Cellex qSARS-CoV-2 NAB Rapid Test

Cellex

CE

REF **Catalog No：5516**

IVD **In Vitro Diagnostic**

INTENDED USE

The Cellex qSARS-CoV-2 NAB Rapid Test is a lateral flow immunoassay intended for the qualitative detection of neutralizing antibodies to SARS-CoV-2 in serum, plasma and whole blood. The Cellex qSARS-CoV-2 NAB Rapid Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The Cellex qSARS-CoV-2 NAB Rapid Test should not be used to diagnose acute SARS-CoV-2 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.

SARS-CoV-2 is a new coronavirus, causes an infectious disease named COVID-19 (Coronavirus disease 2019). 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.

SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N). The spike protein (S) contains a receptor-binding domain (RBD), which is responsible for recognizing the cell surface receptor, angiotensin converting enzyme-2 (ACE2). It is found that the RBD of the SARS-CoV-2 S protein strongly interacts with the human ACE2 receptor leading to endocytosis into the host cells of the deep lung and viral replication.

Infection with SARS-CoV-2 initiates an immune response, which includes the production of antibodies in the blood. Not all antibodies can block cellular infiltration and replication of the SARS-CoV-2 virus. The subpopulation of the antibodies that can block cellular infiltration and replication of the virus are named neutralizing antibodies. It is unknown how long it takes for neutralizing antibodies to be produced, and if they are always produced after SARS-CoV-2 infection. While individuals infected with SARS- CoV-2 develop antibodies to the virus, not all of them develop neutralizing antibodies to SARS-CoV-2.

The Cellex qSARS-CoV-2 NAB Rapid Test is intended for qualitative detection of neutralizing antibodies indicative of SARS-CoV-2 infection and is to be used as a predictor of immunity condition of COVID-19.

TEST PRINCIPLE

The Cellex qSARS-CoV-2 NAB Rapid Test use a recombinant protein representing the RBD of the S antigen in a double-antigen sandwich assay format, which captures predominantly anti-SARS-CoV-2 IgG, but also anti-SARS-CoV-2 IgA and IgM.

The Cellex qSARS-CoV-2 NAB Rapid Test has two pre-coated lines, "C" Control line, "T" Test line on the surface of the nitrocellulose membrane. The nitrocellulose membrane is attached onto a plastic backing card and combined with the other reagents and pads to construct a test strip. The test strip is encased inside a plastic device. Both the control line and test line in the result window are not visible before applying any specimens. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the SARS-CoV-2 antigen-dye conjugate and migrates along the membrane strip to the reading window. On the nitrocellulose membrane within the reading window SARS-CoV-2 S-RBD antigen is precoated at T area and a goat anti-rabbit antibody is precoated at the C area. If antibodies to SARS-CoV-2 S-RBD present in the specimen, the T line will become visible. If the specimen is SARS-CoV-2 S-RBD antibodies negative, only the C line will become visible.

If the C Line does not develop, the assay is invalid regardless of color development of the T Line. 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
Components	Test Cassette (#)	1	25
	Sample Diluent (# of Bottles)	1	1
	Transfer pipette	1	25
	IFU Leaflet	1	1

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 NAB 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.

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 after 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.

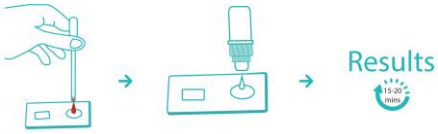
Step 2: When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.

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 40 µL. For better precision, transfer specimen by a pipette capable of delivering 40µL of volume.

Holding the transfer pipette vertically, dispense 40µL of the specimen into the center of the sample well (S well) making sure that there are no air bubbles.

Then, add 1 drop 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

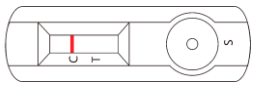
1. Internal Control: This test contains a built-in control to satisfies the quality control requirements. The C Line develops after addition of the specimen and sample diluent. If the C Line does not develop, the test is invalid, indicating that the test should be repeated.
2. Positive and Negative Control: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

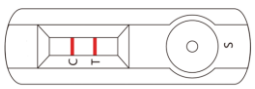
1.1 If only the C band is present, it indicates the neutralizing antibodies are not detected. It is a negative result.

Negative

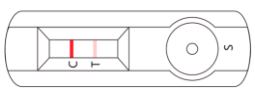


1.2 If the T Line and C Line are developed, it indicates a positive result for neutralizing antibodies.

Strong positive

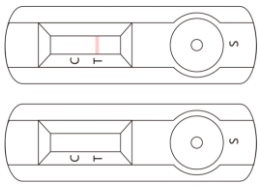


Weak Positive



2. Invalid Assay

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



PERFORMANCE CHARACTERISTICS

1. Clinical Performance

The qSARS-CoV-2 NAB Rapid Test has been evaluated with serum specimens obtained from patients. A commercialized ELISA assay was used as the reference method. The results show that the qSARS-CoV-2 NAB Rapid Test has a high overall accuracy.

Method		Reference method		Total
Cellex qSARS-CoV-2 NAB Rapid Test	Results	Positive	Negative	
	Positive	121	3	124
	Negative	5	160	165
Total Results		126	163	289

Relative Sensitivity: 96.0%
Relative Specificity: 98.2%
Accuracy: 97.2%

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 15°C to 30°C.
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 Cellex qSARS-CoV-2 NAB Rapid Test is a qualitative assay, and the intensity of the test line does not necessarily correlate to SARS-CoV-2 neutralizing antibodies titer in the specimen.
4. A negative or non-reactive result can occur if the quantity of neutralizing antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay.
5. If symptoms persist and the result from the Cellex qSARS-CoV-2 NAB 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. 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.

Index of CE Symbols

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

Cellex Biotech (Suzhou) Co., Ltd
1F, North Block, 16 Building, 8 Jinfeng Road, New District, Suzhou, Jiangsu, P.R. China 215163
Tel：0512-66897003
Email: info@cellex.us

EC REP **Lotus NL B.V.**
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel：+31644168999
E-mail：peter@lotusnl.com

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English version