There are three primary testing types available for detecting COVID-19: Antibody (serology), Antigen and PCR Testing.

There are three primary testing types available for detecting COVID-19: Rapid Antibody (serology) Testing, Rapid Antigen Testing, and Confirmatory PCR Testing. This Q&A explains the difference between the tests, covers testing protocols, and provides manufacturing, ordering, and shipping information for the Cellex point-of-care qSARS-CoV-2 Rapid Antigen Test Kit. For additional questions, please contact: HealthDatix, Inc. office: 727-828-0404 or cell: 727-647-7843

What is an Antigen test?

The Cellex™ 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 nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider. This self-contained, point-of-care (POC) test provides reliable and accurate results in 15 minutes and was developed by Cellex™, a U.S. biotechnology company. The Cellex Antigen test has demonstrated high sensitivity and specificity. It is a portable, lateral-flow cassette (like a pregnancy test) that can be used in any location and does not require a reader or lab equipment. The test is intended to aid in the rapid diagnosis of qSARSCoV-2 infections.

- Product is currently For Research, Screening or Surveillance Use Only
- qSARS-CoV-2 Viral Antigen Test.
- Reliable & Accurate results for the diagnosis of qSARS-CoV-2 infections.*
  - 94.6% Positive Percent Agreement (sensitivity).
  - 99.5% Negative Percent Agreement (specificity).
- Rapid results in only 15 minutes.
- Simple, mid-nasal swab or nasopharyngeal swab test.
- Portable, lateral-flow cassette (like a home pregnancy test) for testing in any location.
- Self-contained kit includes 25 test cassettes & swabs; no reader or lab equipment needed.
- Internal control (C line) on lateral flow to determine validity of test.

What are the advantages of Antigen testing?

An antigen test can be used as a diagnostic test and as a surveillance test. Rapid diagnosis (within 15 minutes) is a prime advantage. The test is also affordable and portable. The test is highly effective in detecting the virus in asymptomatic individuals—those who may not know if they were exposed and/or are not presenting symptoms. The antigen test is comparable to the PCR test, with a marked difference: the antigen rapid test takes minutes and the Molecular or PCR test can take days for results. Quickly identifying asymptomatic individuals allows the individual to quarantine for the recommended time-frame before engaging in social and/or work settings.

Any disadvantages?

Antigen test are faster and less expensive than PCR tests, but they may have a higher risk of false positives, which means that the test results may indicate that you have the virus when you do not.

How is a point-of-care Antigen rapid test administered?

Before collecting a sample, prepare sample extraction tube as follows: Label an extraction tube with the patient identifier. Insert the test extraction tube into the tube rack. Make sure that the tube is standing firm and reaches the bottom of the stand. Add 10 drops (about .25mL) of the sample extraction buffer into the extraction tube.

Collection of a nasopharyngeal or mid turbinate swab specimen

Carefully insert a nasopharyngeal swab into the nostril of the patient reaching the surface of posterior nasopharynx. Rotate the swab several times. Withdraw the swab from the nasal cavity. 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.

How is a point-of-care Antigen rapid test administered?

continued...

Collection of a nasopharyngeal or mid turbinate swab specimen

Carefully insert a nasopharyngeal swab into the nostril of the patient reaching the surface of posterior nasopharynx. Rotate the swab several times. Withdraw the swab from the nasal cavity. 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.

To collect a mid-turbinate swab specimen, tilt the 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. Using the same swab, repeat the process for the other nostril. Withdraw the swab.up into one nostril (until resistance is met at mid-turbinate approx. 1 inch). Rotate the swab 5 times against the nasal wall. Using the same swab, repeat the process for the other nostril. Withdraw the swab.

Sample extraction from a swab

Insert the swab into the extraction tube containing about .25 mLl of the extraction buffer. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube. Leave the swab in the extraction tube for 1 minute. Remove the swab while rubbing against the wall and properly discard the swab. The extracted sample is now ready for use in testing.

Place the nozzle cap tightly onto the sample extraction tube. Invert tube and squeeze to add 4 drops of the test sample into the test cassette well. Start a timer, wait for the colored band(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 20 minutes.

