Evaluate Vantage

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Balancing the accuracy and cost of antigen testing

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Antigen tests for Covid-19 can be useful if used in the right settings, but those settings are expensive.

The advent of antigen tests for the coronavirus prompted a wellspring of hope that these swift and supposedly cheap diagnostics could screen the general population and help lift lockdown restrictions. Today's news that the UK pharmacy chain Boots is to offer an antigen test privately also plays into this narrative.

But only one of the six antigen tests authorised by the US FDA is in the $5-a-pop price range thought necessary to make widespread, repeated testing economically viable. And there are mounting concerns about accuracy: at some healthcare sites the reported rate of false positives has been as high as 50%.

The accuracy figures the makers of these tests have submitted to the FDA vary, though most have positive and negative percent agreement – analogous to sensitivity and specificity respectively – in excess of 90%. But in real-world, point-of-care settings, away from the controlled environment of the lab, some users have found them to be much less precise.

Accuracy of FDA-authorised antigen tests					
Date EUA first granted	**Company**	**Test**	**PPA**	**NPA**	**Suspected positive sample size**
October 8	Access Bio	CareStart Covid-19 antigen test	88.4%	100%	126
October 2	Quidel	Sofia 2 Flu + Sars antigen FIA	95.2%	100%	165
August 26	Abbott Diagnostics	BinaxNow Covid-19 Ag card	97.1%	98.5%	102
August 18	Lumiradx	LumiraDx Sars-CoV-2 Ag test	97.6%	96.6%	257
July 2	Becton, Dickinson and Company	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.					

At the start of this month authorities in Nevada directed nursing facilities to stop using antigen tests after 15 of 30 tests performed using Becton Dickinson's kit were found to be false positives. And of the nine samples that tested positive using Quidel's Sofia Sars antigen FIA assay, eight were found to be false. This directive was later reversed after the US Department of Health and Human Services intervened.

Of course these numbers are small, and the poor accuracy could be down to user error. Buta similar situation occurred in Vermont, where in July an unnamed antigen test indicated 65 people had the virus; only four of these cases were confirmed by viral RNA testing.

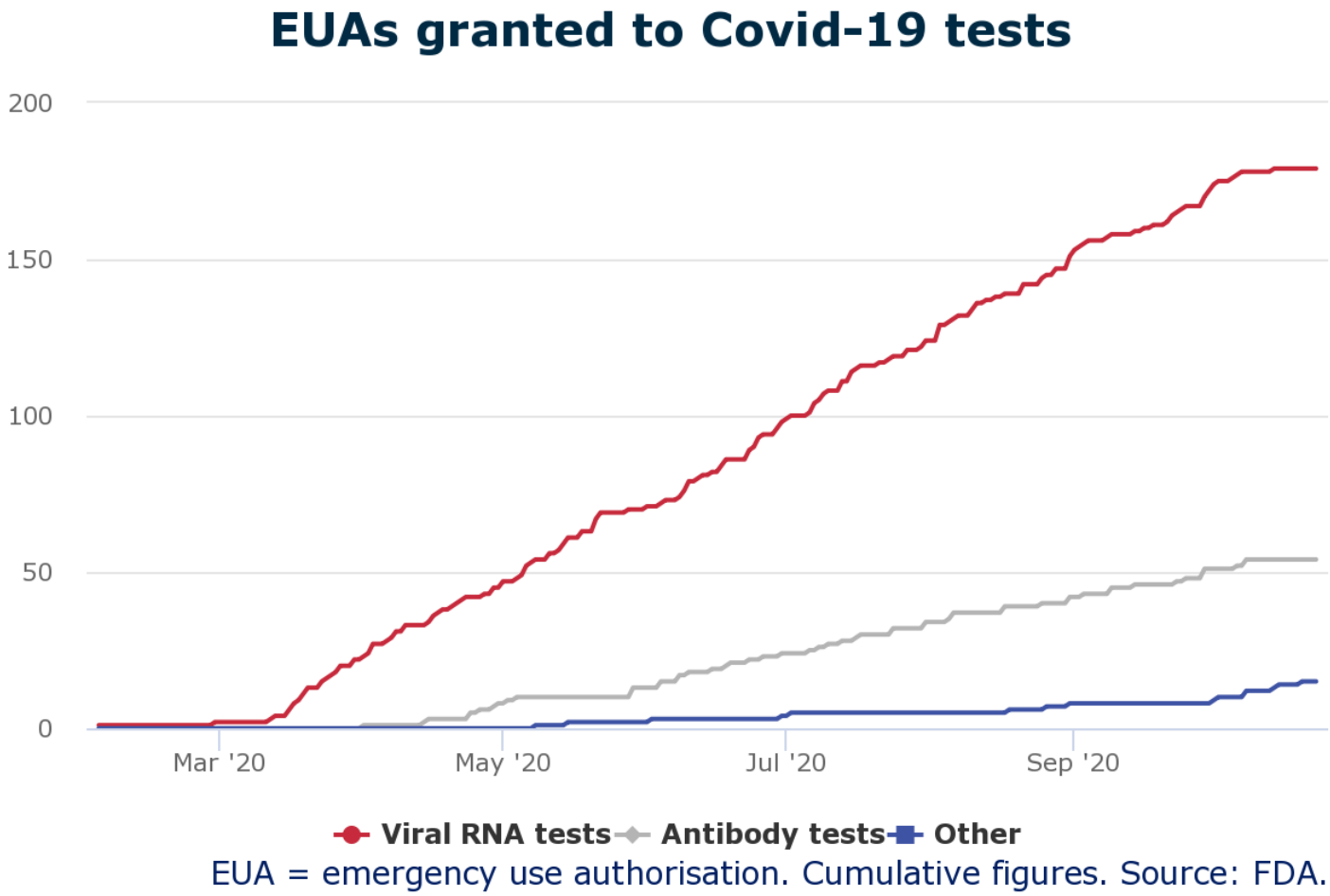
Repeat

Supporters of using antigen tests for the screening of asymptomatic people say they need not be hugely accurate provided the population is screened frequently. A recent modelling study found that test frequency was more important for controlling the spread of infection than test sensitivity. This research found that in theory, screening every two days using a test with sensitivity and specificity of around 70% and 98% respectively, coupled with strict isolation, ought to maintain an acceptably low infection rate.

At this point, however, cost comes into the calculation. Even using the cheapest antigen test – Abbott's BinaxNow, which costs $5 – screening a company with 150 employees, for instance, every other day would cost $137,000 per year. Between the cost and the logistical challenge of administering all these tests it seems fairly unrealistic that such a protocol could be put in place.

The test to be offered at Boots in the UK, made by Lumiradx, will not be administered as a means of screening for Covid-19. It will be up to individuals to use it, at a cost of £120 ($150), paid out of pocket. It can only be used by people who have no Covid-19 symptoms, and as such it is intended to appeal to people who want to be certain they do not have the virus before travelling, or meeting friends or family who are particularly vulnerable to an infection.

Encouraging asymptomatic people to take a test is not necessarily a bad idea; it is estimated that 40% of people infected with the coronavirus have no symptoms but can still transmit it to others. But this kind of fragmented administration is not going to make a difference to quarantine rules or enable public life to return to normal.



Note: "other" includes six antigen tests, five home sampling kits, two IL-6 tests and two saliva collection devices.