Cellex

CE

REF **Catalog Number：5513C**

IVD **In Vitro Diagnostic**

INTENDED USE

The Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a lateral flow immunoassay for the qualitative detection of 2019 novel coronavirus (SARS-CoV-2) in serum、plasma or whole blood specimens. It is intended to be used as a screening test and aid in the diagnosis of SARS-CoV-2 viral infections. Any reactive specimen with the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test must be confirmed with alternative testing method(s).
For in vitro diagnostic use only. For professional use only.

SUMMARY AND EXPLANATION OF THE TEST

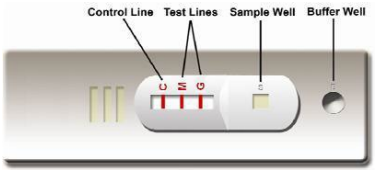
Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). SARS-CoV-2 is a new strain that has not been previously identified in humans. Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Detailed investigations found that SARS-CoV was transmitted from civet cats to humans and MERS-CoV from dromedary camels to humans. Several known coronaviruses are circulating in animals that have not yet infected humans.

2019 Novel Coronavirus (SARS-CoV-2) is a virus (more specifically, a coronavirus) identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Patients with SARS-CoV-2 have reportedly had mild to severe respiratory illness with symptoms of: fever, cough, shortness of breath. The rapid test has become an urgent need for screening patients.

The qSARS-CoV-2 IgG/IgM Rapid Test is intended to meet all requirements for yielding rapid, easily read, qualitative results for the main purpose of SARS-CoV-2 infection diagnosis.

TEST PRINCIPLE

The Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a lateral flow chromatographic immunoassay which can detect antibodies against the SARS-CoV-2 virus. The test cassette consists of: 1) a burgundy colored conjugate pad containing SARS-CoV-2 recombinant antigens conjugated with colloidal gold (SARS-CoV-2 conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing anti human IgG, M band is coated with anti human IgM, and the C band is pre-coated with goat anti rabbit IgG.



When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action along the cassette. IgG anti-SARS-CoV-2 virus, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the anti human IgG band, forming a burgundy colored G band, indicating a SARS-CoV-2 virus IgG positive test result suggesting a secondary CoV infection or previous CoV infection.

IgM anti-SARS-CoV-2 virus, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the anti human IgM band, forming a burgundy colored M band, indicating a SARS-CoV-2 virus IgM positive test result suggesting a fresh primary infection.

If both G band and M band are visible, the test result suggests late primary or early secondary SARS-CoV-2 infection. Absence of both test bands (G and M) suggests a negative result.

The test contains an internal control (C band) which should exhibit a burgundy colored band of goat anti rabbit IgG/rabbit IgG-gold conjugate immunocomplex regardless of the color development on any of the test bands(G and M). Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS

Reagents and Materials Provided

1. 25 test cassettes
2. 25 tubes (contain sample buffer)
3. 25 Capillary tubes
4. Leaflet with instruction for use

Composition and Concentration

Conjugate pad	Monoclonal Anti-SARS-CoV-2 antigen conjugated on the membrane
G line	Anti human IgG
M line	Anti human IgM
C line	Goat anti rabbit IgG
Sample Buffer	0.01M PBS; PH 7.4

Material Required But Not Provided

1. Transfer Pipette Set
2. Timer
3. Specimen Collection Containers

WARNINGS AND PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15℃-30℃) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
8. Dispose of all specimens and materials used to perform the test as biohazardous waste.
9. Handle the Negative and Positive Control in the same manner as patient specimens.
10. The testing results should be read within 15 minutes after a specimen is applied to the sample well. Results read after 15 minutes may give erroneous results.
11. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

STORAGE AND STABILITY

1. Store the detector buffer at 4–30℃. The buffer is stable up to 30 months.
2. Store Helios SARS-CoV-2 IgG/IgM Rapid Test Cassette at 4–30℃, shelf life is up to 18 months.
3. If stored at 2℃-8℃, ensure that the test device is brought to 15℃-30℃ before opening.
4. Do not freeze the kit or expose the kit over 30℃.

SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

Serum

1.Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. If specimens are not tested immediately store at 2°C-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Whole Blood

Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Do not use any hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2℃-8℃) if not tested immediately. The specimens must be tested within 24 hours of collection.

TEST PROCEDURE

Step 1: Bring the specimen and test components to room temperature. Mix the specimen well prior to assay once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen's ID number.

