VIKAND

COVID-19 Diagnostic Point of Care Testing Technology Information

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Covid-19 Diagnostic Point of Care Technology
Information as of 03/09/2021

Contents

Background

The diagnostic testing field for COVID-19 is rapidly evolving and improving in quality every day, with many tests focused on diagnosing patients with active viral infections. It remains challenging to keep up with the changes and provide the most current and best advice to our clients on which test they should invest in when they return to service.

We recognize there are many factors to consider when determining the most appropriate device for each client's needs, including cost, availability, and purpose of the device, whether that is for mass screening or testing symptomatic individuals. While all tests come with some limitations, PCR tests are considered the gold standard for their reliability. Antigen tests are a good diagnostic option however they are not recommended as a screening tool with asymptomatic individuals as the antigen is only detectable when someone is symptomatic. Due to the limitations in detecting the virus in asymptomatic individuals, there is risk with using an antigen test for mass screening purposes as it may result in false negatives. That being said, with consideration to several other factors the antigen test may be the best option to consider if PCR testing is not available for mass screening or may be considered as an interim measure until a suitable PCR testing becomes available.

Dr. Bill Heymann, Chief Medical Officer; Dennis Peyton, Epidemiologist and our Medical Managers are committed to working with our clients individually to make an informed decision, weighing the risks and benefits based on the most current science available on Covid-19 testing options today. If there are testing options not listed on our spread sheet that you would like us to research, please let us know and we will be happy to research and provide you a summary of what we learn.

Our recommendations on the testing spread sheet are based on several key factors, such as FDA emergency use authorized (EUA) or EU CE Certified, availability, accuracy, ease of use, footprint and cost. As more products come to market that meet many of these requirements, we will add them to our Covid-19 test spreadsheet.

Below is an updated summary explaining the Covid-19 testing types available that we hope provides more clarity on this complicated subject.

Definitions

CE: CE Certification is a mandatory conformance mark that certifies that a product has met EU consumer safety, health, or environmental requirements.

EUA: EUA allows FDA to authorize use of an unapproved medical countermeasures, or MCMs, in anticipation of a potential emergency or during an actual emergency involving a chemical, biological, radiological, or nuclear agent, or emerging infectious disease, if criteria in section 564 of the Federal Food, Drug, and Cosmetic Act are met

CLIA Waived: Laboratory testing that employs specific test methods designated under the Clinical Laboratory Improvement Amendments (CLIA) of the Food and Drug Administration (FDA) as "waived" (regulatory term)Waived testing is designated by CLIA as simple tests that carry a low risk for an incorrect result

Point of Care Testing: Refers to the location where the testing occurs. In other words, POCT means the testing is not happening in a central laboratory, it is happening closer to the patient. Some POCT tests are "waived", others can be designated as moderately complex or highly complex.

Overview of Covid Test Types (Molecular PCR, Antigen, Antibody)

Molecular Test (Diagnostic)

The most common molecular tests approved by regulatory bodies across the world for COVID-19 diagnosis are based on Polymerase Chain Reaction (PCR). Molecular tests are considered to be the gold standard diagnostic test for SARS-CoV-2. The diagnostic testing field for COVID-19 is rapidly evolving and improving in quality every day, with many tests focused on diagnosing patients with active viral infections. Diagnostics able to detect current, active infections are typically molecular-based diagnostics, which inform researchers of the presence of the pathogen, either by identifying its genetic material or identifying unique markers of the pathogen itself. The viral genomic material for SARS-CoV-2 is ribonucleic acid (RNA), which remains in the body only while the virus is still replicating. There are also rapid antigen tests in development that act by detecting specific surface markers called "antigen" on the outside of the virus.

What it does: In acute respiratory infections like COVID-19, molecular tests are routinely used to detect the presence of viral genetic material in a sample. The specific technique that is used is

called reverse transcription polymerase chain reaction, or RT-PCR, where genetic material from a sample is copied and then compared to the genetic sequence of the virus you're trying to detect. In a patient with a COVID-19 infection, genetic material from SARS-CoV-2, the virus that causes COVID-19, is generally detectable in upper and lower respiratory specimens.

How it works: This test uses a sample of mucus typically taken from a person's nose or throat. The test may also work on saliva — that is under investigation. It looks for the genetic material of the coronavirus. The test uses a technology called PCR (polymerase chain reaction), which greatly amplifies the viral genetic material RNA if it is present. That material is detectable when a person is actively infected.

