Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

814M	734M	706M	614M	518M
March 2022	April 2022	May 2022	June 2022	July 2022

No changes to capacity estimates this week. Capacity, of course, is highly related to supply and ultimately, demand - and for COVID tests, demand is connected to the real and perceived number of COVID cases. The challenge today, as outlined in The New York Times, is that states are reducing the frequency at which they report cases to the federal system. A quarter of them are no longer reporting daily, and more are expected to move in that direction. In addition, as frequently discussed, the majority of all tests are now done at home, and there is no standard reporting system for home tests. Note: The NYT piece mentioned uses our capacity and test usage estimates.

What Happened Last Week

The FDA issued two new EUAs, nine amendments to existing EUAs, and no new safety/policy communications in the past two weeks:

- New EUA's (2):
  - Antigen (2): Watmind Speedy Swab | Genabio
- Amendments to Existing EUA's (9):
  - Molecular (3): Abbott Alinity | Abbott RealTime | Rheonix
  - Antigen (2): InBios Int'l | iHealth Labs
  - Serology (1): Ortho-Clinical Diagnostics VITROS
  - Collection Kits (3): Quest | Pixel by LabCorp | Yale SalivaDirect

New & Noteworthy

Yes, antigen tests still detect infectivity - even with BA.5

That's the simple answer to the question a lot of people have been asking, but there are some important specifics.

Last week, the FDA speculated that symptomatic patients infected with Omicron may receive false-negative antigen test results up to 40% of the time, due to low viral loads (high Ct). These cases are called "low positives," because they'll still come up positive on PCR. From the FDA's meeting on testing: "Instead of seeing the usual 10% to 20% low positives in clinical studies last year, we saw a jump to 30% to 40% low positives. When you have 40% low positives … you're going to see a really big hit in sensitivity."

High viral load is highly correlated with transmissibility, so these "low positive" cases should be less transmissible, at least for a short period - but as the infection proceeds and viral load increases, that changes. This means that it is important to use antigen tests as they were designed and labeled - twice in 48 to 72 hours.

In SARS-CoV-2 evolving to escape antigen test antibodies the way it has many monoclonal antibody drugs? Antigen tests contain antibodies to detect the N protein, which is nearly the same in all sarbecoviruses, including all SARS-CoV-2 variants. Fortunately, that N protein is also highly conserved (it mutates rarely and slowly). Of its 419 amino acids, only eight are mutated in any SARS-CoV-2 variant; BA.5 has only one more N-protein mutation than BA.4 does. Probably for this reason, there are no reports of widespread antigen test failure to detect any variant so far.

Anecdotally, Omicron BA.5 cases seem to be generating symptoms earlier post-exposure than prior variants, and before infected people test positive on antigen tests. As stated above, it is best to assume early COVID-like symptoms are indeed caused by COVID until at least two antigen tests, 48 hours apart, are both negative. Why? Because a negative antigen test in the face of COVID symptoms could be indicative of a “low positive” case that hasn’t yet blossomed into full infectivity. (Of course, in people who are up to date on their vaccines, those symptoms could simply be caused by a swift and effective immune response. Those folks may never become positive, even on PCR.)

Commentary: Antibodies detect small, specific, uniquely shaped regions of a protein which are not determined by genetic/amino-acid sequence alone. We would like to see more public data on manufacturers’ antibody choices. At the very least, it would be good to know which tests use just one antibody, because that’s riskier than using two or three antibodies.

BA.5 now predominant in US; unclear what will be next

BA.5 has just become the predominant Omicron variant in the US (65% as of yesterday), and concern is already rising about BA.2.75 (currently ~18% of sequenced cases in India, although very few cases there are sequenced). However, at this point in the pandemic it’s hard to predict how well a variant that spreads fast in one location will succeed in another, because each region has such different patterns of prior infection and vaccination, not to mention demographics. For that reason, whether BA.2.75 will eventually beat out BA.5 or any other upcoming sub-variants in the US is unknown at this point. But we must remain vigilant - it was India that gave us early warning of the fall 2021 Delta surge. See William Haseltine’s excellent review for Forbes for further details.