Medical personnel should review and follow the Cellex instructions for use (IFU) to ensure proper execution of the test.

Do all antigen tests produce the same results -- and how are they different than a molecular test ?

Antigen tests can identify active infections by detecting the earliest toxic traces of the virus vs. the genetic code of the virus itself, which is what a PCR test does. Most antigen tests use the same technology as the rapid flu or strep test. Some manufacturers require special equipment to read the test results. The Cellex test does not require special equipment, but they do offer an App to time the test and read the results. The value of using an antigen test is during surveillance of those individuals who are asymptomatic, to test before they go to work or to school. There are significant limitations of quickly returning results with a PCR test, which makes it unrealistic to efficiently and quickly test the masses.

What technology does Cellex Antigen test use?

Cellex uses the same technology as the rapid flu or strep test. The test can be conducted using a nasopharyngeal or mid-turbinate swab to collect the sample. The sample is extracted in a test tube with buffer, and then read on a test cassette within 15 minutes. There is no need for extra lab equipment to read the results.

MANUFACTURING, ORDERING, AND SHIPPING INFO

Where are Cellex tests manufactured?

Cellex has two FDA-compliant manufacturing sites: in Orlando, Florida and in Suzhou, China. For the Made in the USA test kits, everything but the laminated plates will be made in the US, including the boxes. These test kits will have "Made in the USA" stamped on the outside. The test kits produced in China will not have a stamp on the box. Orders submitted, unless otherwise requested, will come from whichever production facility has product available to ship. The intent is to fulfill orders from one production facility, so as to not confuse buyers with box labeling. We may not have control over which facility is used; it will be dependent on the production capacity at the time the order is placed.

How long will it take to receive product once an order is placed?

Depending on the quantity and what is available stateside, it will typically take 10-12 business days pending demand of product.

What are the packaging weights and dimensions?

Cellex qSARS-Cov-2 Antigen Rapid Test

One Box (25 Tests)
Dimensions: 10" x 6" x 3"
Weight: 0.8-0.9 lbs

Master Carton (28 Boxes or 700 Tests)
Dimensions: 28" x 16" x 13"
Weight: 26-28 lbs

MANUFACTURING, ORDERING, AND SHIPPING INFO continued...

Is there a minimum order quantity?

Yes, we recommend ordering by Master Carton, which includes 30 Boxes or 750 test kits. Product is shipped via FedEx and the cost is a standard $30/Master Carton regardless if the Master Carton is partial or full.

Does the product require temperature control?

Temperature and humidity can have a negative effect on the stability of the tests. The recommendation is to store the Cellex test and the reagent between 35.6 (F) degrees and 86 (F) degrees for best results. If the tests are stored at 35.6 (F) degrees, it is best to bring the tests and buffer to between 59 (F) – 86 (F) degrees before opening the test kits.

What is the distributor's or buyer's recourse if the product was affected by uncontrolled temperature during shipment?

Cellex has in place very stringent quality control procedures while in production through packaging. Unfortunately, once the product leaves the factory there could be uncontrolled temperature events that could alter the stability of the product. Cellex has a separate Quality Control Set that can be purchased to test product once it is received. If the Quality Control determines the shipment was damaged the Manufacturer will replace the damaged product.

What is included in the Quality Control Set?

Buffer and Control Sets from different lots should not be mixed. For large orders, we recommend that a control set be ordered at the same time as the tests are ordered, since the controls from that lot# were tested on the test cassettes from that lot# and have shown to give the expected test results (positive, negative). It is possible for a control set to give the expected results on multiple lots, but without it being tested by Cellex to make sure that the results are in compliance, it cannot be verifi ed with 100% certainty, that the control sets would be good for allpast/present/future test cassettes.

Do distributors need to register or require approval from the FDA to warehouse the Cellex product?

No, Cellex is the importer of record and has registered with the FDA. The "domestic distributor" who does not import does not need to register with the FDA. Nor does the warehouse need to have FDA approval. Nor are there any special registration numbers required to ship within the US.