How accurate is it: Generally speaking, these are the most reliable tests. However, a few days may pass before the virus starts replicating in the throat and nose, so the test will not identify someone who has recently been infected. And swabs can sometimes fail to pick up signs of active infection.

A positive result indicates an active COVID-19 infection but does not rule out bacterial infections or co-infections with other viruses. However, there is a small chance that it could be a false positive, meaning that the test is positive, but you actually don't have a COVID-19 infection.

With every test, there is a limit at which you can still detect a signal. A negative result with the molecular test means that the virus that causes COVID-19 was not found in the sample above the limit of detection, but it is still possible to have very low levels of the virus in the body.

A false negative is also possible, and should be considered in combination with your symptoms, travel history, and other possible ways of having been exposed. Additionally, the FDA advises anyone who tests negative with the saliva-based test to confirm the results with a second testing method.

How quick is it: These samples are generally sent to centralized labs for analysis, so it can take several days to get the test results back. Wait times were longer earlier in the pandemic because of a testing backlog. There are also two rapid PCR tests, which can be run on specialized equipment already widely distributed throughout the U.S. The speediest one, by Abbott Laboratories, can provide a result in 13 minutes, but one study suggests this test can miss more than 10% of cases.

While PCR-based tests are highly sensitive, specific, and remarkably reliable, they have many limitations ranging from the requirement of sophisticated laboratories, need of skilled personnel, use of complex protocol, long wait times for results, and an overall high cost per test. These

limitations have inspired researchers to search for alternative diagnostic methods that are fast, economical, and executable in low-resource laboratory settings. The discovery of Loop-mediated isothermal Amplification (LAMP) has provided a reliable substitute platform for the accurate detection of low copy number nucleic acids in the diagnosis of Covid-19. LAMP is an isothermal nucleic acid amplification technique. In contrast to the polymerase chain reaction (PCR) technology in which the reaction is carried out with a series of alternating temperature steps or cycles, isotheral amplification is carried out at a constant temperature, and does not require a thermal cycler. At present, a cocktail of LAMP assay reagents along with reverse transcriptase enzyme (Reverse Transcription LAMP, RT-LAMP) can be a robust solution for the rapid and cost-effective diagnosis for COVID-19

Note on sensitivity and specificity data: A highly sensitive test should capture all true positive results. A highly specific test should rule out all true negative results. If sensitivity or specificity is not listed, it was not available from the manufacturer at the time of posting. When available, the number of samples used for sensitivity/specificity definitions are listed in the product description.

It should also be noted that the terms “sensitivity” and “specificity” may not appears in the manufacturers’ information sheets, but rather these values are often reported as “positive percent agreement” and “negative percent agreement.” Sensitivity may also be measured by calculating the limit of detection (LOD), which is the lowest detectable number of virus copies in a sample at which the test will return a positive result at least 95% of the time. Essentially, a lower limit of detection indicates a more sensitive test, with fewer viral copies per sample necessary to elicit a positive test result.

What does cycle threshold (CT) value mean? CT indicates how much virus an infected person harbors. Standard PCR tests identify SARS-CoV-2 infections by isolating and amplifying viral RNA using a procedure known as the polymerase chain reaction (PCR), which relies on multiple cycles of amplification to produce a detectable amount of RNA. The CT value is the number of cycles necessary to spot the virus; PCR lab machines stop running at that point. If a positive signal is not seen after 37 to 40 cycles, the test is negative. But samples that turn out positive can start out with vastly different amounts of virus, for which the CT value provides an inverse measure. A test that registers a positive result after 12 rounds, for a CT value of 12, starts out with more than 10 million times as much viral genetic material as a sample with a CT value of 35.

Antigen Test (Diagnostic)

Rapid antigen tests directly detect the presence or absence of specific surface markers on the outside of the virus referred to as an antigen. These tests are relatively inexpensive, offer a short turnaround time and are commonly used to diagnose patients in point-of-care settings such as doctors' offices. Currently available antigen tests for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-have reported significantly lower sensitivity than most nucleic acid (i.e., molecular tests) but have also reported high specificity.

