INTENDED USE:
The Cellex qSARS-CoV-2 IgG/IgM Rapid Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in serum, plasma (EDTA, citrate) or venipuncture whole blood specimens from patients suspected of COVID-19 infection by a healthcare provider. The qSARS-CoV-2 IgG/IgM Rapid Test is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Results from the qSARS-CoV-2 IgG/IgM Rapid Test should not be used as the sole basis for diagnosis.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate and high complexity tests. Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. A CLIA categorization of this device would be consistent with other serology lateral flow moderate complexity devices.

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 qSARS-CoV-2 IgG/IgM Rapid Test 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.

At this time, it is unknown how long IgM or IgG antibodies may persist following infection.

For prescription use only. For in vitro diagnostic use only. For emergency use authorization use only.

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

2019 Novel Coronavirus (SARS-CoV-2) is a coronavirus identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Patients with SARS-CoV-2 report a 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 Cellex qSARS-CoV-2 IgG/IgM Rapid Test is intended for qualitative detection of antibodies indicative of SARS-CoV-2 infection and is to be used as an aid for diagnosis of SARS-CoV-2 infection. 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 Lines). If no control band is observed, the test result is invalid and the specimen must be retested.

When a correct 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. If IgG is present in the specimen, the immunocomplex will then be captured by the anti-human IgG line, forming a burgundy colored G Line, indicating a SARS-CoV-2 virus IgG positive test result.

The anti-SARS-CoV-2 virus IgM, 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. Information regarding the immune response to SARS-CoV-2 is limited and still evolving.

At this time, it is unknown how long IgM or IgG antibodies may persist following infection.

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 Lines). If no control band is observed, the test result is invalid and the specimen must be retested.

REAGENTS AND MATERIALS

Reagents and Materials Provided

<table>
<thead>
<tr>
<th>Components</th>
<th>Catalog #</th>
<th>Kit Size (# of Tests)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Cassette (#)</td>
<td>5515C025</td>
<td>25, 50, 100</td>
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<tr>
<td>Sample Diluent (# of Bottles)</td>
<td>5515C050</td>
<td>25, 50, 100</td>
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<tr>
<td>Positive Control (Vial)</td>
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<td>25, 50, 100</td>
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<tr>
<td>Negative Control (Vial)</td>
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<td>1</td>
</tr>
<tr>
<td>Positive Control (Vial)</td>
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<tr>
<td>Negative Control (Vial)</td>
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<tr>
<td>IFU Leaflet</td>
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Transfer pipette is packaged inside the test cassette pouch.

Composition

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

Negative Control: Negative human serum, chemically inactivated.
**Storage and Stability**

1. Other Material Required But Not Provided
   - Timer

**Specimen Collection and Preparation**

**Plasma**
1. Collect blood specimen into a lavender or blue top collection tube (containing EDTA or citrate, respectively, in a Vacutainer®) by venipuncture.
2. Allow the blood to clot.
3. Carefully withdraw the plasma into a new pre-labeled tube.

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

**Serum and Plasma Stability**

- Test specimens as soon as possible after collection. If specimens are not tested immediately, store at -2-8°C for up to 3 days. The specimens should be frozen at -20°C for longer storage.
- For frozen samples, avoid more than 4 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**
1. Drops of whole blood can be obtained by venipuncture. Do not use hemolyzed blood for testing. The Cellex qSARS-CoV-2 IgG/IgM Rapid Test has not been tested with fingerstick blood.
2. Whole blood specimens should be stored at 2-8°C if not tested immediately. The specimens must be tested within 24 hours of collection.

**Test Procedure**

**Step 1:** For fresh samples, begin with Step 2. For frozen samples, bring the specimens and test components to room temperature, and mix the specimen well once thawed.

**Step 2:** When ready to test, open the pouch at the notch and remove the test 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, careful not to exceed the specimen well. The volume of the specimen is around 10μL. For better precision, transfer specimen by a pipette capable of delivering 10μL of volume.

