



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

516M	593M	631M	732M	907M
November 2021	December 2021	January 2022	February 2022	March 2022

Significant changes in capacity estimates for the start of 2022. Largest drivers:

- EUAs for two large-volume rapid antigen OTC self-tests: SD Biosensor Test (Roche distribution rights in US) and Siemens CLINITEST (licensed from Healgen)
- Manufacturers with existing EUAs have increased their capacity, including Abbott, ACON, and iHealth.
- Important Note: We don't know how the administration's RFP for 500 million tests will be fulfilled, or how that it will impact these numbers. Critical to understand: Which tests are involved; How they will be distributed; Who will have priority access and over what time period; Will there be new EUAs or new capacity for the 500 million, or will they be drawn from existing supplies?

What Happened Last Week

The FDA issued four new EUAs, 21 amendments to existing EUAs, and two safety/policy communications in the last three weeks:

- New EUAs (4):
 - Molecular Tests (1): [UCSD EXCITE COVID-19 Test](#)
 - Antigen Tests (2): [SD Biosensor COVID-19 At-Home Test](#) | [Siemens CLINITEST Rapid COVID-19 Antigen Self-Test](#)
 - Flu/RSV Panels (1): [Applied BioCode CoV-2 Flu Plus Assay](#)
- New Amendments to Existing EUAs (21):
 - Molecular Tests (9): Quest Diagnostics x4* | Amazon (STS Labs Holdco) x4** | Tide Laboratories
 - * original PCR test + assays for use with Roche cobas (RC), Panther Fusion (PF) and Hologic Aptima (HA)
 - ** Amazon Real-Time RT-PCR + DTC version, Amazon Multi-Target Real-Time RT-PCR + DTC version
 - Antigen Tests (3): Salofa Oy | Quanterix | Simoa | iHealth Labs
 - Serology Tests (6): Babson Diagnostics | Biohit Healthcare (Hefei) | Shenzhen New Industries MAGLUMI IgM/IgG | ACON Labs IgM/IgG | NanoEntek America | Beckman Coulter IgG | Zeus ELISA Total Ab
 - Collection Kits (1): Quest Diagnostics
 - Flu/RSV Panels (2): Quest Diagnostics | PerkinElmer
- Safety/Policy Communications (2):
 - FDA (1): Revision to [SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests](#) containing:
 - Background on Omicron and its impact on antigen diagnostics tests
 - Early data suggests antigen tests detect the Omicron variant but may have reduced sensitivity
 - Revised info on the impact of the SARS-CoV-2 Omicron variant on molecular diagnostic tests

- Revised recommendations for clinical laboratory staff and health-care providers
- Press (1): Assistant Secretary for Preparedness and Response/FDA [Joint Statement](#) on how circulating variants may be associated with resistance to monoclonal antibodies

New & Noteworthy

CDC Updates to Isolation Duration Don't Pass the Goldilocks Test

CDC issued [new guidance](#) for people who test positive for COVID-19 or who are exposed to someone who's infected. The executive summary: Instead of 10 days of isolation or quarantine, it's now five days, plus five days of masking around other people. Other rules and restrictions apply, depending on whether you're asymptomatic, symptomatic, ill, immunocompromised, or a health-care professional.

Commentary: Good concept – but we are challenged on the details.

- A decrease in the duration of quarantine and isolation is frankly welcome, given that (pre-Omicron) “On average, [viral clearance](#) is about 5.5 days among vaccinated [and] 7.5 days for unvaccinated people,” as epidemiologist Katelyn Jetelina explains. However, five days is too big a reduction for unvaccinated people, who can still be infectious as long as 14 days after exposure. [Even the CDC website](#) acknowledges that modeling data from the UK shows that 31% of people are still infectious on Day 5.
- A negative antigen test on Day 5 should be required. While we know antigen self-tests are in short supply now - and of course they're not perfect - they are perfectly reasonable for exiting isolation. Plus, they'll resolve the problem of the potential difference in duration of infectiousness between the vaccinated and unvaccinated. With the approach they've chosen, CDC is repeating the mistake they made in the spring 2020, when they downplayed mask-wearing out of a fear that a run on N95s would leave too few for health-care workers.
- Wearing well-fitted masks for five days after isolation is very important - but alas, it is also important to acknowledge how few people actually meet the well-fitted and truly protective criteria. In addition, the folks who most need to mask (unvaccinated) may be the least likely to do so.