Three novel tests caught our attention

#1: A safe, simple(-ish), and fast (~30 minute) lab test method to quantify neutralizing antibody effectiveness (i.e., degree of protection from infection). In this test, an assay mixture of two tagged proteins fluoresces only when the two proteins are free to bind. If neutralizing antibodies are present in the sample, they block binding and prevent fluorescence.

#2: Variant detection with Crispr - Cas 12. Commentary: The biggest commercial challenge to current Crispr COVID tests is that samples must be reverse transcribed and amplified before using Crispr. These are the same first two steps as PCR, so why not just use PCR, since the hard work has already been done? As sensitivity and specificity of Crispr improve, the need for these pre-processing steps will decline, and the greater specificity of Crispr will make it more competitive with PCR (especially for variant detection).

#3: PCR with a small panel of variant-specific primers. The gold standard for variant detection is sequencing. However, by using variant-specific primers and probes, some PCR approaches can identify not just whether there’s SARS-CoV-2 in a sample, but which variant is present. A recent publication in Nature reports that just 16 PCR regions are enough to identify current variant types.

Commentary: In practice, S Gene Target Failure (SGTF) has been a surprisingly effective practical tool for identifying variants. But that’s because we’ve been “lucky”: Up to this point, there have rarely been more than two primary variants circulating at a time, one of which shows SGTF and the other of which doesn’t. (Wild type = no; Alpha = yes; Delta = no; Omicron BA.1 = yes; BA.2 = no; BA.5 = yes). We can’t reasonably expect for that to continue forever, so there’s still a need for PCR panel tests that cover circulating COVID variants - not to mention other viral respiratory diseases.

CDC and private labs partner to decrease COVID testing deserts

Both Quest and Color Health have signed on to provide no-cost testing in underserved communities through the CDC’s Increasing Community Access to Testing (ICATT) program - a welcome development, now that un- and under-insured people can’t always get testing without at least an up-front cost.

Access to Quest sites is based on insurance and health status. Folks who want to get tested fill out an on-line questionnaire through QuestDirect - if they're uninsured and meet the qualifications (they have symptoms, have recently been exposed to someone with COVID, and/or have other health risks), they can schedule an appointment at one of Quest's ICATT-participating locations.

Color Health's setup is based on geography. They're using the CDC's Social Vulnerability Index to pick out locations (most of them rural) where people are likely to be under- or uninsured and/or at high risk of severe disease, and providing free testing kits at public libraries, pharmacies, and other places there. Folks who want to get tested can pick up a kit, swab themselves, and drop the sample off for PCR testing.

Food for Thought

The Good News Is…

Pharmacists can prescribe Paxlovid

File this one under "every little bit helps": The FDA has updated the EUA for Paxlovid so that pharmacists can now prescribe it. Pharmacies can decide whether or not to offer that service, so this change won't completely solve the access problem unless by some miracle we see universal uptake. But it's a step in the right direction.

Latest Monthly Capacity Estimates

Test Type	Mar '22	April '22	May '22	June '22	July '22
ANTIGEN					
Antigen Professional + Point of Care EUA	181	165	156	131	105
Antigen OTC: Home/Self EUA	462	418	422	380	320
Antigen Total	**643M**	**583M**	**578M**	**511M**	**425M**
MOLECULAR					
Molecular Professional, Point of Care, OTC EUA	34	33	32	30	28
Lab Based PCR	124	108	90	68	62
Addt'l Lab Based PCR with Pooling	12	11	7	5	4
Molecular Total	**171M**	**151M**	**128M**	**103M**	**93M**
Total Test Capacity	**814M**	**734M**	**706M**	**614M**	**518M**

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