Cellex

CE

REF **Catalog No：5515C025, 5515C050, 5515C100**

IVD **In Vitro Diagnostic**

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 for 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:

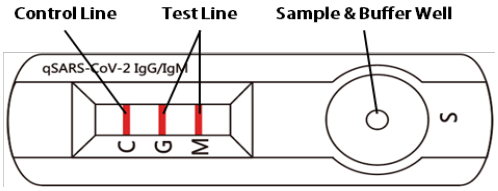
Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS-CoV). SARS-CoV-2 is a new strain that has not been previously identified in humans. Coronaviruses are zoonotic, meaning they are transmitted 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. 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.

TEST PRINCIPLE

The Cellex qSARS-CoV-2 IgG/IgM 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 (S and N proteins) 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 control line (C Line) coated with goat anti-rabbit IgG.



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 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 in Kits

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

	Catalog #	5515C025	5515C050	5515C100
	Kit Size (#of Tests)	25	50	100
Components	Test Cassette (#)	25	50	100
	Sample Diluent (# of Bottles)	1	1	1
	Transfer pipette (#)*	25	50	100
	IFU Leaflet	1	1	1

*Transfer pipette is packaged inside the test cassette pouch.

Reagents and Materials Purchased Separately

A control set consisting of a positive and a negative control is provided and purchased separately from the kit. A vial of positive or negative control contains approximately 40 microliters of specimens. Each control vial is sufficient for conducting 3 tests. See instruction on the use of control under Quality Control.

Composition

Conjugate Pad	SARS-CoV-2 antigen coated gold particles
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.
Positive Control	Negative human serum spiked with positive serum, chemically inactivated. It may be reactive to the IgM line, IgG line or both.

Other Material Required But Not Provided

Timer

STORAGE AND STABILITY

1. Store the detector buffer at 2-30˚C. The buffer is stable up to 12 months.
2. Store the Cellex qSARS-CoV-2 IgG/IgM Rapid Test at 2-30˚C; its shelf life is up to 12 months.
3. If stored at 2-8˚C, ensure that the test device is brought to 15-30˚C before opening.
4. Do not freeze the kit or store the kit over 30˚C.

SPECIMEN COLLECTION AND PREPARATION

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

Plasma

1. Collect blood specimen into a lavender or blue top collection tube (containing EDTA or citrate, respectively, in a Vacutainer®) by venipuncture.
2. Separate the plasma by centrifugation.
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. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. 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 specimen should be frozen at -20°C for longer storage.

For frozen samples, avoid more than 3 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 specimens. Use with fingerstick blood is not recommended.
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.

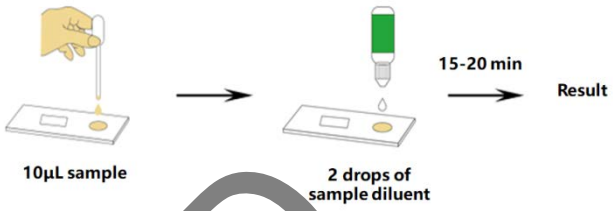
TEST PROCEDURE

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.



Holding the transfer pipette vertically, dispense 10µL of the specimen into the center of the sample well (S well) making sure that there are no air bubbles.

Then, add 2 drops of Sample Diluent immediately into the sample well (S well).

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 Control: Positive and negative controls should be tested to ensure the proper performance of the assay, particularly under the following circumstances:

   A. A new operator uses the kit;
   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°C ;
   E. The temperature of the test area falls outside of 15-30°C;
   F. To verify a higher than expected frequency of positive or negative results;
   G. To investigate the cause of repeated invalid results; or
   H. 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 is/are visible for the positive controls. The positive control may contain IG 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.

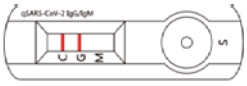
Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test is necessary to rule out infection in these individuals.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

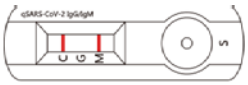
False positive results may occur due to cross-reacting antibodies from previous infections, such as other coronaviruses, or from other causes

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

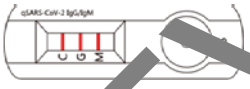
IgG positive



IgM Positive



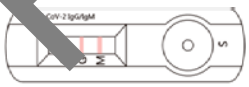
IgG and IgM Positive



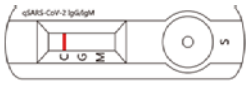
IgG weak positive

IgM weak positive

IgG and IgM weak Positive

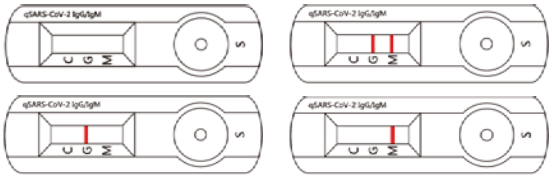


Negative



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.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance

1.1 Study of: Testing of RT-PCR positive clinical specimens

Ninety-eight (98) positive serum or plasma samples collected from individuals who tested positive with a 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 collection, 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 278 positive samples, ninety-one (91) were tested positive with IgG or IgM or both. Of the 180 negative samples, one hundred seventy four (174) were tested negative.

Another 100 samples were collected from hospitalized individuals who were clinically confirmed positive for SARS-CoV-2 infection 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 100 positive samples, twenty-nine (29) were tested positive with IgG or IgM or both. Of the 70 negative samples, sixty-five (65) tested negative. The day of collection relative to the onset of illness was unknown.

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

			Comparator		Subtotal
			Pos	Neg	
qSARS-CoV-2 IgG/IgM Rapid Test	Pos	IgG+/IgM+	62	0	62
		IgG-/IgM+	43	4	47
		IgG+/IgM-	15	6	21
	Neg	IgG-/IgM-	8	240	248
Subtotal			128	250	378

Positive Percent Agreement (PPA)= 120/128 (93.8%), 95% CI: 88.2% to 96.8%

Negative Percent Agreement (NPA)= 240/250 (96.0%), 95% CI: 92.8% to 97.8%

1.2 Study of: Venous Whole blood specimens spiked with positive samples

Fifty (50) negative whole blood samples were spiked with positive serum at 1:100. Another fifty (50) whole blood specimens were spiked with negative serum at the 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. Thus, there was a 99% concordance rate with expected results when venous whole blood specimens are used.

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
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

3. Potentially Endogenous Interfering Substances

Low titer SARS-CoV-2 antibody positive serum samples and SARS-CoV-2 antibody negative serum samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positivity or false negativity was found with the following:

Hemoglobin	10 mg/mL
Bilirubin Conjugated	4 mg/mL
Bilirubin Unconjugated	0.4 mg/mL
Triglycerides	15 mg/mL
Cholesterol	4 mg/mL
Human Anti-mouse Antibody (HAMA)	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

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.
   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 detected by the test.
4. If symptoms persist and the result from the qSARS-CoV-2 IgG/IgM 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

CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The Cellex qSARS-CoV-2 IgG/IgM Rapid Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

However, to assist clinical laboratories using the Cellex qSARS-CoV-2 IgG/IgM Rapid Test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories1 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.

B. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

C. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

D. 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.

E. 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 You (tech@cellex.us) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F. All laboratory personnel using your product must be appropriately trained in immunochromatographic 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.

G. Cellex Inc., 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.

1 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 and high complexity tests" as "authorized laboratories".

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
REF Catalog #	LOT Lot Number	Tests per kit
Store between 2-30°C	EC REP Authorized Representative	Do not reuse
Manufacturer	Date of manufacture	

Cellex Inc.
76 TW Alexander Drive, [illegible] Park, NC 27[illegible]0002, USA

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