Evaluate Vantage

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# A new setting for antigen testing

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**It is vital that the first authorised at-home, non-prescription Covid-19 antigen test be used in the right way.**

The US FDA yesterday granted emergency use authorisation for an antigen test for Covid-19 that can be sold over the counter and performed entirely at home. The agency believes that this will expand access and reduce the burden on laboratories.

And so it will. However, there is a risk here that a result with the Ellume Covid-19 Home Test will be used by individuals as a one-off definitive diagnosis, and they will adapt their behaviour accordingly. This is not by any means how antigen tests are best used, and if the assay is employed in this way it could be ineffective at helping to halt the coronavirus's spread.

Ellume's test kit includes a nasal swab, a dropper, processing fluid, and a Bluetooth-connected analyser which connects to an app on a smartphone. The app provides video instructions for the test, and the result is displayed in the app in under 15 minutes, with options to share the results with healthcare professionals, authorities, employers and educators.

The private Australian group says it plans to deliver 20 million of the tests to the US during the first half of 2021; they will retail for around $30.

**Strategy**

Antigen tests are fast, cheap and easy to produce, and have definite value in combating the pandemic – but they are only of real use when employed to test entire communities repeatedly, in a co-ordinated manner (*The promise and the perils of antigen testing, December 1, 2020*).

As Eric Yager, associate professor of microbiology at Albany College of Pharmacy and Health Sciences, put it when he spoke to *Evaluate Vantage* last month: "A negative [result with an antigen test] does not mean the person does not have an infection or is not infectious. It's something you wouldn't want to use in an airport or at a restaurant and say, 'oh, take this test, and if you're negative come on in'."

This is because antigen tests are less accurate than assays that detect viral genetic material, which can be regarded as a pretty definitive yes or no, and therefore can be used as the basis for a person deciding whether to isolate or not.

The accuracy of Ellume's test is roughly mid-table compared with the eight other antigen tests the FDA has authorised. But none of these are as accurate as molecular diagnostics, and the FDA stated that as with other

antigen tests, negative results with Ellume's assay "do not preclude an individual from Sars-CoV-2 infection".

| Accuracy of FDA-authorised antigen tests | | | | | |
|---|---|---|---|---|---|
| **EUA first granted** | **Company** | **Test** | **Sensitivity/ PPA** | **Specificity/ NPA** | **Suspected positive sample size** |
| Dec 15 | Ellume | Ellume Covid-19 home test | 96.0% | 100% | ? |
| Dec 7 | Luminostics | Clip Covid rapid antigen test | 96.9% | 100% | 32 |
| Oct 23 | Celltrion | Sampinute Covid-19 antigen MIA | 97.2%* | 100%* | 41** |
| Oct 8 | Access Bio | CareStart Covid-19 antigen test | 88.4% | 100% | 126 |
| Oct 2 | Quidel | Sofia 2 Flu + Sars antigen FIA | 95.2% | 100% | 165 |
| Aug 26 | Abbott Diagnostics | BinaxNow Covid-19 Ag card | 97.1% | 98.5% | 102 |
| Aug 18 | Lumiradx | LumiraDx Sars-CoV-2 Ag test | 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 |

**Average in two studies. **Total in two studies. PPA and NPA = positive and negative percent agreement in symptomatic patients. Source: FDA & Ellume.*

The accuracy figures in this table refer to the test's use in detecting symptomatic Covid-19 when compared to an emergency use authorised lab-based molecular test. When used to detect asymptomatic infection, the test demonstrated a sensitivity of 91% and specificity of 96%. There is some evidence that other antigen tests can be useful in pinpointing symptom-free carriers of the virus, but again they must be deployed strategically (*Abbott's Covid-19 antigen test shows promise in asymptomatics, November 5, 2020*).

Because the FDA's authorisation of Ellume's test allows individuals to buy it with no oversight from a healthcare professional or co-ordinating authority, it could increase the chance that a user self-isolates unnecessarily, or, worse, goes out and mixes with other people on the strength of a false-negative result.