Scenarios Where SARS-CoV-2 Antigen Tests May Be Considered for Use

Due to the rapid time to result of antigen tests, SARS-CoV-2 antigen tests have utility in symptomatic patient populations with high pre-test probability that the patient has COVID-19 (i.e., symptomatic patients in high prevalence populations). Use of these tests should be reserved for instances where a positive result would direct immediate clinical decisions or infection control measures. Negative results in this scenario should be confirmed with a laboratory-based molecular PCR test and downstream costs of that confirmatory testing should be considered when making implementation decisions. Below are some example scenarios in which SARS-CoV-2 antigen tests may reasonably be used.

- Deployed with strike teams to provide targeted testing in emergency or outbreak situations.
- Triaging individuals with respiratory symptoms in an Emergency Department or similar setting.
- In prisons, long-term care facilities or other high risk, congregate settings where cases have been confirmed.
- Off hour testing in hospital settings when the patient will benefit from a rapid result and the laboratory will repeat the test by another method when staff are available.
- Symptomatic individuals in remote populations such as small rural hospitals, tribal nations or other jurisdictions with known high prevalence and limited alternative access to testing.

Scenarios Where SARS-CoV-2 Antigen Tests Should NOT Be Considered for Use

Due to the lower sensitivity of antigen tests relative to molecular test, SARS-CoV-2 antigen tests should only be considered for use in situations where a positive result would indicate immediate, specific clinical action and **should not be used** under the following circumstances:

- Limited data is available to guide the use of rapid antigen tests as screening tests on

asymptomatic persons to detect or exclude COVID-19

- Screening of healthcare workers, emergency responders and other essential personnel.
- Population-based surveillance studies.
- Testing underserved or marginalized populations where access to testing is limited.
  - In these scenarios, efforts to improve access to molecular testing should be explored rather than implementing an antigen test — antigen tests should not be considered a "better than nothing" alternative as the results for asymptomatic populations could be falsely positive or negative.
  - Alternatives, such as courier services and public service testing resources should be sought, with transfer of specimens to a laboratory for molecular testing.

How it works: Antigen tests can identify virus in nose and throat secretions. It does this by looking for proteins (nucleocapsid protein) from the virus (as opposed to the diagnostic test, which looks for genetic RNA material). This is the same technology used in your doctor's office for rapid strep testing.

How quick is it: These tests should provide results in just a few minutes. As a result, they could be used to screen people in hospitals, certain workplaces, or in other instances where it is important to find out quickly whether someone is currently at risk of spreading the disease. But unless these tests are proven to be highly accurate, physicians would still need to follow up a positive result with a PCR test to make a medical diagnosis.

Antibody Test (Non-Diagnostic of an Active Infection)

What it does: Antibody tests identify people who **have previously been infected with the coronavirus. They do not show whether a person is currently infected.** This is primarily a good way to track the spread of the coronavirus through a population.

How it works: This is a blood test. It looks for antibodies to the coronavirus. About six to 10 days after viral exposure, the body begins to develop antibodies that bind and react specifically to the proteins found on SARS-CoV-2. The first antibody produced is called immunoglobulin m (IgM), which is short-lived and only stays in the bloodstream for a few weeks. The immune system continues to refine the antibodies and just a few days later will start producing immunoglobulins G (IgG) and A (IgA), which are much more specific. IgG stays in the blood and can confer immunity for months, years, or a lifetime, depending on the disease it is protecting against.

The test tells us who has been infected and who should be immune to the virus because they have

already had an infection, even if the symptoms were very mild. It is not currently being used for detection of an active infection because it takes some time for the body to make the antibodies. Antibody tests can detect exposure to the virus even after the patient has recovered.

How accurate is it: There are more than 120 antibody tests on the market. The Food and Drug Administration has allowed them to be marketed without FDA authorization, and quality is a great concern. A few tests have voluntarily submitted to extra FDA approval. Other tests are being validated by individual medical labs or university researchers.

In general, these tests aren't reliable enough for individuals to act based on the results. And researchers say, even if you were certain you had antibodies to the coronavirus, it is still unknown if that protects you from getting sick again. Still, these tests can provide good information about rates of infection in a community, where errors in an individual result have less impact.

How quick is it: These tests generally produce results in a few minutes, based on a drop of blood taken from the finger. Some research labs use a more sophisticated antibody test, called an Elisa (Enzyme-linked immunoassay) that are more accurate but are not as widely
available but are becoming more widely available in hospital and commercial labs such as LabCorp and Quest.

