Cellex qSARS-CoV-2 Antigen Rapid Test

Cellex

CE

Catalog No：5512C025

IVD **In Vitro Diagnostic**

INTENDED USE

The qSARS-CoV-2 Antigen Rapid Test is an in vitro immunochromatographic assay for qualitative detection of nucleocapsid antigens of the SARS-CoV-2 virus in nasopharyngeal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections.

In U.S., testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), *i.e.*, in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

BACKGROUND

COVID-19 is an acute respiratory infectious disease caused by infection of the SARS-CoV-2 virus, a novel coronavirus belonging to the beta genus of the coronaviruses. After infection, there is an incubation period of 1 to 14 days, mostly 3 to 7 days before disease onset. The disease symptoms include fatigue, dry cough, loss of taste and smell, nasal congestion, runny nose, sore throat, myalgia and/or diarrhea. This rapid test was designed to detect viral antigens in upper respiratory specimens collected during the acute phase of infection.

TEST PRINCIPLE

The qSARS-COV-2 Antigen Rapid Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect viral proteins of SARS-CoV-2 in nasopharyngeal or mid-turbinate swab samples. The test strip is composed of the following parts: sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the microparticles conjugated with the monoclonal antibodies against the N protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies against the SARS-CoV-2 antigens. The strip is immobilized inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigens are present in the sample, a complex formed between the anti-SARS-2 conjugate and the viral protein is captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line indicates a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) to indicate that a proper volume of sample has been added and membrane wicking has occurred.

REAGENTS AND MATERIALS

Reagents and Materials Provided in Kits

There is one kit size. The kit component configuration is provided below:

	Catalog #	5512C025
	Kit Size (#of Tests)	25
Components	Test Cassette (#)	25
	Sample Buffer (# of Bottles)	1
	Sample Swab* (#)	25
	Sample Extraction Tube (#)	25
	Quick Reference Guide	1

*Sample swabs may be provided separately

Materials Purchased Separately

A control set containing a positive control and a negative control vial are provided and purchased separately.

Other Materials Required but Not Provided

Timer
Sample Tube Rack or Holder

STORAGE

1. Store the kit at 2-30˚C.
2. If stored at 2-8˚C, ensure that the test device is brought to 15-30˚C before opening.
3. Do not freeze the kit or store the kit over 30˚C.

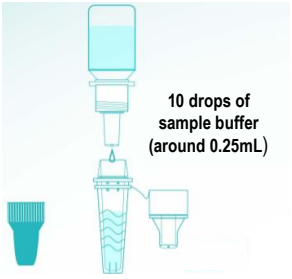
SPECIMEN COLLECTION AND PREPARATION

Preparation for sample collection

Please refer to the following CDC guidelines on COVID-19 sample collection: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

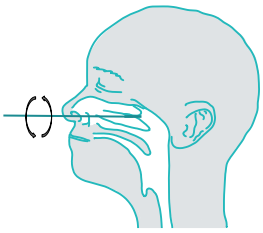
Before collecting a sample, prepare sample extraction tube as follows (refer to the diagram below):

1. Label an extraction tube. Insert the test extraction tube into the tube rack. Make sure that the tube is standing firm and reaches the bottom of the stand.
2. Add 10 drops (about 0.25 mL) of the sample extraction buffer into the extraction tube.



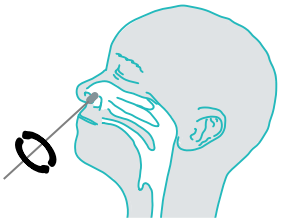
Collection of a nasopharyngeal swab specimen

1. Carefully insert a nasopharyngeal swab into the nostril of the patient, reaching the surface of posterior nasopharynx.
2. Rotate the swab several times.
3. Withdraw the swab from the nasal cavity.
4. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
5. Follow "Sample Extraction from a Swab" to extract the sample.



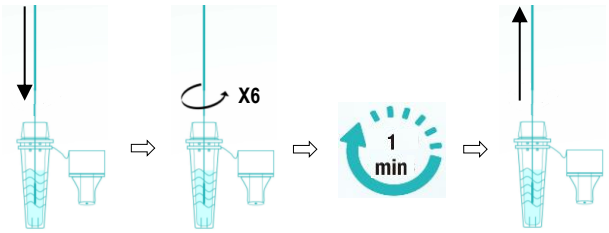
Collection of a mid-turbinate swab specimen

1. Tilt patient's head back 70 degrees. While gently rotating a flocked tapered swab, insert swab up into one nostril (until resistance is met at mid turbinate, approx. 1 inch). Rotate the swab 5 times against the nasal wall.
2. Using the same swab, repeat the process for the other nostril. Withdraw the swab.
3. Follow "Sample Extraction from a Swab" to extract the sample.



