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 qualitative detection of antibodies to 2019 novel coronavirus (SARS-CoV-2) in serum、plasma or whole blood specimens. It is intended to be used as an 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 prescription use only. For in vitro diagnostic use only. For emergency use, authorization use only.

## SUMMARY AND EXPLANATION OF THE TEST

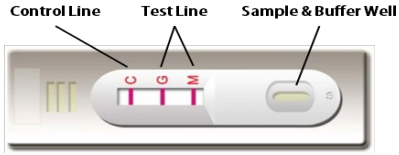
Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). SARS-CoV-2 is a new strain that has not been previously identified in humans. 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 infected humans yet.

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 reported with SARS-CoV-2 viral infections had mild to severe respiratory illness with symptoms of: fever, cough, shortness of breath. There is an urgent need for rapid tests to manage the ongoing pandemic.

The qSARS-CoV-2 IgG/IgM Rapid Test is intended for rapid and qualitative detection of antibodies indicative of SARS-CoV-2 infection and used as an aid for diagnosis of SARS-CoV-2 infection.

## 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 an IgG line (G Line) coated with anti-human IgG, an IgM line (M Line) coated with anti-human IgM, and the C line (C Line) 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. The anti-SARS-CoV-2 virus IgG, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the anti-human IgG line, forming a burgundy colored G line, indicating a SARS-CoV-2 virus IgG positive test result suggesting a secondary infection or previous 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 line, forming a burgundy colored M line, indicating a SARS-CoV-2 virus IgM positive test result suggesting a fresh primary infection.

If both G line and M line 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 line) 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 again.

## REAGENTS AND MATERIALS

**Reagents and Materials Provided**

There are three kit sizes. Their kit component configurations are provided below:

| | Kit Size (#of Test) | 1 | 25 | 50 | 100 |
|---|---|---|---|---|---|
| Components | Test Cassette (#) | 1 | 25 | 50 | 100 |
| | Sample Diluent (# of Bottle) | 1 | 1 | 1 | 1 |
| | Transfer pipette (#) | 1 | 25 | 50 | 100 |
| | IFU Leaflet | 1 | 1 | 1 | 1 |

**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. Once opened, the cassettes should be used within 2 hours.
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 between 15 and 20 minutes after a specimen is applied to the sample well. Results read after 20 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 sample diluent at 4-30℃. The buffer is stable up to 30 months.
2. Store Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test at 4-30℃; shelf life is up to 30 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 store 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, and then separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.
5. 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.

For frozen samples, 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:** For fresh sample, begin with Step 2. For frozen samples, bring the specimens 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.

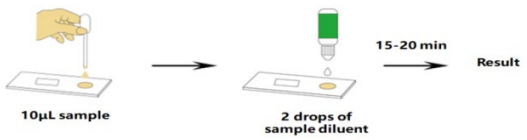
**Step 3:** Label the device with specimen ID number.

**Step 4:** Using a transfer pipette, transfer serum, plasma or whole blood not to exceed the specimen line. The volume of the specimen is around 10μL. For better precision, transfer specimen by a pipette capable of delivering 10μL of volume.

Holding the transfer pipette 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 15-20 minutes.

Don't read result after 20 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.

H. A new test environment is used (e.g., natural light vs. artificial light).

When performed properly, in addition to the presence of C band, no line should be visible for the negative control and the G or M or both lines are visible for the positive control. Additional controls may be qualified and tested by the user.

## INTERPRETATION OF ASSAY RESULT

**2. 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.


**3. POSITIVE RESULT:**

3.1 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.


3.2 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.


3.3 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.

**4. 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


## PERFORMANCE CHARACTERISTICS

### 1. Clinical Performance

**1.1 Testing of clinical specimens**

Ninety-eight (98) positive serum or plasma samples collected from individuals who were tested positive with an RT-PCR method for SARS-CoV-2 infection and were quarantined in a makeshift hospital were used in this study.

These patients, at the time of sample collected, exhibited mild or no clinical symptoms. These samples, along with 180 negative serum or plasma samples collected prior to September 2019, were coded and tested together with the qSARS-CoV-2 IgG/IgM Rapid Test. Of the 98 positive samples, ninety-one (91) were tested positive with IgG or IgM or both bands. Of the 180 negative samples, one hundred seventy four (174) were tested negative.

Another 30 samples were collected from hospitalized individuals who were clinically confirmed positive and exhibited severe symptoms. These samples, along with 70 negative serum or plasma samples collected prior to September 2019, were coded and tested together with the qSARS-CoV-2 IgG/IgM Rapid Test. Of the 30 positive samples, twenty-nine (29) were tested positive with IgG or IgM or both bands. Of the 70 negative samples, sixty-five (65) were tested negative.