TEST DETAILS	Abbott ID NOW System (PCR)
Type of Test	Isothermal nucleic acid amplification technology
	Molecular Diagnostic Test to Detect Viral Genetic Material
Gene Tested	RdRP Genes
Test Producer/Manufacture	Abbott Diagnostics
Website	https://www.alere.com/en/home/product-details/id-now.html
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Throat swab, nasal swab, or nasopharyngeal swab
POC or Shoreside LAB	POC
Time to Results	Results in 15 minutes or less. Positive results in as little as 5 minutes and negative results in as little as 15 minutes.
# of COVID tests run at one time	One
Capable of doing other tests	Yes - Flu A/B, Strep, RSV, etc.
EUA Certified	Yes
CE Marked	No
CLIA Waived	Yes
Sensitivity (Likelihood of returning pos when virus is present)	≥94.7% positive agreement
Specificity (Likelihood of returning neg when virus is not present)	≥98.6% negative agreement
Price	Instrument- $6,250.00 and tests will be in the $60 range for each test.
Testing Supplies included in price	Yes, swabs, medium and pipette depending on testing method.
Kit includes:	24 tests, swabs for sample collection 1 Positive Control Swab (Sterile swab to be used as Negative Control Swab)
Order Requirements	No minimum order requirement.
Footprint	Small footprint-benchtop
Availability	Lead Time is currently around 2 weeks.
Calibration & Maintenance Requirements	Device is factory calibrated. However, Quality Control test is required to be completed prior using the device for the first time, when the software is upgraded and, in some situations, when the device is moved. Room temperature
How are testing cartridges stored?	Room -temperature storage.
Comments/Information	Pack of 12 Positive Control Swabs + 12 Negative Control Swabs are available for purchase

TEST DETAILS	Cepheid GeneXpert Express System (PCR)
Type of Test	Real-time RT-PCR Molecular Diagnostic Test to Detect Viral Genetic Material
Gene Tested	N2 & E Genes
Test Producer/Manufacture	Cepheid
Website	https://www.cepheid.com/coronavirus-product-resources
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasopharyngeal swab, Nasal swab, and Nasal wash/aspirates
POC or Shoreside LAB	POC
Time to Results	Results in 30-45 minutes – depending on instrument. System can do 4 tests at a time. Positive results are given in about 15 minutes.
# of COVID tests run at one time	Multiple modules available for testing including systems that can perform 1, 4, and up to 16 tests at a time
Capable of doing other tests	Yes - Flu A/B, Strep, RSV.
EUA Certified	Yes
CE Marked	Yes
CLIA Waived	Yes
Sensitivity (Likelihood of returning a pos when virus is present)	97.8% positive agreement
Specificity (Likelihood of returning a neg when virus is not present)	95.6% negative agreement
Price	$18,500- for 2 module systems $35K for 4 modules. FLU and COVID tests will be in the $ $65-70 range per test
Testing Supplies included in price	Swab and viral transport medium are not included
Kit includes:	10 Cartridges with integrated Reaction Tubes, 10-12 Disposable Transfer Pipettes, 1 CD, and 1 Flyer
Order Requirements	No minimum order requirement.
Footprint	Small footprint. Dimensions can vary depending on module size.
Availability	Up to 7 weeks after PO is placed both for the device and the cartridges
Calibration & Maintenance Requirements	Each cartridge includes a Sample Processing Control and Probe Check Control. External controls are provided separately and should be used in accordance with local, state, and federal accrediting organizations as applicable
How are testing cartridges stored?	Cartridges are stored at room temperature and have an 18-month shelf life
Comments/Information	

