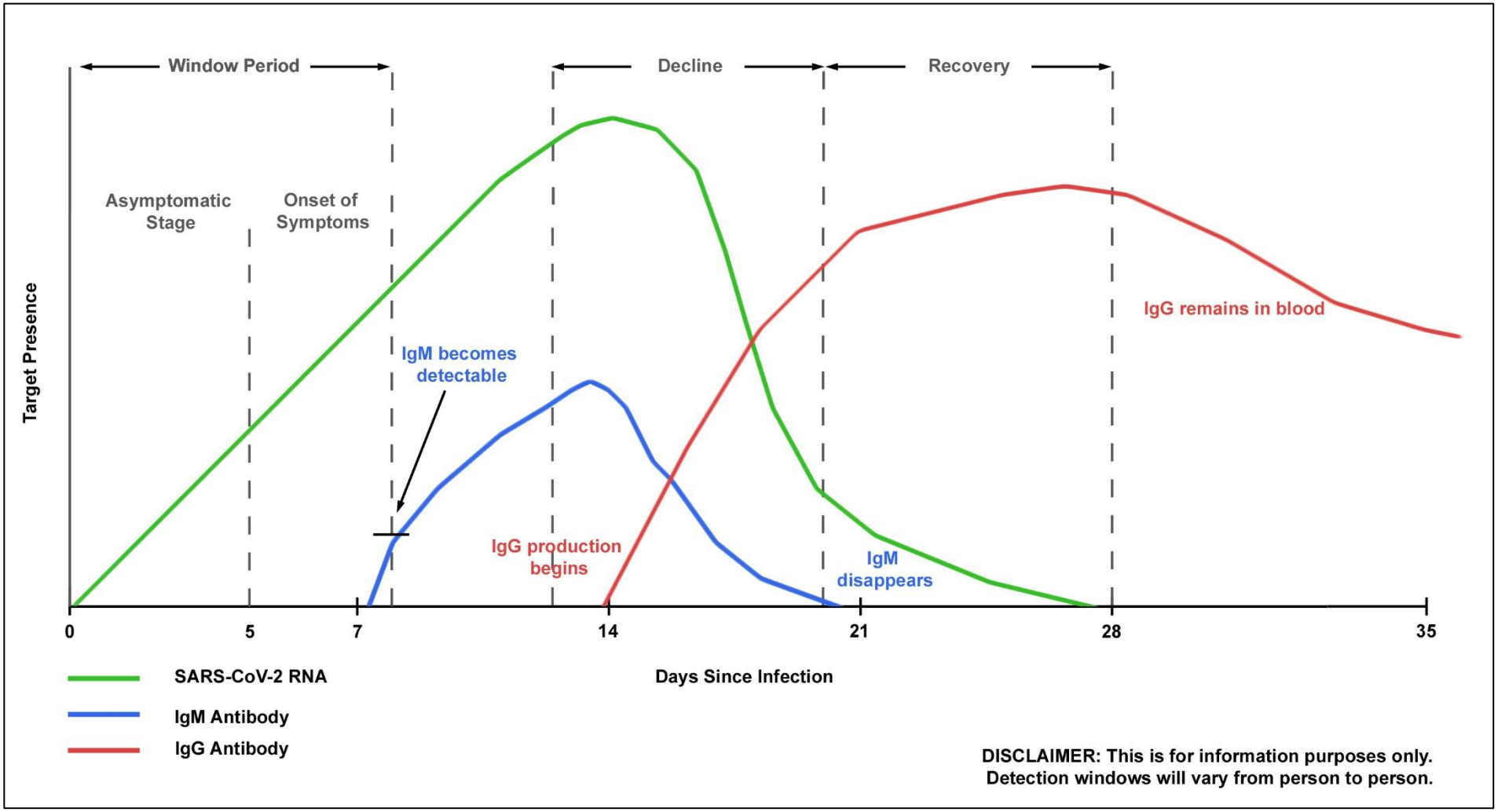
This product is intended for professional use and not for home use. Results from antibody testing are presumptive and should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

A negative result may appear and not correlate with symptoms. A medical professional is required to consider various factors, including confirmation testing, when receiving a presumptive result.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible.
2. Lay device on flat surface and add specimen (see specific instructions for each specimen type below):
   A) For Serum or Plasma Specimen: With the plastic dropper provided, draw serum/plasma specimen to exceed the specimen line, as shown in the diagram below. Hold the dropper vertically and transfer drawn serum/plasma specimen into the sample well (S). Immediately add 2 drops (about 80 µL) of sample buffer to the buffer well (B) ensuring that buffer vial tip does not touch the sample. Avoid air bubbles.
   B) For Whole Blood Specimen: Hold the plastic dropper vertically and transfer 1 drop of whole blood (about 10 µL) to the sample well (S) of the test device. Immediately add 2 drops (about 80 µL) of sample buffer to the buffer well (B) ensuring that buffer vial tip does not touch the sample. Avoid air bubbles.
3. Wait for the control line (C) to change from blue to a red color. If, after 2 minutes, the sample has not moved across the test window or if blood is still present in the sample well (S), add 1 additional drop of sample buffer to the buffer well (B).
4. The results should be read in 10 minutes. Do not interpret the result after 15 minutes.



