Q&A FOR COVID-19 TESTING

There are two primary testing types available for detecting COVID-19: Antibody (serology) Testing and 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 CV-19 Antibody Rapid Test Kit. For additional questions, please contact: Healthdatix, Inc.
office: 727-828-0404 or cell: 727-647-7843

Box of 25 Rapid Tests with results in 15 minutes and proven accuracy of 95% Confidence Interval.

ANTIBODY TESTING

What is Antibody testing?

When a person is infected with a virus for the first time, the immune system triggers the production of antibodies that are specific to the virus. These antibodies have the power to attach themselves to the virus so that the immune system can destroy it. If antibodies are present, they will be found inside plasma, serum, and whole blood. However, it does take the body a while to produce the antibodies; in the case of COVID-19, antibodies typically appear within 1-3 weeks.

What are the advantages of Antibody testing?

One advantage of antibody testing is the speed and simplicity. It can be provided at the point of care, with no additional equipment, and results are available within minutes.

The other, very important, advantage is that it detects IgM antibodies, which indicate a recent or active infection, as well as IgG antibodies, which indicates a past infection.

How is a point-of-care Antibody IgG/IgM rapid test administered?

To conduct the test, the healthcare provider 1) collects the patient's blood either through a venipuncture or fingerstick; 2) places one drop in the center of the well of the cassette and adds two drops of buffer solution; 3) sets timer. The results will appear within 10-15 minutes. The test is invalid after 20 minutes. Medical personnel should review and follow the Cellex Instructions for Use (IFU) to ensure proper execution of the test.

Do all serology tests produce the same results -- and are there any differences?

All serology tests are intended for the qualitative detection of the SARS-CoV-2 antibodies. One cannot claim quantitative even with an analyzer that provides a reading number. So even the immunoassays like Abbott's are still considered qualitative; they are also sometimes referred to as semi-quantitative. Quantitative assays are validated with completely different methods. It can be complicated and confusing.

The key differences are in process and time. Lateral flow rapid tests, like the Cellex™ Rapid Antibody tests, produce results in as little as 15-20 minutes. The procedure is only three steps, and it is straightforward. Lateral flow rapid tests also do not require any special equipment/reader/analyzer.

Other technologies require multiple steps that require incubation periods, special equipment, and a longer duration of test procedure/time to get results. If an analyzer/reader is used, it may minimize human error related to someone reading a test with the naked eye. But an analyzer/reader requirement makes the test less versatile and mobile.

What technology does Cellex Antibody IgG/IgM test use?

Cellex uses lateral flow technology to detect the presence of IgG and IgM antibodies in a sample without the need for lab equipment, much like a home pregnancy test can detect the HCG hormone.

Does the EUA for Antibody tests include blood from a fingerstick?

The FDA has approved Antibody testing on blood obtained through a venipuncture. Currently, it is a recommendation not to use blood from a fingerstick. However, this is up to the laboratory and physician to determine if it is in the best interest of the patient to use blood from a fingerstick.

Cellex has performed one study and is in the process of a 2nd fingerstick study to be submitted to the FDA as an addendum to their existing EUA. Below are the results from the first fingerstick study performed:

A total of 70 participants were enrolled in this study. Fingerstick, venipuncture blood and saliva specimens were collected from each participant. The saliva samples were tested with PCR while the fingerstick and venipuncture samples were tested with Cellex's test. Initially there were two discordant results, which gave a concordance rate of 97%. The participants with the two discordant test results were called back and retested with the venipuncture and fingerstick specimens. The fingerstick re-retest results remained unchanged while the venipuncture retested results were the same as fingerstick sample. Therefore, after retesting, the concordance rate was 100%.

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?

Receipt of product is 2-5 or 10-12 business days pending the size of the order.

What are the packaging weights and dimensions?

One Box (25 Tests)
9.75" x 5.70" x 2.75" Weight 1.5 lbs

Master Carton (30 Boxes or 750 Tests)
27.50L" x 16" x 12.60"
Weight 27.40 lbs

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?

The control sets cannot be shipped in ambient temperature and must be shipped overnight on ice. Upon delivery, the control sets must be refrigerated. The MSRP of the P/N Control set is $29.00 plus $30.00/ shipping. It comes with 1 negative control and 1 positive control. The test is designed to test the shipment. The shelf life of the Quality Control Set is three months and the distributor or buyer is responsible for purchasing extra tests when they place their orders to be tested.

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 verified with 100% certainty, that the control sets would be good for all past/present/future test cassettes.

Cellex is in the process of lyophilizing (freeze drying) the controls. Then the Quality Control Set Set can be shipped with the regular order and will not require refrigeration. We expect these new QC Control Sets to be available in September, 2020.

MANUFACTURING, ORDERING, AND SHIPPING INFO (continued)

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/clia-categorizations%20on%20CDC.gov or https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-categorizations.

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.

If at any time a patient-specific result is to be reported by a facility, the facility must first obtain a CLIA certificate and meet all requirements to perform testing.

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 or PCR?

Both 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 antibody test would be the first test to be administered. The asymptomatic individual with COVID-19 is more likely to unintentionally spread the virus.