Are distributors required to capture the High or Mid complexity CLIA Registration from the buyer?

The FDA is not requiring the distributor to capture the final buyer CLIA Registration number. However, it is clearly stated in the Cellex IFU, that "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." We suggest that all distributors remind customers of this limitation when they place orders with us. For more information, visit https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia. If you need help obtaining moderate or high-complexity status during the COVID-19 Pandemic, please visit https://www.cms.gov/files/document/qso-20-21-clia.pdf-0

Are distributors required to report laboratory results?

No, distributors are not required to report any results. Results are to be reported by the healthcare organization or laboratory to the appropriate public health authority. The FDA provided reporting guidelines to the manufacturer requesting the laboratory administering the test comply with the following:

- Authorized laboratories that receive Cellex product will notify the relevant public health authority of their intent to run the Cellex product prior to initiating testing.
- Authorized laboratories using the Cellex product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, when appropriate.
- Authorized laboratories will collect information on the performance of the Cellex product and report to DMD/OHT-01R/OEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and support@healthdatix.com any suspected occurrences of false positive or false negative results and significant deviations from the established performance characteristics of the Cellex product of which they become aware.

What happens when the EUA is removed by the FDA?

When the FDA determines COVID-19 is no longer a major threat, they may deem the product to no longer be for emergency use. The FDA will require all manufacturers to submit their product through the FDA normal approval procedures. Cellex is currently working on additional

MANUFACTURING, ORDERING, AND SHIPPING INFO continued...

What happens when the EUA is removed by the FDA?

When the FDA determines COVID-19 is no longer a major threat, they may deem the product to no longer be for emergency use. The FDA will require all manufacturers to submit their product through the FDA normal approval procedures. Cellex is currently working on additional studies and validation to submit for a 510(K) with the current test kit.

PCR TESTING

What is a PCR Test?

The PCR (Polymerase Chain Reaction) test can detect the genetic materials of SARS-CoV-2, the virus that causes COVID-19. Samples are collected from the upper respiratory tract using a nasopharyngeal swab. The test requires a PCR machine along with chemicals from the PCR test kit. The chemicals strip down the sample into RNA and then the RNA is used to create thousands of copies of DNA.
PCR testing can take from a couple of hours to a couple of days to determine if the virus is present. One major limitation of the PCR test is that it can only detect the active virus. If an individual has recovered from COVID-19 and has antibodies, the PCR test will not detect the Coronavirus and neither will it verify the presence of antibodies.

Are there special shipping and warehouse requirements for PCR tests?

Yes, the product must be shipped in a cold chain system. It must be stored at 38 (F) degrees or below.

TEST SELECTION AND PROTOCOLS

Which test is best, antibody, antigen or PCR?

All tests have a specific use case. And testing should not be viewed as a "one and done." If someone is presenting symptoms, as defined by the CDC (fever, chills, shortness of breath), then administering the PCR test to determine if the patient has a current infection would be advised. If the individual is not presenting any symptoms and has a concern they may have been exposed, then the antigen test would be the first test to be administered. The asymptomatic individual with COVID-19 is more likely to unintentionally spread the virus. Both the antibody and the antigen tests are good for surveillance screening. The best fit for the antibody test is after someone is diagnosed or surveilled as positive for the antigen or IgM. Re-testing after quarantine would be advised using the antibody test, which will show that the individual has accumulated IgG antibodies, which provides a level of immunity.

What is the protocol for testing?

These are our recommended guidelines, based on CDC guidelines for which and when each test should be administered:

1. Symptomatic – PCR Test
2. Asymptomatic – Antibody Test or Antigen Test
3. If Antibody Test results are IgM positive, then confirmatory PCR Test
4. If Antigen Test results are positive, then confirmatory PCR Test
5. Positive PCR Test – depending on the symptoms – re-test with Antibody Test and PCR test within 5-10 days
6. Negative IgG and IgM – test again if suspected exposure. Note: Testing positive for IgG provides an assumption, but no guarantee, of immunity. It is too soon to determine if full immunity is achieved, but recent studies are showing the antibodies are staying in an individual's systems for six months to a year after initial infection. The CDC recommendation is to continue to wear masks and social distance.

