Evaluate Vantage

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Abbott rides to the rescue with $5 Covid-19 test

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The BinaxNow antigen test is fast and acceptably accurate – but above all, cheap.

As Covid-19 continues to scorch its way across the US, the FDA has increasingly prioritised mass testing over individual precision. In granting emergency use authorisation for Abbott's cheap and easy Covid-19 antigen test yesterday the agency has continued this approach, and at $5 a pop, BinaxNow could enable widespread, repeated testing – including, the FDA says, in schools.

There is huge demand for feasible screening tests for the coronavirus that could get around the current bottleneck caused by overwhelmed lab capacity in the US. As a result Abbott's stock was trading up 8% at the open. And those who were concerned about Abbott's previous attempt at a fast point-of-care test, ID Now, will be mollified by the respectable accuracy figures Abbott has reported for its new diagnostic.

BinaxNow is a lateral flow assay, in which a liquid sample is applied to a membrane impregnated with antibodies specific to the coronavirus nucleocapsid antigen – very similar in concept to a pregnancy test. In this case a nasal sample is taken from a patient by a healthcare professional and applied to the BinaxNow test card; after allowing 15 minutes for the reaction to develop, the test will display one line for negative and two for positive.

Accuracy and simplicity

In the assay's instructions for use Abbott reports positive and negative percent agreement – analogous to sensitivity and specificity, respectively – in the high 90s. This is pretty similar to the other three antigen tests the FDA has authorised. But BinaxNow was tested on just 102 subjects, less than half as many as the others. All the tests were evaluated on symptomatic patients suspected of having Covid-19, except LumiraDx's assay, which was also used to test key workers at high risk of catching the bug.

Accuracy of FDA-authorised antigen tests					
Date of EUA	**Company**	**Test**	**PPA**	**NPA**	**Suspected positive sample size**
Aug 26	Abbott	BinaxNow	97.1%	98.5%	102
Aug 18	LumiraDx	LumiraDx Sars-CoV-2 Ag	97.6%	96.6%	257
Jul 2	Becton Dickinson	BD Veritor system for Sars-CoV-2	84.0%	100%	226
May 8	Quidel	Sofia Sars antigen FIA	96.7%	100%	209
PPA and NPA = positive and negative percent agreement. Source: FDA.					

It should be noted that these percentages are notably lower than the accuracy shown by Covid-19 antibody tests, the other kind of protein-based assays used for the disease. But antibody tests are used to detect prior infection, rather than active cases.

The antigen tests are also less accurate than viral RNA tests using PCR or next-generation sequencing technologies; these remain the gold-standard for detecting active Covid-19, but must be performed in labs away from the patient. The tests are fast enough but transporting the samples takes time. Moreover, the sheer volume of tests being taken has led to some diagnostics companies reporting backlogs and delays.

All the antigen tests are performed at the point of care, meaning samples do not have to be sent to a lab. Four rapid viral RNA tests used at the point of care are also authorised by the FDA, including Abbott's own ID Now test. That assay was a rare misstep from Abbott, having been the subject of an FDA statement in mid-May suggesting that it might return false negative results. Its authorisation was not withdrawn.

Cost

Abbott's test has an advantage over the other three authorised antigen assays in its simplicity. The others must all be fed into handheld, portable machines, whereas the result with Abbott's test is read off the test card.

The killer app for BinaxNow, however, is not simplicity or accuracy but price. Abbott does not claim that BinaxNow is the cheapest point-of-care Covid-19 test authorised in the US – and but at $5 there cannot be many cheaper. Even the saliva test developed by researchers at Yale is expected to cost around $10 per sample.

Abbott will start selling BinaxNow in the next two weeks, and says it can make "up to" 50 million tests available monthly in the US from the beginning of October 2020. According to Abbott the test can be performed by doctors, nurses, school nurses, medical assistants and technicians, pharmacists, employer occupational health specialists, and possibly other people after they are trained. However, the place where it is performed must have a Clia waiver, certificate of compliance or certificate of accreditation, which might rule some workplaces or schools out.

Abbott also intends to launch an optional app, Navica, which is linked to the test and allows the patient to display their result as a sort of passport, allowing Covid-19-negative people to return to work or school. It displays a "digital health pass" similar to a train ticket or boarding pass, which expires after a period specified by organisations that accept the app.

This shows how keen Abbott is on repeat testing. Presumably a patient would have to get a test every time they catch a cold or other infection with symptoms similar to coronavirus, which for many people, such as nurses, teachers or schoolchildren, could mean several times a year. Provided BinaxNow does not prompt accuracy concerns as ID Now did, those $5 payments could really mount up.

That said, the company has perhaps been dealt a blow by the CDC's controversial new recommendation that asymptomatic people who have been in contact with a Covid-19 patient do not necessarily need a test. This could have been a lucrative market, with a cheap test appealing to people who might well be free of the virus. But using BinaxNow as a screen in asymptomatic patients would have its own hazards: its accuracy figures being what they are the risk of false negatives is around 3%, making it less appropriate for broad screening than PCR-based viral RNA tests. The US needs accurate, widespread screening of asymptomatic people, but scientifically speaking BinaxNow is not the right tool for that job.

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