COVID-19 Stages, Target Timelines and Clinical Significance



Test Results			Clinical Significance
RNA	IgM	IgG	
+	-	-	Patient may be in the **window period** of the infection
+	+	-	Patient may be in the **early stage** of infection
+	+	+	Patient is in the **active phase** of infection
+	-	+	Patient may be in the **late or recurrent stage** of infection
-	-	+	Patient may have had a **past infection**, and has recovered

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

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INTENDED USE

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) must be confirmed with clinical findings and alternative testing method(s) for example molecular testing such as Real- Time PCR. IgM antibodies will appear within blood as soon as 3-5 days for symptomatic patients and 7 days for asymptomatic patients. IgG antibodies appear in blood within 2 weeks after infection. Over time blood concentrations of both IgM and IgG decrease, where IgM will become undetectable, but IgG will remain elevated.

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..

The test has been validated but independent review by FDA is not yet complete

INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds 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. 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, some patients with negative nucleic acid findings could be screened out through antibody testing. Combining RNA and antibody tests can significantly raise the sensitivity for detecting COVID 19 in infected patients. Antibody testing can be an important tool to supplement molecular methods such as RNA detection.

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 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 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 confirm 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, dropper, and desiccant)
1 Buffer vial
1 package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Gloves
3. Centrifuge (for plasma and serum)
4. Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C/36-86°F). 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. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the vial/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. AVOID CROSS CONTAMINATION: Do not allow buffer vial tip to touch specimen in device sample well.
6.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.
7. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
8. Humidity and temperature can adversely affect results.
9. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

SPECIMEN COLLECTION

1. COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using either whole blood, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. 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/ 36-46°F for up to 3 days. For long term storage, specimens should be kept below -20°C / -4°F. Whole blood collected by venipuncture should be stored at 2-8°C/ 36-46°F if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. 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 and buffer to equilibrate to room temperature (15-30°C / 59-86°F) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible.

2. Lay device on flat surface and add specimen

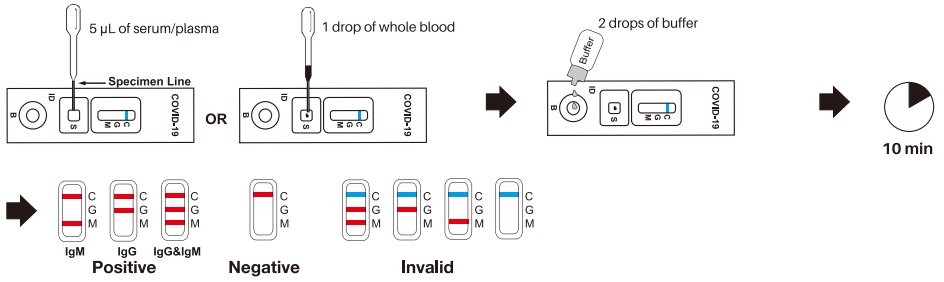
For Serum or Plasma Specimens:
With a 5 µL mini plastic dropper provided, draw serum/plasma specimen to exceed the specimen line as shown in the following image and then transfer drawn serum/plasma specimen into the sample well (S). Immediately add 2 drops (about 80 µL) of buffer to the buffer well (B) ensuring that buffer vial tip does not touch the specimen. Avoid air bubbles.

For Whole Blood Specimen:
Hold the 5 µL mini plastic dropper vertically and transfer 1 drop of whole blood (about 10 µL) to the sample well (S) of the test device, immediately add 2 drops (about 80 µL) of buffer to the buffer well (B) ensuring that buffer vial tip does not touch the specimen. 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 of delivering 5 µL of volume.

3. Wait for the colored line (C) to change from blue to red color. If after 2 minutes, the sample has not moved across the test window or if blood is still present in the sample well (S), add 1 additional drop of the sample buffer to the buffer well (B).

4. The result should be read in 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

Refer to illustration above
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 result is anti-COVID-19 IgM positive.
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 result is anti-COVID-19 IgG positive.
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 result is anti-COVID-19 IgM and IgG positive.
INVALID:
Control line is still completely or partially blue 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.

LIMITATIONS

1. 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.
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. A negative result for an individual subject indicates absence of detectable anti-COVID-19 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19.
4. A negative result can occur if the quantity of the anti-COVID-19 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.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.
7. 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

PERFORMANCE CHARACTERISTICS

Clinical Performance
The COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) has been evaluated with 113 blood samples obtained from patients exhibiting pneumonia or respiratory symptoms. The results were compared to RT-PCR or clinical diagnosis (including chest Computed Tomography and clinical signs etc.) of “Diagnosis and treatment of novel coronavirus pneumonia”.

Regarding the IgM test, the result comparison to RT-PCR.

Method		RT-PCR		Total
		Positive	Negative	
COVID-19 IgG/IgM Rapid Test	Positive	87	0	87
	Negative	12	14	26
Total		99	14	113

Regarding the IgG test, we have counted the positive rate of the 36 of 113 patients during the convalescence period.

Method		Number of patients during the convalescence period	Total
COVID-19 IgG/IgM Rapid Test	Positive	35	35
	Negative	1	1
Total		36	36

The sensitivity of IgM test is 87.9% (87/99) and specificity is 100% (14/14) when compared to RT-PCR.
The sensitivity of IgG test is 97.2% (35/36) during the convalescence period, and specificity is 100% (14/14).

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.

INDEX OF SYMBOLS

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

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REF GCCOV-402a

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