Note: Testing positive for IgG provides an assumption, but no guarantee, of immunity. It is too soon to determine if full immunity is achieved until further studies have been performed. Until then, social distancing is highly recommended

Q&A FOR COVID-19 TESTING

What is the difference between Antigen and PCR?

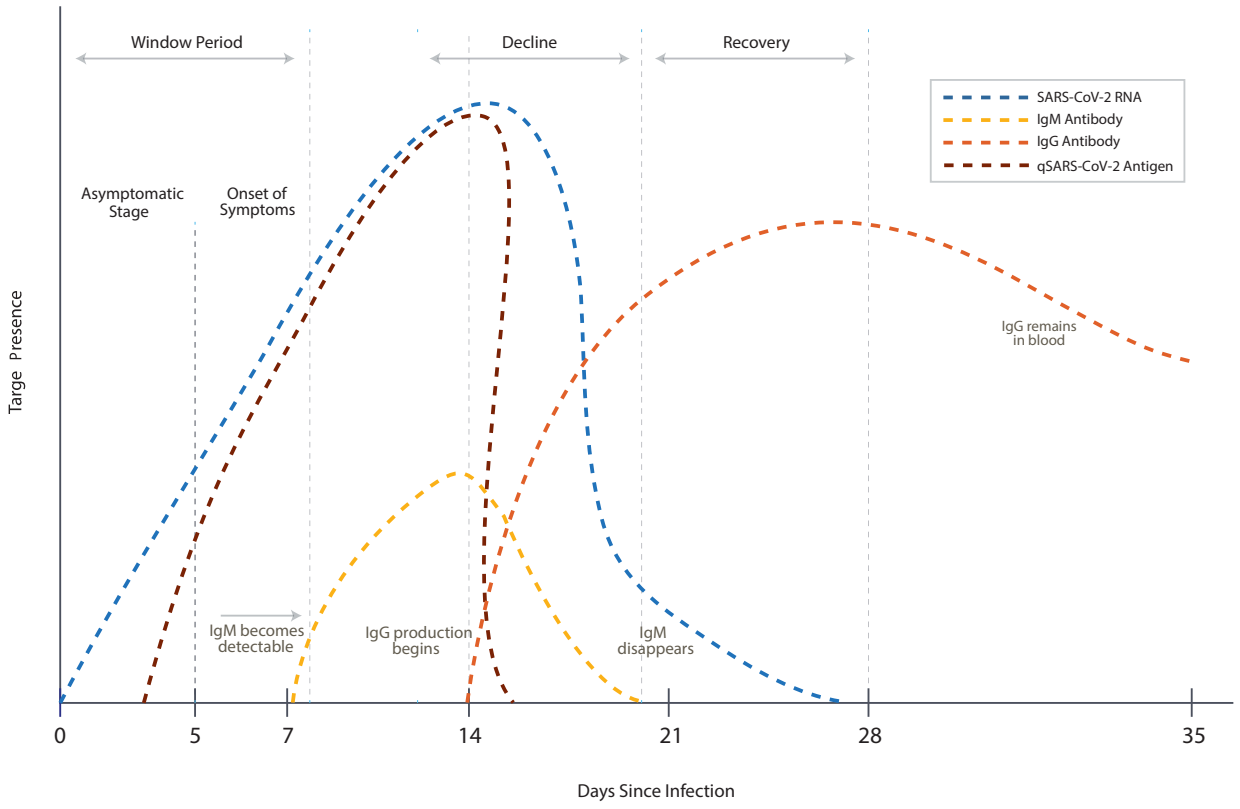
An antigen test checks to see if an individual is infected with the corona virus. The test looks for proteins (antigens) in a sample taken from the nose or throat. A RT PCR test looks for the RNA of the virus and samples are taken from the nose and throat using an nasopharyngeal swab.

What is the best use case for an antigen test?