TEST SELECTION AND PROTOCOLS (continued)

It is important for people to get PCR tested early, when the symptoms first present, because as COVID-19 progresses, the coronavirus takes up residence in different places in the body. As time goes by, it is less likely to be detected by a standard nasopharyngeal swab because the virus is just not there anymore. According to a https://www.acpjournals.org/doi/10.7326/M20-1495review, a RT-PCR test for COVID-19 is at its most accurate about three days after symptoms appear, with a false negative rate of about 22%.The false negative rate climbs slowly as the disease progresses. By the time patients are feeling very ill, 16 days after symptoms start, as many as 66% of swabs come back with false negatives.

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
3. If Antibody Test results are IgM positive, then PCR Test
4. Positive PCR Test – depending on the symptoms – re-test with Antibody Test and PCR test within 5-10 days
5. 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 until further studies have been performed. Until then, social distancing is highly recommended.

What is the difference between IgM and IgG?

IgM Only – Patient is fighting the infection

Immunoglobulin M (IgM), which is found mainly in the blood, is the first antibody to be made by the body to fight a new infection.

IgG Only – Patient Has Recovered

Immunoglobulin G (IgG), is the most abundant type of antibody found in all body fluids, and protects against bacterial and viral infections.

Both – Patient is still fighting infection

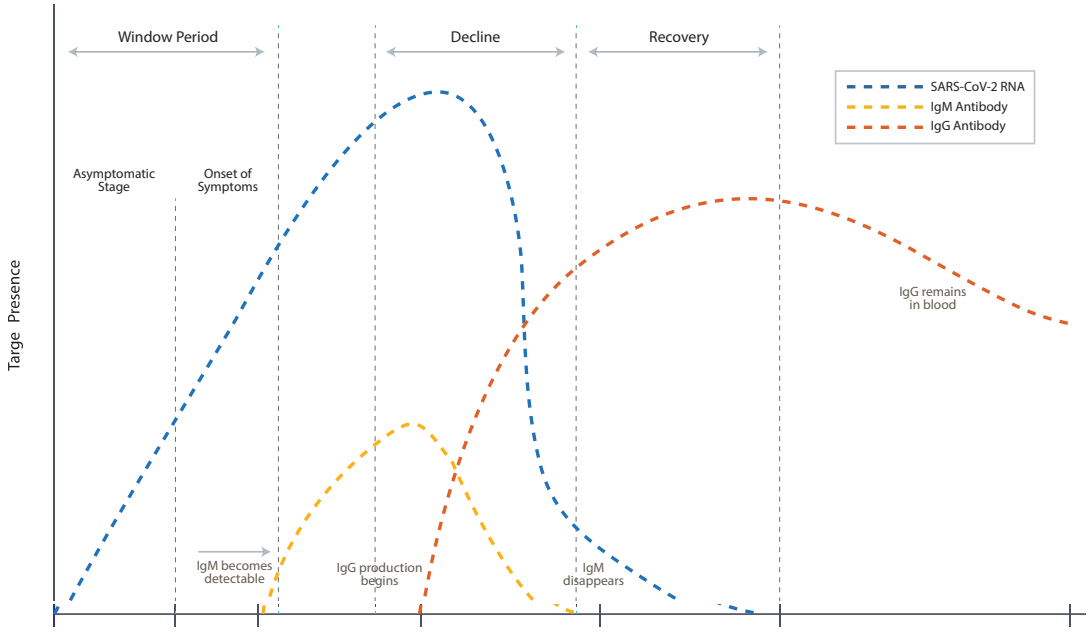
What is the clinical significance of the tests?

Test Results			
RNA	IgM	IgG	Clinical Significance
+	-	-	Patient may be in the window period of the infection
+	+	-	Patient may be in the early stage of the infection
+	+	+	Patient is in the active phase of infection
+	-	+	Patient may be in the late or recurrent stage of infection
-	-	+	Patient may have had a past infection and has recovered

COVID-19 ANTIBODIES - stages, target timelines and clinical

What are the COVID-19 Stages and Target Timelines?

Disclaimer: The chart to the right is for information purposes only. Detection windows vary from person to person.



TEST SELECTION AND PROTOCOLS (continued)

What is the best use case for an antibody (serology) test?

High quality serological tests can help us understand whether a person or population of people have developed antibodies indicative of an adaptive immune response to COVID-19.

Because a serology test can yield a negative test result even in infected patients (e.g., if antibody has not yet developed in response to the virus) or may be falsely positive (e.g., if antibody to a coronavirus type other than the current pandemic novel strain is present), antibody tests should not be used in the immediate diagnosis of a patient where COVID-19 infection is suspected. That is, these tests should not be used to diagnose acute COVID-19 infection.

Positive results from appropriately validated serology tests that are designed to be very specific to the SARS-CoV-2 virus can indicate whether a patient has had recent or prior COVID-19 infection. In addition, although not everyone who is infected will develop an antibody response, appropriately validated serology tests, when used broadly, can be useful in understanding how many people have developed an adaptive immune response to the virus and how far the pandemic has progressed.

Serology tests can play a critical role in the fight against COVID-19 by helping healthcare professionals identify individuals who have antibodies to SARS-CoV-2 virus and have developed an adaptive immune response. In the future, this may potentially be used to help determine, together with other clinical data, whether these individuals may be less susceptible to infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. In addition, these test results can aid in determining who may be eligible to donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19. (FDA FAQ 5/4/2020)

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.