Sample extraction from a swab

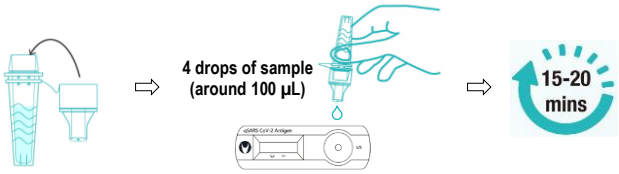
1. As shown in the diagram below, insert the swab into the extraction tube containing about 0.25 mL of the extraction buffer.
2. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
3. Leave the swab in the extraction tube for 1 minute.
4. Remove the swab while rubbing against the wall and properly discard the swab.
5. The extracted sample is now ready for use in testing.



TEST PROCEDURE

Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
2. Place the nozzle cap onto the sample extraction tube tightly.
3. Invert the sample extraction tube and add 4 drops (about 100 µL) of the extracted sample into the sample well by squeezing the sample tube.
4. Start a timer or use the Artemis App's built-in timer
5. Wait for the colored band(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 20 minutes.



QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C Line. The C Line develops after addition of the extracted sample. 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 are recommended to 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 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).

USE OF CONTROLS

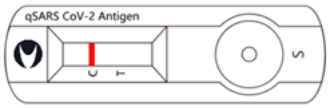
The controls are provided as solutions in vials. To test a control, the swab is inserted into the control solution and rub the swab against the control vial. Remove the swab and go through sample extraction and testing as a clinical sample.

INTERPRETATION OF ASSAY RESULTS (VISUAL READING METHOD)

1. Valid Assay

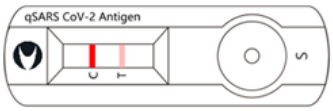
1.1 A test is valid when the C line develops.

1.2 When only the C line develops, the test result indicates the absence of SARS-CoV-2 virus antigen in the sample and hence, likely no infection (Negative).

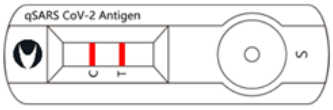


Negative

1.3 When both the C and T line develop, the test result indicates the presence of SARS-CoV-2 virus antigen in the sample and hence, likely infection (Positive).



Weak Positive

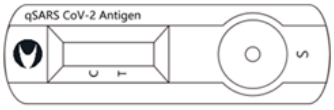


Strong Positive

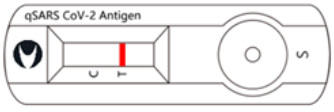
2. Invalid Assay

If the C Line does not develop, the assay is invalid regardless whether the color of T line is present. Repeat the assay with a new device.

Invalid



Invalid



PERFORMANCE CHARACTERISTICS

CLINICAL PERFORMANCE

Nasopharyngeal swab specimens

Clinical performance characteristics of the qSARS-CoV-2 Antigen Rapid Test was evaluated in a multi-site prospective study in the U.S. where 219 direct nasopharyngeal swabs were prospectively collected from enrolled patients. A total of three (3) investigational POC sites throughout the U.S. participated in the study. Testing was performed by operators with no laboratory experience and who represent the intended users at CLIA waived testing sites. Operators used only the test's Quick Reference Guide and received no training. To be enrolled in the study, patients had to be suspected of SARS-CoV-2 infection by exhibiting COVID-19 symptoms or having been exposed to COVID-19 patients.

In this study, FDA Emergency Use Authorized real-time PCR (RT-PCR) assays for the detection of SARS-CoV-2 were used as the comparator method. Compared to RT-PCR, the qSARS CoV-2 Antigen Rapid Test result demonstrated Positive Percent Agreement of 94.6% (95% confidence interval: 81.81-99.34%) and Negative Percent Agreement of 99.5% (95% confidence interval: 96.98-99.99%), respectively.

qSARS-CoV-2 Antigen Rapid Test Performance vs. RT-PCR (Nasopharyngeal Swab Specimens)

Method		FDA EUA-authorized RT-PCR		Total
qSARS-CoV-2 Antigen Rapid Test	Results	Positive	Negative	
	Positive	35	1	36
	Negative	2	181	183
Total Results		37	182	219

ANALYTICAL PERFORMANCE

Limit of Detection
Limit of Detection (LOD) studies determined the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates tested positive. The confirmed LOD for direct swab and visual read is 80 $TCID_{50}$ / mL.

