



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

516M	593M	631M	912M	1,035M
November 2021	December 2021	January 2022	February 2022	March 2022

No changes to capacity this week.

What Happened Last Week

The FDA issued no new EUAs, five amendments to existing EUAs, and three new safety/policy communications in the past week:

- New Amendments to Existing EUAs (5):
 - Molecular Tests (2): LumiraDX | Sherlock BioSciences
 - Antigen Tests (3): DiaSorin Liaison | LumiraDx | ACON FlowFlex Home Test
- Safety/Policy Communications (3):
 - Warning Letters (3): [CytoDyn, Inc.](#) | [rxshopmed.com](#) | [Extrapharmacy.ru](#) ["for marketing unapproved and misbranded drugs for multiple diseases, including COVID-19" per [FDA press announcements](#)]

New & Noteworthy

BA.2 is growing and may be worse than BA.1 - but it may not matter much.

Omicron sister variant BA.2 accounts for only 3.8% of sequenced cases in the US right now, but it has become dominant in India, Denmark, Sweden, and South Africa. A comprehensive [laboratory and animal study](#) from Tokyo showed BA.2 to be 1.4x more transmissible than BA.1, consistent with early [clinical experience](#) in South Africa.

Is BA.2 more dangerous? South Africa's data says no. However, the Tokyo study indicated that BA.2's fundamental severity is more similar to Delta than to the milder BA.1, with more lung damage, 5x higher lung viral load, and sicker animals. That being said, BA.1 has already infected so many people - and so many of the rest are vaccinated - that the practical consequences may be limited.

Don't bother with vaccine updates - just boost.

Several small ([mouse](#) and [macaque](#)) studies over the past month reveal that boosting with existing vaccines is as effective as boosting with an Omicron-specific vaccine. If those initial results continue to be confirmed, it begs the question: Is it really worth creating variant-specific vaccines? Both Pfizer/BNT and Moderna are starting trials of Omicron-modified vaccines now. By the time they're likely to be authorized in late 2022 (a super-fast but realistic estimate), will Omicron still be the biggest threat we face? Given past variant history, probably not. If a Delta-specific vaccine had been created, it would have offered [no additional value](#) against Omicron.

And Omicron BA.2 is as different from Omicron BA.1 as the latter is from Delta. [Hybrid boosters](#) containing mRNA from several variants may still be worthwhile, but the bottom line is this: After a successful first encounter with a pathogen, the human immune system both maintains and [continually diversifies](#) its reserve of [memory B and T cells](#) over time. That gives it the power to effectively address a microbe that's [broadly similar](#) to what it's seen before - even if it isn't exactly the same. So, tailoring a round of vaccines to every variant that comes along may not, in the end, be necessary.

Food for Thought

Applying the Lessons of the Pandemic: Testing Edition, Episode 3

Please, please, please - don't forget COVID lessons learned.

The UK is in the process of removing all COVID-era precautions, including the provision of free self-tests. The District of Columbia, Philadelphia, and Boston are abandoning proof of vaccination. Reported tests (mostly PCR for the more seriously ill) are down nearly 50% from their peak in early January, and self-tests are now widely available at retail, reflecting increased supply but also reduced demand.

All of us are desperate to return to some measure of normalcy. But we sincerely hope that the decline of Omicron in spring 2022 will not usher in a repeat of the delusions we saw when Alpha declined in spring 2021. As much as we might wish it, going back to pre-COVID times just isn't possible. The "new normal" has to take into account the continuous possibility of a COVID re-emergence. We must continue to push vaccination levels, routine self-testing, and systematic viral surveillance (sequencing & wastewater), or when the next more-transmissible variant arrives, we will head right back to where we were.

California's Evergreen Endemic COVID Experience

This week, California became [the first state](#) to formally announce a (comprehensive but not detailed) [plan](#) for how to live with COVID - for now and forever. The focus is all about readiness. It starts with wastewater surveillance - the intention is to recognize any new variant early and assess and adjust the statewide response within 45 days. The state committed to maintaining the ability to administer 500,000 tests and 200,000 vaccines daily. They will create a stockpile of masks, ventilators, and OTC tests. Critically - they intend to have 3,000 additional health-care professionals ready for an outbreak.

Commentary: We love this. First, we love that they have a plan. Second, we love that they are making the plan public. Third, we love that the plan acknowledges that COVID is not going away. And fourth, we love that though they are lowering all sorts of precautions today, they recognize that they may have to raise them again in the future - and they're preparing for that eventuality.

K-12 Round Up:

The masks continue to come off in schools

Burbio has reinstated its [state-by-state mask tracker](#). In the last two weeks, we continued to see masks come off throughout the country. In the top 500 districts, the percentage that require masks moved from 60% to 51%, while the percentage that do not require masks moved from 35% to 48%.

The Good News is...

We have a twofer this week in the good news department!

New protein-based vaccines from Novovax and Sanofi/GSK are on the horizon. Protein-based vaccines are cheaper to manufacture and have easier storage regimens, and early announcements report similar performance to mRNA vaccines.

Scientists and clinicians are beginning to unravel the complex [cardiovascular](#) and neurological effects that seem to drive Long COVID. Intriguingly, there are parallels to chronic fatigue syndrome, offering the hypothesis that CFS may be due to past viral infections. *Most reassuring:* [Vaccination reduces the chance of getting Long COVID](#). New data from a UK study shows that not only are vaxxed people less likely to get Long COVID, but if an unvaccinated person does get it, a vaccine helps reduce their symptoms. Might this offer hope for tailored vaccination plans for CFS sufferers?

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	535	654
Antigen Central Lab Today	11	7	7	7	7
Antigen Total	326M	408M	454M	729M	852M
MOLECULAR					
Molecular Professional, Point of Care, OTC EUA Today	32	36	36	36	37
Lab Based PCR Today	130	130	125	130	130
Addtl Lab Based PCR with Pooling	29	20	16	16	16
Molecular Total	190M	185M	177M	182M	183M
Total Test Capacity	516M	593M	631M	912M	1,035M

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