Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test

Cellex

REF **Catalog No：5513C**

IVD **In Vitro Diagnostic**

INTENDED USE

The Cellex qSARS-CoV-2 IgG/IgM Cassette 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 Cassette 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 Cassette Rapid Test should not be used as the sole basis for diagnosis.

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.

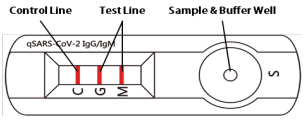
2019 Novel Coronavirus (SARS-CoV-2) is a coronavirus identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Patients with SARS-CoV-2 report a mild to severe respiratory illness with symptoms of: fever, cough, shortness of breath. There is an urgent need for rapid tests to manage the ongoing pandemic.

The Cellex qSARS-CoV-2 IgG/IgM Cassette 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 based on a sandwish method.

The SARS-CoV-2 recombinant antigens labeled by colloidal gold (SARS-CoV-2 conjugates) in burgundy colored conjugate pad can bind to the antibodies against the SARS-CoV-2 virus, such that if the anti-SARS-CoV-2 virus IgG or IgM or both present in the specimen, the IgG or IgM can be binded with the conjugates to form the IgG- SARS-CoV-2 conjugates or IgM-SARS-CoV-2 conjugates immunocomplex.



Migrating through the nitrocellulose matrix, the immunocomplex of IgG-(SARS-CoV-2) conjugates will then captured by the anti-human IgG line, forming a burgundy colored G Line. The result is IgG positive or reactive, consistent with a recent or previous infection.

And the immunocomplex of IgM- (SARS-CoV-2) conjugates will then captured by the anti-human IgM line, forming a burgundy colored M Line. The result is IgM positive or reactive. Information regarding the immune response to SARS-CoV-2 is limited and still evolving..

This test contains a built-in control feature, the C Line. The goat anti-rabbit IgG bound in the C line, can bind with the rabbit IgG-gold conjugates which from the conjugate pad. The C Line develops after addition of the specimen and sample diluent. 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.

REAGENTS AND MATERIALS

Reagents and Materials Provided

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

	Kit Size (#of Tests)	1	25	50
Components	Test Cassette (#)	1	25	50
	Sample Diluent (# of Bottles)	1	1	1
	Transfer pipette	1	25	50
	IFU Leaflet	1	1	1

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

Other Material Required But Not Provided

Timer

STORAGE AND STABILITY

1. Store the detector buffer at 2-30˚C.
2. Store the Cellex qSARS-CoV-2 IgG/IgM Rapid Test at 2-30˚C; It can be stable until the expiration date.
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.

Collection:

Serum or Plasma or Whole Blood

No special preparation or fasting of the patient is necessary. Serum or plasma derived from citrate or EDTA (ethylenediaminetetraacetate) as anticoagulants may be used.

Drops of whole blood can be obtained by venipuncture. Do not use hemolyzed blood for testing. Currently, no experimental data exists to support the use finger stick specimens.

Storage:

Serum or plasma specimens should be tested as soon as possible after collection. If specimens are not tested immediately, store at 2-8°C for up to 7 days. For long-term storage, specimens should be frozen at –20°C or colder. Specimens repeatedly frozen and thawed more than five (5) times or those containing particulate matter may give erroneous results.

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.

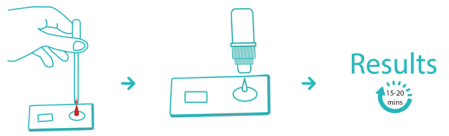
Step 2: When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.

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 1: Add 10µL sample | Step 2: Add 2 drops of sample diluent | Step 3: Read results in 15-20 minutes

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

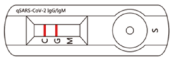
1. Internal Control: This test contains a built-in control to satisfies the quality control requirements. The C Line develops after addition of the specimen and sample diluent. If the C Line does not develop, the test is invalid, indicating that the test should be repeated.

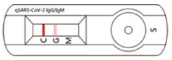
2. Positive and Negative Control: Positive and negative controls should be tested to ensure the proper performance of the assay, particularly under the following circumstances: 1) new kits (new lot or new shipment); 2) new user; 3) new test environment (e.g., natural light vs. artificial light).; 4)abnormal storge enviroment (outside of 2-30°C); 5) abnormal working enviroment (outside of 15-30°C); 6)To investigate the cause of repeated invalid results;

INTERPRETATION OF ASSAY RESULT

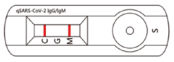
1. Valid Assay

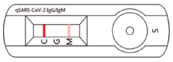
1.1 If only the G Line and C Line are developed, this is result is IgG positive or reactive, in another word, that indicates the presence of IgG anti- SARS-CoV-2 virus, consistent with a recent or previous infection.

IgG positive 

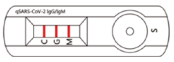
IgG weak Positive 

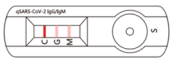
1.2 If only the M Line and C Line are developed, this is result is IgM positive or reactive, in another word, that indicates the presence of IgM anti- SARS-CoV-2 virus, consistent with an acute or recent SARS-CoV-2 virus infection.

IgM positive 

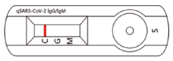
IgM weak Positive 

1.3 If all of G,M Lines and C Line are developed, this is result is IgG and IgM positive or reactive, in another word, that indicates the presence of IgG and IgM anti- SARS-CoV-2 virus, suggesting current or recent SARS-CoV-2 virus infection.

IgG and IgM positive 

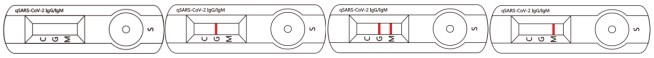
IgG and IgM weak Positive 

1.4 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..

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 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. Of the 180 negative samples, one hundred seventy five (175) were tested negative.

Another 30 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 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. Of the 70 negative samples, sixty-five (65) tested negative. The day of collection relative to the onset of illness was unknown.

			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

Taken together,

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

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.

3. 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.

WARNINGS

Inadequate adherence to package insert instructions may result in erroneous results.

1. Caution: Handle all Cellex, Inc. biological materials as though capable of transmitting infectious agents.
2. Specimens should not be transported under extreme adverse temperature conditions.
3. Kits should not be used past their expiration dates.
4. All clinical specimens and materials used to collect these specimens should be considered potentially infectious and handled accordingly.
5. The assay should be performed at 15ºC to 30ºC.
6. Do not smoke, eat, or drink in areas where specimens or kit regents are handled.
7. Use disposable gloves and handle all materials used in the test (including samples, and controls) cautiously as though capable of transmitting infectious agents.
8. Dispose of all materials that have come into contact with specimens and reagents in accordance with local, state, and federal regulations.

LIMITATIONS OF THE PROCEDURE

1. Serum or plasma derived from sodium citrate, sodium heparin, or EDTA (ethylenediaminetetraacetate) as anticoagulants or whole blood may be used with this assay. Using other types of samples may not yield accurate results.
2. A test result that is INVALID should not be reported and the sample(s) should be retested.
3. The qSARS-CoV-2 IgG/IgM Rapid Test is a qualitative assay, and the intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
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 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.
5. 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.
6. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.
7. This test should not be used for screening of donated blood
8. 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.
9. 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.
10. 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.

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, Research Triangle Park, NC 27709-0002, USA

EC REP **MedPath GmbH**

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

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English version