Covid-19 Diagnostic Point of Care Technology Data as of 8.12.20

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v2.0

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TEST DETAILS	Abbott ID NOW System (PCR)	Cepheid GeneXpert Express System (PCR)
Type of Test	COVID-19 PCR Molecular Test- Isothermal amplification (targeting the coronavirus (COVID-19) RdRp Gene.	Molecular-Real time PCR
Test Producer/Manufacture		
Website	https://www.alere.com/en/home/product-details/id-now.html	https://www.cepheid.com/en_US/tests
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Throat swab, nasal swab or nasopharyngeal swab	Nasopharyngeal swab or Naso swab
POC or Shoreside LAB	POC	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.	Results in 30-45 minutes – depending on instrument. System can do 4 tests at a time. Positive results in about 15 minutes.
# of Covid tests run at one time	One	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, etc.	Yes - Flu A/B, Strep, RSV, etc.
EUA Certified	Yes	Yes
CE Marked	No	No
CLIA Waived	Yes	Yes
Sensitivity (Liklihood or returning a + when virus is present)	> 94.7%	>95% with 95% confidence
Specificity (Liklihood of returning a neg when virus is not present)	>98,6%	
Price	Instrument- $6,250.00 and tests will be in the $60 range for each test	$18,500- for 2 module systems $35K for 4 module. FLU and Covid tests will be in the $45-$50 range per test
Testing Supplies included in price	Yes, swabs, medium and pipette depending on testing method	No, Swab and transport medium is not included
Kit includes:	24 tests, swabs for sample collection, + & - control swabs	
Order Requirements	No minimum order requirement. If the placement/lease then it's 900 tests per unit per year	
Footprint	Small footprint-benchtop	Small footprint-benchtop
Availability	If order placed and commitment for purchase made, then system and tests would be available my mid-September.	Will not be available until first quarter of 2021 and that is only if orders are placed in thenext couple of weeks.
Calibration & Maintenance Requirements		
How are testing cartridges stored?	Room -temperature stroage No refrigeration required	Cartridges are stored at room temperature and have an 18-month shelf life
Comments/Information		

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TEST DETAILS	Qiagen QiaSTAT System (PCR)	Randox/Bosch Vivalytic System (PCR)
Type of Test	PCR Nucleic Acid	PCR Nucleic acid based testing
Test Producer/Manufacture		
Website	https://qiastat-dx.com/na/	https://www.bosch-vivalytic.com/en/
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasopharyngeal swab	Nasopharyngeal or Oropharyngeal swab
POC or Shoreside LAB	POC	POC
Time to Results	Approximately 67 minutes	Less than 2.5 hours
# of Covid tests run at one time	Depends on the system: System requires 1 Operational module connected to 1 Analytical module. This will run 1 test. You can link up to an additional 3 Analytical modules to the Operational module and run a total of 4 tests at one time.	1
Capable of doing other tests	Can perform COVID-19 testing and an additional 20 target tests including Flu A/Flu B/RSV and others. *See additional information below	Currently the cartridges only run COVID-19 tests, but they are planning to release new cartridges which will be able to run an additional 10 viral pathogen tests. Additionally, they have cartridges for use that run testing for 10 sexually transmitted diseases
EUA Certified	Yes	In the process of submission to the FDA
CE Marked	No	Yes
CLIA Waived	Yes	
Sensitivity (Liklihood or returning a + when virus is present)		95%
Specificity (Liklihood of returning a neg when virus is not present)		95%
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.) The test cartridge is in the $137/each range. Service contract $3633 per year for analytical module and $1640 per year for operational module.	Approx $46,250 as an end user price and approx Cartridges are approx $115
Testing Supplies included in price	Pippettes for use with the cartridge	Cartridges only
Kit includes:	1 cartidge kit includes 5 testing cartridges and necessary pippettes-does not include swab or medium	No kits. Pippettes and reagant sold separately and can be purchased via Randox/Bosch
Order Requirements	No special ordering requirements.	Orders are prepaid. Otherwise, no special order requirements.
Footprint	Both modules have a small footprint for use as benchtop euqipment	Small benchtop analyzer
Availability	Modules and cartridges available in the US. European availability not known at this time, pending call with Rep	Depends on number needed, machines are available or could take 2-3 weeks. Cartridges are available in smaller amounts 200 or less Reagent can be obtained but is difficult to obtain in larger quantities.
Calibration & Maintenance Requirements	Operational module and Analytical module require a service contract as part of the purchase.	Virtually maintenance free, software updates and most technical support can be supported remotely.
How are testing cartridges stored?	Room temperature with a 6 month shelf life	Room temperature
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.	System is available for use right out of the box