TEST DETAILS	Qiagen QiaSTAT System (PCR)
Type of Test	Multiplex real-time RT-PCR
	Molecular Diagnostic Test to Detect Viral Genetic Material
Gene Tested	E & RdRP Genes
Test Producer/Manufacture	Qiagen
Website	https://qiastat-dx.com/row/qiastat-dx-sars-cov-2/
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasopharyngeal swab
POC or Shoreside LAB	POC
Time to Results	Approximately 67 minutes
# of COVID tests run at one time	System requires 1 Operational module connected to 1 Analytical module. This will run 1 test. Additional 3 Analytical modules can be linked to the Operational module and run a total of 4 tests at one time.
Capable of doing other tests	COVID-19 testing cartridge targets other 21 pathogens*. Gastrointestinal panel runs with same device and targets 24 pathogens that cause gastrointestinal infections.
EUA Certified	Yes
CE Marked	Yes
CLIA Waived	Yes
Sensitivity (Likelihood of returning a pos when virus is present)	> 95%
Specificity (Likelihood of returning a neg when virus is not present)	>99.5%
Price	Approximately $8,000 for the operational module and $20,000 for each analytical module. (multiple analytical modules can be linked to the operational module to run more tests at a time.) Each test is in the $137/each range. Service contract $3633 per year for analytical module and $1640 per year for operational module. $3500 installation fee
Testing Supplies included in price	Pipettes to use with the cartridges
Kit includes:	1 kit includes 6 Testing Cartridges and 6 Transfer Pipettes. It does not include swabs or viral transport medium.
Order Requirements	No special ordering requirements.
Footprint	Both modules have a small footprint for use as benchtop equipment
Availability	Lead time is 2-3weeks
Calibration & Maintenance Requirements	No calibration is required. Air filter must be replaced every year. An internal control is included within each SARS-CoV-2 Panel Cartridge and runs automatically
How are testing cartridges stored?	Room temperature with a 6-month shelf life
Comments/Information	Test results also produce available CT levels which will provide the information as to the “degree” of illness i.e. positive tests for 2 illnesses, and which is more relevant and also the “stage” of the illness.

*Bacterial Pathogens: Mycoplasma Pneumoniae, Legionella pneumophila, Bordetella Pertussis. Viral Pathogens: Influenza A, Influenza A subtype H1N1/2009, Influenza A subtype H1, Influenza A subtype H3, Influenza B, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Parainfluenza viruses 1, 2, 3, 4, Adenovirus, Respiratory Syncytial virus A/B, Human Metapneumovirus A/B, Bocavirus, Rhinovirus/Enterovirus

TEST DETAILS	Randox/Bosch Vivalytic System (PCR)
Type of Test	PCR Nucleic acid-based testing
Gene Tested	Not currently available. We will update when information becomes available
Test Producer/Manufacture	Bosch
Website	https://www.bosch-vivalytic.com/en/product/vivalytic-tests/pcr-test-for-sars-cov-2/
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasopharyngeal or Oropharyngeal swab
POC or Shoreside LAB	POC
Time to Results	SARS-CoV-2 Test Cartridge – 39 mins
# of COVID tests run at one time	1
Capable of doing other tests	Respiratory Tract Infections Test (RTI) cartridges can also run on the same device
EUA Certified	No
CE Marked	Yes
CLIA Waived	Not currently available. We will update when information becomes available
Sensitivity (Likelihood of returning a + when virus is present)	SARS-CoV-2 Test Cartridge – Not currently available
Specificity (Likelihood of returning a neg when virus is not present)	SARS-CoV-2 Test Cartridge – Not currently available
Price	Approx. $46,250 as an end user price. Cartridges are $78.25 each
Testing Supplies included in price	Cartridges only
Kit includes:	Pipettes and reagent sold separately and can be purchased via Randox/Bosch
Order Requirements	Orders are prepaid. Otherwise, no special-order requirements.
Footprint	Small benchtop analyzer
Availability	.Currently available
Calibration & Maintenance Requirements	Virtually maintenance is free, software updates and most technical support can be completed remotely. Air filter is to be replaced every 6 months. Application-specific is required for regular quality control testing.
How are testing cartridges stored?	Room temperature
Comments/Information	System is available for use right out of the box

TEST DETAILS	Coyote Bioscience (PCR) Mini8 Plus System
Type of Test	Real-time RT-PCR
Gene Tested	ORF1ab/RDRP, N gene
Test Producer/Manufacture	Coyote Bioscience
Website	http://www.coyotebio.com/
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasopharyngeal, Oropharyngeal
POC or Shoreside LAB	POC
Time to Results	Sample processing – 1 min Results obtained in 90 mins
# of COVID tests run at one time	8 samples at one time
Capable of doing other tests	RT-PCR test with two fluorescence, Fam and Rox
EUA Certified	Submitted
CE Marked	Yes
CLIA Waived	Yes
Sensitivity (Likelihood of returning a + when virus is present)	>95%
Specificity (Likelihood of returning a neg when virus is not present)	>95%
Price	Not currently available. We will update when information becomes available
Testing Supplies included in price	Not currently available. We will update when information becomes available
Kit includes:	SARS-CoV-2 PCR Mix I, SARS-CoV-2 PCR Mix II, SARS-CoV-2 Positive Control, Negative Control, Respiratory sample buffer, IFU
Order Requirements	No other requirements
Footprint	Small benchtop analyzer
Availability	In stock. Airfreight can take one week
Calibration & Maintenance Requirements	No specific requirements
How are testing cartridges stored?	All contents should be stored at -20±5°C and avoid direct light
Comments/Information	