We understand the need for shortening isolation times - for the economy and for essential workers, especially in health care – but if people are still infectious and further spread disease, is it helping or hurting? Yes, 10 days is too long for most vaccinated people. But five days is too short without a negative test guard rail.

Snoot and Spit? Omicron May Require Change of Sample Type

The lay press has (rightly) made a fuss about Omicron's ability to reproduce shockingly well in the human [bronchus](#) and less efficiently in the lung than previous variants. Turns out that the locations where the new virus variant shows up most prominently may cause testing repercussions. A preprint by Marais et al. has presented evidence that, unlike Delta, the Omicron variant is more effectively diagnosed using [saliva](#) as a sample instead of a mid-turbinate nasal swab. Adamson et al. found that PCR using saliva samples diagnosed Omicron at high, potentially infectious viral loads, [days before](#) antigen tests using nasal samples showed up positive.

Some physicians, seeing that Omicron has altered the primary COVID-19 symptoms to include a [sore throat](#), have started coming to similar conclusions. They're recommending that in addition to swabbing your nose, if you're self-testing, you should also [#SwabYourThroat](#) – and posting pics of rapid antigen tests that only showed up positive when patients swabbed both.

Commentary: We understand the theory behind #SwabYourThroat, but important to recognize that the antigen self-tests were designed for nasal secretion samples - we do not know how they will function with other samples - but we hope test manufacturers are actively testing this theory.

Food for Thought

Sometimes Doing Things Wrong Means You Get It Right

A fascinating analysis of the causes behind breakthrough infections appeared in [Science](#) recently - and buried deep within it was a tiny little bombshell. Because of vaccine shortages, some countries chose to increase the interval between the first two doses of mRNA vaccine beyond what was recommended by

the manufacturers. Turns out they were right, from an immunological standpoint: The optimal interval between initial doses of mRNA vaccine isn't four weeks - it's [16 weeks](#). Not only does that interval give you the most antibody bang for your buck right up front, it increases the duration of immunity, as well.

The upshot: When spaced only three to four weeks apart, those first two doses of mRNA vaccine may have acted as a "primary immunization," like the series of vaccines your pandemic puppy got when she was 8, 12, and 16 weeks old. That series gave her strong immunity for a short period of time, but it didn't last. She'll still need a booster when she's a year old - just like we all do right now.

K-12 Round Up:

99% of kids in School? That is SO last year.

Great news! Last month, the Department of Education's [School Pulse Panel](#) reported that "nearly 100% of public-school students were offered in-person learning." But then . . . Omicron.

[Burbio](#) is estimating that 4,561 schools were disrupted this week. Most of the closures were caused by staffing issues, while some schools chose to open a day or two late to allow for COVID-19 testing before bringing kids back into classrooms. The results, in some places, were startling. In eastern Massachusetts, two districts that, pre-Omicron, had never seen more than 3% of their pools come back positive saw 15 to 20% of their pools turn up positive this week. In [Cambridge, Massachusetts](#), a whopping 43% of the pools returned a positive result.

CDC Endorses Test to Stay – Yay?

Last month, CDC endorsed [Test to Stay \(TTS\)](#) which allows unvaccinated close contacts to remain in school in person as long as they continue to test negative (vaccinated close contacts don't need to test or quarantine). CDC stopped short of specifying a protocol, saying only that students should be tested at least twice "during a seven-day period post-exposure." While this is still great news, the timing is . . . unfortunate. With test positivity rates skyrocketing, it's unclear whether many communities have the staff or the tests to implement TTS right now. Here's hoping the US follows South Africa's lead and gets through the Omicron surge quickly.

Latest Monthly Capacity Estimates

Estimated Monthly Capacity of All Tests (M)

Test Type	Nov '21	Dec '21	Jan '22	Feb '22	Mar '22
ANTIGEN					
Antigen Professional + Point of Care EUA Today	174	185	187	187	191
Antigen OTC: Home/Self EUA Today	141	216	260	355	526
Antigen Central Lab Today	11	7	7	7	7
Antigen Total	326M	408M	454M	549M	724M
MOLECULAR					
Molecular Professional, Point of Care, OTC EUA Today	32	36	36	36	37
Lab Based PCR Today	130	130	125	130	130
Add'l Lab Based PCR with Pooling	29	20	16	16	16
Molecular Total	190M	185M	177M	182M	183M
Total Test Capacity	516M	593M	631M	732M	907M

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