Cross Reactivity
All of the FDA recommended organisms were tested at the concentrations listed below in the table. No impact was observed to the performance of the qSARS-CoV-2 Antigen Rapid Antigen Test. No false positive results were observed when testing these organisms at the concentrations below and no false negative results were observed when testing these organisms with weak positive SARS-CoV-2 antigen in the samples.

Organism Strain	Concentration
Human coronavirus, 229E	1.6 x 10^6 $TCID_{50}$ / mL
Human coronavirus, OC43	8.9 x 10^4 $TCID_{50}$ / mL
Human coronavirus, NL63	1.41 x 10^5 $TCID_{50}$ / mL
Human adenovirus 10, Strain J.J.	3.2 x 10^5 $TCID_{50}$ / mL
Human adenovirus 21, Strain AV 1645	2.5 x 10^7 $TCID_{50}$ / mL
Human metapneumovirus TN/83-1211	2.8 x 10^6 $TCID_{50}$ / mL
HPIV 1, Strain HPIV/FRA/29221106/2009	8.9 x 10^6 $TCID_{50}$ / mL
HPIV 2, Greer	1.0 x 10^8 $TCID_{50}$ / mL
HPIV 3	2.82 x 10^7 $TCID_{50}$ / mL
HPIV 4A, Strain M-25	1.6 x 10^4 $TCID_{50}$ / mL
Influenza A H3N2, (Brisbane/ 10/07)	5.01 x 10^5 $TCID_{50}$ / mL
Influenza B virus, Strain B/New York/1056/2003	1.6 x 10^6 $TCID_{50}$ / mL
Enterovirus species D type 68, USA/2018-23087	8.9 x 10^6 $TCID_{50}$ / mL
Human respiratory syncytial virus, Strain A2001/2-20	2.8 x 10^5 $TCID_{50}$ / mL
Human rhinovirus 20, Strain [15-CV19]	5 x 10^5 $TCID_{50}$ / mL
Streptococcus pneumoniae 19F, Strain Z022	4.16 x 10^8 CFU/mL
Streptococcus pyogenes, Strain Z018	2.66 x 10^9 CFU/mL
Candida albicans Strain Z006	4.50 x 10^8 CFU/mL
Bordetella pertussis, Strain A693	1.13 x 10^{10} CFU/mL
Mycoplasma pneumoniae, Strain M129	3.16 x 10^8 CCU/mL
Chlamydophila pneumoniae Z500, Strain IOL207	2.12 x 10^8 IFU/mL
Legionella pneumophila, Strain Philadelphia	1.63 x 10^{10} CFU/mL

Potentially Interfering Substances
The following potential interference materials were evaluated with the qSARS-COV-2 Antigen Rapid Test at the concentrations listed below and were found not to affect test performance.

Substance	Concentration
Whole blood	5% (v/v)
Mucin	0.5%
Cough drops (menthol)	1.5g/ml
Oseltamivir phosphate	5 mg/mL
Ribavirin	5 mg/mL
Levofloxacin	5 mg/mL
Azithromycin	5 mg/mL
Meropenem	5 mg/mL
Tobramycin	2 mg/mL
Phenylephrine	20% (v/v)
Oxymetazoline	20% (v/v)
0.9% sodium chloride	20% (v/v)
A natural soothing ALKALOL	20% (v/v)
Sore throat phenol spray	15% v/v
Nasal Drops (Phenylephrine)	15% v/v

Flex Study
A flex study was conducted testing the variation of seven factors. The study demonstrated the antigen test is very robust. The only factor that could have significant impact is sample volume as less than two drops used could cause an invalid result due to inappropriate flow.

WARNINGS

1. This package insert must be read completely before performing the test. Failure to follow insert directions may yield inaccurate test results.
2. Test results should be read between 15 and 20 minutes after a test sample 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 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 etiology of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test. The qSARS-CoV-2 Antigen Rapid Test is capable of detecting both viable and non-viable SARS-CoV-2. The performance of the qSARS-CoV-2 Antigen Rapid Test depends on antigen load and may not correlate with viral culture results performed on the same specimen.
2. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of SARS-CoV-2 antigens in the specimen, as antigens may be present below the minimum detection level of the test, or if the sample was collected or transported improperly.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Positive test results do not rule out co-infections with other pathogens.
6. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
7. Negative results should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control.

INQUIRIES AND GENERAL INFORMATION
Please visit website www.cellexcovid.com

ORDERING
1. Contact Cellex's distributors or
2. Contact Cellex via email: sales@cellexinc.com

CUSTOMER SERVICE
1. Email services@cellexinc.com or
2. Call (800)780-3358.

GENERAL INFORMATION
1. Email info@cellexinc.com

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


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

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