Rapid antigen tests are commonly used in the diagnosis of respiratory pathogens, including influenza viruses and respiratory syncytial virus (RSV). The FDA has granted emergency use authorization (EUA) for antigen tests that can identify SARS-CoV-2. Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies a viral infection. Antigen tests are relatively inexpensive, can be used at point-of-care, and can return results in 15 minutes. Antigen tests perform the best when the individual is in the early stage of infection, when the viral load is generally at its highest point. The Antigen test can be deployed for diagnostic testing to identify current infection in individuals presenting symptoms. It is a much easier and less expensive test than the molecular RT-PCR test, which can take up to 24-48 hours to return results. In order to deploy diagnostic testing the manufacturer must have EUA on the antigen assay.

The key advantage to the antigen test over the RT-PCR test is time and money. The RT-PCR test was never designed for mass testing of asymptomatic individuals due to the length of time to analyze the sample and the high cost of the test material.

The antigen test can also be used for both screening and surveillance testing to identify infected person who are asymptomatic and may be contagious to reduce the spread of the virus. Screening is typically defined to include testing in congregate settings, such as long-term care facilities, correctional facilities, workplace and schools. Screening is typically focused on the individual, whereas surveillance testing is used to gain information at a population level, rather than an individual level. Surveillance testing does not require test result notification to the individual nor does it have to comply with FDA and CLIA requirements.



What is the FDA Policy on mass screenings for COVID-19?

According to the FDA, screening for COVID-19 is looking for occurrence at the individual level even if there is no individual reason to suspect infection such as a known exposure. This includes broad screening of asymptomatic individuals without known exposure with the intent of making individual decisions based on the test results. Screening tests are intended to identify infected individuals prior to development of symptoms or those infected individuals without signs or symptoms who may be contagious, so that measures can be taken to prevent those individuals from infecting others. FDA regulates screening tests as in vitro diagnostic devices and has provided recommendations and information regarding EUA requests for COVID-19 screening tests in the Policy for Coronavirus Disease-2019 Tests and the EUA templates referenced in that Policy. Examples of screening include testing plans developed by a workplace to test all employees returning to the workplace regardless of exposure or signs and symptoms, and testing plans developed by a school to test all students and faculty returning to the school regardless of exposure or signs and symptoms, with the intent of using those results to determine who may return or what protective measures to take on an individual basis.

CMS, CDC and the FDA have updated the proposed strategy on who, when and where Rapid Antigen and Antibody tests can be administered, "A covid-19 test used for screening and surveillance purposes is not regulated by the FDA". As long as, the manufacturer has submitted for EUA the product may be marketed and distributed in the US as a surveillance test. The broad description of surveillance testing is when an individual has no known exposure to the virus and is not presenting symptoms. CDC Link: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html.

Surveillance testing may be conducted at POC, nursing homes for staff, visitors and residents, private and public schools for students, teachers and staff, sport teams for players, staff, and fans. Because of the ease of use and rapid results of both the Antigen and the Antibody test kits, the best use case for all organizations is to schedule regular surveillance testing. Due to the nature of the virus spread, the tests are most effective when a testing protocol is in place. If an individual tests positive then the recommendation would be for the individual to contact their healthcare provider and take a confirmatory PCR test.

What is the difference between surveillance, screening, and diagnostic testing for COVID-19 testing? (Updated 11/16/20)

Surveillance for COVID-19 includes ongoing systematic activities, including collection, analysis, and interpretation of health-related data, essential to planning, implementing, and evaluating public health practice. It is generally used to monitor for an occurrence, such as an infectious disease outbreak, in a population or community, or to characterize the occurrence once detected, such as looking at the incidence and prevalence of the occurrence. Surveillance testing is primarily used to gain information at a population level, rather than an individual level. Surveillance testing may be random sampling of a certain percentage of a specific population to monitor for increasing or decreasing prevalence and determining the population effect from community interventions such as social distancing. FDA generally does not regulate surveillance testing. An example of surveillance testing is a testing plan developed by a State Public Health Department to randomly select and sample 1% of all individuals in a city on a rolling basis to determine local infection rates and trends.