Taken together, the qSARS-CoV-2 IgG/IgM Rapid Test had a sensitivity and specificity of 93.75% (95% CI: 88.06-97.26%) and 96.40% (95% CI: 92.26-97.78%), respectively.

| qSARS-CoV-2 IgG/IgM Rapid Test | | | | | | |
|---|---|---|---|---|---|---|
| N/A | | IgG+ IgM+ | IgG- IgM+ | IgG+ IgM- | IgG- IgM- | Sub |
| Clinical Status | Pos. | 65 | 46 | 9 | 8 | 128 |
| | Neg. | 0 | 5 | 4 | 241 | 250 |
| Subtotal | | 65 | 51 | 13 | 249 | 378 |

**1.2 Testing of Specimens that were RT-PCR negative but clinical positive**

Fifty (50) specimens collected from suspected patients who were RT-PCR negative but had history of being exposed and showed clinical symptoms consistent with an infection were tested with the qSARS-CoV-2 IgG/IgM Rapid Test. Of these samples, twelve (12) or 24% were positive with the test.

**1.3 Whole blood specimens spiked with positive samples**

Fifty negative whole blood samples were spiked with positive serum at 1:100. Another 50 whole blood specimens were spiked with negative serum at same dilution. These 100 specimens were coded and tested with the qSARS-CoV-2 IgG/IgM Rapid Test. All spiked samples were correctly identified by the test except for one of the negative samples, which was tested positive with the test.

### 2. Limit of Detection

Four positive samples were serially diluted, coded and tested in 20 replicates. The most diluted replicates at which 19 or 20 replicates were tested positive for these four samples were 1:60,000, 1:11,000, 1:2000, and 1:500, respectively.

### 3. Assay Cross Reactivity

A low titer sample was diluted 1:100 to a serum or plasma sample containing antibodies reactive to one of following pathogens were tested along with unspiked samples in duplicate. No false positivity or false negativity was found:

Human coronavirus(collected before Oct 2019)
HBV
HCV
HIV-1
HIV-2
Adenovirus
Human Metapneumovirus (hMPV)
Parainfluenza virus 1-4
Influenza A
Influenza B
Enterovirus 71
Respiratory syncytial virus
Rhinovirus
Chlamydia pneumoniae
Streptococcus pneumoniae
Mycobacterium tuberculosis
Mycoplasma pneumoniae
EB Virus

### 4. Potentially Interference Substances

A low titer positive serum sample or negative serum sample was spiked with one of the following substances to specified concentrations and tested in duplicate. No false positivity or false negativity was found:

| | |
|---|---|
| Hemoglobin | 10 mg/mL |
| Bilirubin Conjugated | 0.4 mg/mL |
| Bilirubin Unconjugated | 0.4 mg/mL |
| Triglycerides | 15 mg/mL |
| Cholesterol | 4 mg/mL |
| Human Anti-mouse Antibody | 800 ng/mL |
| Rheumatoid Factor | 2000 IU/mL |

| | |
|---|---|
| Human Serum Albumin | 60 mg/mL |
| Histamine hydrochloride | 4 mg/L |
| α-IFN | 200 mg/L |
| Zanamivir | 1 mg/L |
| Oseltamivir carboxylate | 1 mg/L |
| Abidol | 40 mg/L |
| Levofloxacin | 200 mg/L |
| Ceftriaxone | 400 mg/L |
| Meropenem | 200 mg/L |
| Tobramycin | 10 mg/L |
| Ribavirin | 40 mg/L |
| Human IgG | 8 mg/mL |
| Human IgM | 0.4 mg/mL |

**5. Hook Effects**

Positive samples with titers up to 1:60,000 were found to be reactive when tested with the qSARS-CoV-2 IgG/IgM Rapid Test.

## 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 specific antibodies 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 IgG/IgM Cassette Rapid Test is limited to the qualitative detection of antibodies specific for SARS-CoV-2 virus. The intensity of the test line does not necessarily have linear correlation with virus titer in the specimen.
3. A negative or non-reactive result for an individual subject indicates absence of detectable antibodies for 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 antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limits of the assay, 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 IgG/IgM 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.

## OTHER INFORMATION

1. This test is being reviewed by the FDA
2. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
3. 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.
4. 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.
5. Not for the screening of donated blood.

**ORDERING INFORMATION**

Contact Cellex's distributors or

Contact Cellex via email: sales@cellex.us

**TECHNICAL INFORMATION**

Via email: tech@cellex.us

**Index of CE Symbols**

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

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