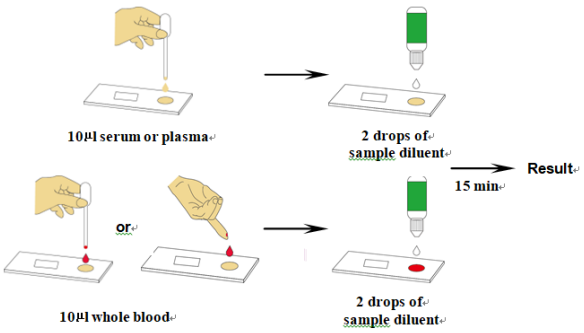
Step 4: Fill the capillary tube with the serum, plasma or whole blood not to exceed the specimen line as shown in the following image. The volume of the specimen is around 10μL. For better precision, transfer specimen by a pipette capable of delivering 10μL of volume.

Holding the capillary tube vertically, dispense the entire specimen into the center of the sample well (S well) making sure that there are no air bubbles.

Then add 2 drops (about 70-100 μL) of Sample Diluent immediately into the sample well (S well).

Step 5: Set up a timer.

Step 6: Read the result in 15 minutes.



Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result

QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. If the C line does not develop, review the whole procedure and repeat test with a new device.

2. External Control: Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:

A. New operator uses the kit, prior to performing testing of specimens.

B. A new lot of test kits is used.

C. A new shipment of kits is used.

D. The temperature used during storage of the kit falls outside of 2-30℃.

E. The temperature of the test area falls outside of 15 -30℃.

F. To verify a higher than expected frequency of positive or negative results.

G. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT:** If only the C band is present, the absence of any burgundy color in the both test bands (G and M) indicates that no anti-SARS-CoV-2 virus antibodies are detected. The result is negative or non-reactive.

2. **POSITIVE RESULT:**

2.1 In addition to the presence of C band, if only G band is developed, the test result indicates for the presence of IgG anti- SARS-CoV-2 virus; the result is IgG positive or reactive, suggesting late stage primary, early secondary or previous infection.

2.2 In addition to the presence of C band, if only M band is developed, the test indicates for the presence of IgM anti-SARS-CoV-2 virus. The result is IgM positive or reactive, suggesting fresh primary SARS-CoV-2 virus infection.

2.3 In addition to the presence of C band, both G and M bands are developed, the test indicates for the presence of IgG and IgM anti-SARS-CoV-2 virus. The result is IgG and IgM positive or reactive, suggesting current primary or early secondary SARS-CoV-2 virus infection.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

3. **INVALID:** If the C line is not developed, the assay is invalid regardless of color development of the T band as indicated below. Repeat the assay with a new device.

CLINICAL PERFORMANCE

A total of 40 patient samples from susceptible subjects were tested by the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test and by a commercial PCR. Comparison for all subjects is shown in the following table:

CLINICAL PERFORMANCE		Reference Method		Total
		+	-	
Test Method	+	24	1	25
	-	6	9	15
Total		30	10	40

Relative Sensitivity: 80%, Relative Specificity: 90%, Overall Agreement: 82.5%

LIMITATIONS OF THE PROCEDURE

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus in the serum or 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.

2. The Cellex qSARS-CoV-2 Cassette Rapid Test is limited to the qualitative detection of SARS-CoV-2 virus. The intensity of the test band does not have linear correlation with virus titer in the specimen.

3. A negative or non-reactive result for an individual subject indicates absence of detectable SARS-CoV-2 virus. However, a negative or non-reactive result does not preclude the possibility of SARS-CoV-2 virus infection.

4. A negative or non-reactive result can occur if the quantity of the SARS-CoV-2 virus present in the specimen is below the detection limits of the assay, or if the virus that are detected are not present in the swab specimen sampled, or the viruses have undergone minor amino acid mutation in the epitope recognized by the antibody utilized in the test.

5. If symptoms persist, while the result from the Cellex qSARS-CoV-2 Cassette Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.

6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Index of CE Symbols

Consult instructions for use		For in vitro diagnostic use only		Use by	
REF	Catalog #	LOT	Lot Number	Σ	Tests per kit
2℃ 30℃	Store between 2-30°C	EC REP	Authorized Representative		Do not reuse
	Manufacturer		Date of manufacture		

Cellex, Inc.
76 TW Alexander Drive,
Research Triangle Park, NC
27709-0002, USA
Tel: 1-919-314-5535,
Fax:1-919-314-5336,
E-mail: info@cellex.us

EC REP **MedPath GmbH**
Mies-van-der-Rohe-strasse 8, 80807
Munich, Germany

DR5513 Rev. A00
English version