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TEST DETAILS	Quidel Diagnostics Sofia System (Antigen)	BD Veritor Plus System (Antigen)
Type of Test	Antigen fluorescent immunoassay	Antigen
Test Producer/Manufacture		
Website	https://www.quidel.com/immunoassays/sofia-tests-kits	https://www.bd.com/en-us/offerings/capabilities/microbiology-solutions/point-of-care-testing/veritor-plus-system
Sample Source: (Nasopharyngeal, Nasal, Oral, Breathalyzer, blood)	Nasal swab, with release of oral swab testing pending	Nasopharyngeal swab
POC or Shoreside LAB	POC	POC
Time to Results	15 minutes, with a batch mode that will provide results of subsequent samples within 10 seconds.	15 minutes
# of Covid tests run at one time	1 - Has a batch mode that will allow up to 50 tests per hour, but would suggest planning for around 40.	1. No batch process capability
Capable of doing other tests	Yes, Flu A/B, Strep, RSV and other viral tests	Yes- Flu A/B, RSV, Strep
EUA Certified	Yes	Yes
CE Marked	Yes	
CLIA Waived	Yes	Yes
Sensitivity (Liklihood or returning a + when virus is present)	>96.4%	84%
Specificity (Liklihood of returning a neg when virus is not present)	100%	100%
Price	Instrument $1,750.00 and tests $31 per test, sold in a box of 25	No charge for the analyzer itself with the purchase of 2 boxes of Flu A/B tests. COVID-19 tests are priced in the $55.00 to $60.00 range.
Testing Supplies included in price	All items included	Cartridges
Kit includes:		
Order Requirements	One box of Flu A/B tests are required with each unit purchased and 300 Covid tests	No charge for the analyzer itself with the purchase of 2 boxes of Flu A/B tests.
Footprint	Small footprint, benchtop analyzer	Small - handheld device
Availability	Currently looking at a mid-September availability for both units and cartridges.	Taking oderes for the analyzer now and tests should be available by the end of September. (Timeline could change and will be updated when additional information obtained)
Calibration & Maintenance Requirements		
How are testing cartridges stored?	Room temperature and at least 12 months dating.	
Comments/Information		Hss a shelf life of approximately 200 uses and then is suggested to be replaced.

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CE, EUA & CLIA Waived 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." Waived testing is designated by CLIA as simple tests that carry a low risk for an incorrect result

Overview of Test Types

Diagnostic or PCR Gene Test

What it does: Doctors use this test to diagnose people who are currently sick with COVID-19. This is the one we've been hearing so much about.

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's 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 won't identify someone who has recently been infected. And swabs can sometimes fail to pick up signs of active infection.

How quick is it: These samples are generally sent to centralized labs for analysis, so it can take several days to get 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.

Antigen test

What it does: This test identifies people who are currently infected with the coronavirus. It may be used as a quick test to detect active infections. Initially it will not be used to diagnose disease, but it may be used to screen people to identify those who need a more definitive test.

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 accurate is it: The first of these tests gained FDA clearance on May 8. The company, Quidel Corp., says it will use the first 40,000 tests to get a better idea about the accuracy of its test. Researchers do not expect it to be as accurate as the PCR diagnostic test, but it is possible the antigen tests could be used to screen patients for infection. Dr. Jordan Laser, a lab director at Northwell Health, notes antigen testing is used for rapid strep tests, which are reliable, and rapid flu tests, which are not. Antigen tests are less sensitive than PCR tests because the PCR tests have an amplification step that makes them able to detect very tiny quantities of viral genetic RNA material.

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's 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

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. Your body produces antibodies in response to an infectious agent such as a virus. These antibodies generally arise after four days to more than a week after infection, so they are not used to diagnose current disease.

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's 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.

References

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