TEST DETAILS	Quidel Diagnostics Sofia System (Antigen)
Type of Test	Antigen fluorescent immunoassay
Gene Tested	N/A
Test Producer/Manufacture	Quidel Corporation
Website	https://www.quidel.com/immunoassays/sofia-tests-kits
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasal swab, with release of oral swab testing pending
POC or Shoreside LAB	POC
Time to Results	15 minutes, with a batch mode that will provide results of subsequent samples within 10 seconds.
# of COVID tests run at one time	Batch mode available to allow up to 50 tests per hour but planning for around 40 is suggested
Capable of doing other tests	Yes, Flu A/B, Strep, RSV and other viral tests
EUA Certified	Yes
CE Marked	Yes
CLIA Waived	Yes
Sensitivity (Likelihood of returning a + when virus is present)	>96.4%
Specificity (Likelihood of returning a neg when virus is not present)	100%
Price	Instrument $1,750.00 and tests $31 per test, sold in a box of 25
Testing Supplies included in price	All items included
Kit includes:	As per above
Order Requirements	One box of Flu A/B tests are required with each unit purchased and 300 COVID tests
Footprint	Small footprint, benchtop analyzer
Availability	Swabs are on backorder. No date available currently.
Calibration & Maintenance Requirements	Calibration check must be performed every 30 days or less Calibration Cassette is provided with the device.
How are testing cartridges stored?	Room temperature and at least 12 months dating.
Comments/Information	

TEST DETAILS	BinaxNOW Covid-19 Card (Antigen)
Type of Test	*In Vitro* diagnostic rapid test for qualitative detection of SARS-CoV-2 antigen
Gene Tested	N/A
Test Producer/Manufacture	Abbott Diagnostics
Website	https://www.abbott.com/corpnewsroom/product-and-innovation/upping-the-ante-on-COVID-19-antigen-testing.html
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasopharyngeal swab
POC or Shoreside LAB	POC
Time to Results	15 minutes
# of COVID tests run at one time	No Instrumentation or device is needed. Results can be read from a test card. Each test card performs one test. NAVICA app allows test results to be received through: • temporary encrypted digital health pass via QR code (similar to a boarding pass) - for negative results • message with advice to quarantine and speak to own doctor - for positive results
Capable of doing other tests	No
EUA Certified	Yes
CE Marked	Not currently available. We will update when information becomes available
CLIA Waived	Yes
Sensitivity (Likelihood of returning a + when virus is present)	97.1%
Specificity (Likelihood of returning a neg when virus is not present)	98.5%
Price	Not currently available. We will update when information becomes available
Testing Supplies included in price	All items included
Kit includes:	Test Cards (40) Extraction Reagent (1) Nasal Swabs (40) Positive Control Swab (1) Negative Control Swab (1) Product Insert (1) Procedure Card (1)
Order Requirements	Pending confirmation
Footprint	Each card dimensions are equivalent to a credit card
Availability	Not currently available. We will update when information becomes available
Calibration & Maintenance Requirements	Control test required with Positive and Negative swabs included when pack of 40 is opened
How are testing cartridges stored?	Room temperature
Comments/Information	