**Step 5:** Set up a timer.

**Step 6:** Read the results in 15-20 minutes.

Don't read results 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 addition of the specimen and sample diluent. If the C Line does not develop, the test is invalid. Review the procedure and repeat the test with a new device.

2. **Positive and Negative Controls:** 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;
   - The temperature used during storage of the kit falls outside of 2-30°C;
   - The temperature of the test area falls outside of 15-30°C;
   - A new lot of test kits is used;
   - To verify a higher than expected frequency of positive or negative results;
   - To investigate the cause of repeated invalid results;
   - A new test environment is used (e.g., natural light vs. artificial light).

**Note:** The positive and negative controls should be spun down before use. When performed properly, in addition to the presence of C Line, no line should be visible for the negative control and the G Line or M Line or both lines are visible for the positive controls. The positive control may contain IgG or IgM or both analytes. Additional controls may be qualified and tested by the user.

**Interpretation of Assay Result**

1. **Valid Assay**
   1.1 In addition to the presence of the C Line, if only the G Line is developed, the test result indicates the presence of IgG anti-SARS-CoV-2 virus. The result is IgG positive or reactive, consistent with a recent or previous infection.

   1.2 In addition to the presence of the C Line, if only the M Line is developed, the test indicates the presence of IgM anti-SARS-CoV-2 virus. The result is IgM positive or reactive, consistent with an acute or recent SARS-CoV-2 virus infection.
1.3 In addition to the presence of the C Line, if both G and M Lines are developed, the test indicates the presence of IgG and IgM anti-SARS-CoV-2 virus. The result is IgG and IgM positive or reactive, suggesting current or recent SARS-CoV-2 virus infection.

Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test is necessary to rule out infection in these individuals.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection. False positive results may occur due to cross-reacting antibodies from previous infections, such as other coronaviruses, or from other causes.

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

2. Invalid Assay

If the C Line does not develop, the assay is invalid regardless of color development of the G or M Lines as indicated below. Repeat the assay with a new device.

<table>
<thead>
<tr>
<th>Comparator</th>
<th>Subtotal</th>
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2. Assay Cross Reactivity

Cross-reactivity of the Cellex qSARS-CoV-2 IgG/IgM Rapid Test was evaluated using serum or plasma samples which contain antibodies to the pathogens listed below. No false positivity or false negativity was found with the following:

- Human coronavirus panel (collected before Oct 2019)
- HBV
WARNINGS

1. This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
2. Test 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.
3. Do not open the sealed pouch until you are ready to conduct the assay. Once opened, the cassettes should be used within 2 hours.
4. Do not use expired devices.
5. Bring all reagents to room temperature (15-30°C) before use.
6. Do not use the components of any other type of test kit as a substitute for the components in this kit.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as biohazardous waste.
10. Handle the negative and positive controls in the same manner as patient specimens for operator protection.
11. Do not perform the test in a room with strong air flow, i.e., an electric fan or strong air-conditioning.

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, 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 qSARS-CoV-2 IgG/IgM Rapid Test 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.
3. 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 limit of the assay, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody utilized in the test.
4. If symptoms persist and the result from the qSARS-CoV-2 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.
5. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.
6. This test should not be used for screening of donated blood.

INQUIRIES AND GENERAL INFORMATION

Please visit website www.cellexcovid.com

ORDERING

1. Contact Cellex’s distributors or
2. Contact Cellex via email: sales@cellex.us

TECHNICAL

1. Via email: tech@cellex.us

Index of CE Symbols

Consult instructions for use

For in vitro diagnostic use only

Use by

Tests per kit

Authorized Representative

Date of manufacture

Cellex, Inc.

76 TW Alexander Drive, Research Triangle Park, NC 27709-0002, USA

MedPath GmbH

Mies-van-der-Rohe-strasse 8, 80807 Munich, Germany