TEST DETAILS	Panbio Covid-19 Test (Antigen)
Type of Test	*In Vitro* diagnostic rapid test for qualitative detection of SARS-CoV-2 antigen
Gene Tested	N/A
Test Producer/Manufacture	Abbott
Website	https://www.globalpointofcare.abbott/en/product-details/panbio-covid-19-ag-antigen-test.html
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasopharyngeal swab
POC or Shoreside LAB	POC
Time to Results	15 minutes
# of COVID tests run at one time	No Instrumentation or device is needed. Results can be read from a test card. Each test card performs one test.
Capable of doing other tests	No
EUA Certified	No
CE Marked	Yes
CLIA Waived	Not currently available. We will update when information becomes available
Sensitivity (Likelihood of returning a + when virus is present)	93.3%
Specificity (Likelihood of returning a neg when virus is not present)	99.4%
Price	$325.00 per box of 25 tests. Prices may fluctuate according to demand
Testing Supplies included in price	All items included
Kit includes:	25 Test devices with desiccant in individual foil pouch Buffer (1 x 9 ml/bottle) 25 Extraction tubes 25 Extraction tube caps 1 Positive control swab 1 Negative control swab 25 Sterilized nasopharyngeal swabs for sample collection 1 Tube rack 1 Quick reference guide (Nasopharyngeal) 1 Instructions for use
Order Requirements	Pending confirmation
Footprint	N/A
Availability	No availability in the USA. Other markets with some restrictions due to high demand.
Calibration & Maintenance Requirements	Control test required with Positive and Negative swabs included when pack of 25 is opened
How are testing cartridges stored?	Room temperature
Comments/Information	No Instrumentation or device is needed. Self-contained tube with "break off" swab minimizes staff exposure. Extraction tube is fully enclosed for disposal

TEST DETAILS	LumiraDx SARS-CoV-2 Antigen Test
Type of Test	Antigen Microfluid Immunofluorescence assay
Gene Tested	N/A
Test Producer/Manufacture	Lumira DRx
Website	https://www.lumiradx.com/uk-en/what-we-do/diagnostics/test-technology/antigen-test
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasopharyngeal swab. Sample from both nostrils is required using same swab
POC or Shoreside LAB	POC
Time to Results	Approximately 12 minutes
# of COVID tests run at one time	1
Capable of doing other tests	No
EUA Certified	Yes
CE Marked	No
CLIA Waived	Yes
Sensitivity (Likelihood of returning a + when virus is present)	97.6% positive percent agreement
Specificity (Likelihood of returning a neg when virus is not present)	96.6% negative percent agreement
Price	Prices estimated as per below: • Test analyzer $4000.00 • Test strip $22.00 (in boxes of 48 – price per box is $1100.00)
Testing Supplies included in price	Pending confirmation
Kit includes:	LumiraDx Test Strips packed individually in sealed desiccant foil pouches. LumiraDx Test Product Insert RFID (Radio frequency ID) Tag held inside the Test Strip carton Extraction Buffer Vials Dropper Lids LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions
Order Requirements	Pending confirmations
Footprint	Small footprint, benchtop analyzer
Availability	December 2020
Calibration & Maintenance Requirements	Not currently available. We will update when information becomes available
How are testing cartridges stored?	Room temperature and at least 12 months dating.
Comments/Information	RT-PCR comparable results within 12 days of onset of symptoms

TEST DETAILS	CareStart COVID-19 Antigen
Type of Test	Antigen lateral flow immunochromatographic Assay
Gene Tested	NA
Test Producer/Manufacture	Manufactured by Access Bio, Inc. & Distributed by Intrivo Diagnostics
Website	https://carestartantigen.com/
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasopharyngeal swab
POC or Shoreside LAB	POC
Time to Results	Results in 10 minutes
# of COVID tests run at one time	Single Cartridge Test
Capable of doing other tests	No
EUA Certified	Yes
CE Marked	
CLIA Waived	Yes
Sensitivity (Likelihood of returning a pos when virus is present)	88.4%
Specificity (Likelihood of returning a neg when virus is not present)	99.6%
Price	$21.50/ each
Testing Supplies included in price	
Kit includes: 20 each	20 tests/kit including: Test device, extraction vial, Nasopharyngeal swab. One Positive & one Negative control swab. It does NOT include (micropipette, gloves, timer, or sharps container)
Order Requirements	
Footprint	Very small cartridge
Availability	Available while stocks last.
Calibration & Maintenance Requirements	It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user. External positive and negative control swabs are provided in the kit. The external control should be tested using the nasopharyngeal swab test procedure provided in the package
How are testing cartridges stored?	Store the kits as packaged between 1 ~30C. Do not Freeze
Comments/Information	Technical Support at +1- 888-898-1270 (Available Hours: Mon. to Fri.: 8 a.m. – 5 p.m.) or TShelp@accessbio.net (24/7 available).

References

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- https://www.npr.org/sections/health-shots/2020/05/01/847368012/how-reliable-are-covid- 19-tests-depends-which-one-you-mean
- https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics
- https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars- cov-2
- https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized- serology-test-performance
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