



# Tracking US Coronavirus Testing Capacity

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## Updated Monthly Capacity Numbers: Current EUA's

<b>624M</b>	<b>904M</b>	<b>814M</b>	<b>731M</b>	<b>683M</b>
January 2022	February 2022	March 2022	April 2022	May 2022

*No update on capacity estimates this week.*

## What Happened Last Week

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

- New Amendments to Existing EUAs (7):
  - Molecular Tests (3): Lucira | Abbott Alinity | Pixel by LabCorp
  - Antigen Tests (3): iHealth | SD Biosensor Pilot | BinaxNOW
  - Antibody Tests (1): Luminex xMax igG

## New & Noteworthy

*\$10 billion of COVID funding (maybe)*

We thought that Step 1 was done. The Senate had finally reached a bipartisan agreement on [\\$10 billion in funding](#) for ongoing COVID-related needs by taking money from COVID allocations that have not been spent to date by other federal agencies. What was in: Continued funding for treatments, tests and vaccines. What was out: Funding for the uninsured and funding for vaccines outside of the US. Then we heard the late-breaking news - a group of Senators are preventing a vote until an amendment is added on border control. *Commentary:* We don't want to give back the gains that we have made to date. If you have read our Commentary and Lessons Learned in the last few weeks, you know how we feel. Now is not the time to haggle over funding. Wishing this virus away is not a strategy.

*Medicare free-test promise fulfilled*

As the Biden administration promised a while back, [Medicare](#) recipients are now on the list of folks who can get free OTC antigen tests. The details: All Medicare part B enrollees as well as those in Medicare Advantage plans can get [up to eight free tests per month](#) from the usual suspects - large national and regional retail pharmacies and supermarkets. This is important for two reasons: #1 This program extends free COVID tests to the 59 million Americans at the greatest risk for complications and death. #2 This marks the first time that Medicare has given free access to any OTC test. *Commentary:* Well done!

*Antigen tests are black boxes. That needs to change.*

The world is shifting to rely heavily on antigen tests, which look for mutations in the virus's N protein. A recently posted [pre-print](#) cleverly investigates N-protein mutations in a small (17) subsample of real-life cases in which subjects had a high viral load but negative antigen tests. Could immunodominant N-region mutations be causing antigen false positives?

Apparently yes, although the evidence is circumstantial: 7 of 8 of these discordant cases had key N mutations, while only 2 of 9 antigen positives did. *Commentary:* This study makes a very strong argument for increased disclosure of antigen test methods, which has been almost universally absent to date. Without data on manufacturers' N protein epitopes, we have no way of knowing how novel VOCs' mutations may affect sensitivity.

## Food for Thought

*Applying the Lessons of the Pandemic: Testing Edition, Episode 9*

*To get enough tests online, it takes all hands on deck*

A recent [360Dx article](#) looked back at the earliest days of the pandemic. At the time, the FDA's authorization system for diagnostics simply wasn't set up to make a tremendous volume of tests available as fast as possible, which is what's required in a pandemic. The result - too few authorized tests for far too long.

The big takeaway from this trial by fire: **Pandemics require all-hands-on-deck teamwork from the very beginning.** All government agencies involved in testing must be in on the effort, as well as folks in industry and academia. When everyone is beaver away at their own tests in their own silos, things just take too long. Better to figure out as a team which are the best tests *that can be quickly manufactured, scaled up, and distributed*, and focus everyone's energies on those. (Two of the experts interviewed in the article cited South Korea's example as one to follow.) Other useful tidbits:

- **Have the government handle test validation.** They know how to do it properly, and they have the earliest access to clinical samples.
- **De-risk companies' investments in tests.** Companies need purchase guarantees or the like from government, or they won't invest adequate resources.
- **Don't forget the supply chain.** To make tests, you need reagents. To administer tests, you need swabs. The folks who make those need support, too.

*Commentary:* A pandemic is a war, people - government has to be willing to both act and spend as it would during any other major-league wartime. We've learned the hard way - let's not forget how to do this in the future.

*K-12 Roundup*

*Schools get an extension on ELC's assignment (testing)*

Back in April 2021, the ELC division of the CDC [awarded \\$10 billion](#) to states and territories specifically for COVID testing in K-12 schools. One of the first allocations from the American Rescue Plan, the monies have been used across 48-plus states to enable regular surveillance and diagnostic testing in schools. Allocations were set to expire this July, but the administration recently announced that this funding can be used through July 31, 2023, for most recipients. *Commentary:* This is great news. While only about 25% of schools chose to implement a regular testing program, it did help those that did so. Note: Mara is involved in coordinating the National Testing Action Program (NTAP), a network of some of the school testing providers.

*Asymptomatic screening still helps*

As schools across the nation are considering whether to ramp down their asymptomatic screening programs - and what to do about the 2022-23 school year - a [modeling study](#) from The Lancet provides some relevant data. [Under Omicron conditions](#), weekly asymptomatic testing of 75% of a school population would "reduce the overall epidemic size by 10%" over the course of a 90-day trimester, the authors say; twice-a-week testing would reduce it by 20%.

*Don't want to test at school? Send the tests home.*

As part of the [ELC Reopening Schools](#) program (see above), CDC is making available five million free rapid COVID tests for K-12 schools each month. Now, jurisdictions can choose whether they will receive point-of-care tests or OTC ones that kids can do at home. *Commentary:* For the many schools who do not want to implement an in-school testing program, these tests allow a great Backpack Testing Program.

The Good News is...

If you can pick your nose, you can self-swab.

When given age-appropriate instructions (via a video and a handout), researchers found that children ages four to 14 years old were able to collect “an adequate anterior nares (AN) swab for SARS-CoV-2 testing.” If you’re the parent of anyone preschool age or older, you already knew that. Now we have a [study](#) to prove it.

## Latest Monthly Capacity Estimates

Test Type	Nov '21	Dec '21	Jan '22	Feb '22	Mar '22	April '22	May '22
<b>ANTIGEN</b>							
Antigen Professional + Point of Care EUA	174	185	187	187	181	165	156
Antigen OTC: Home/Self EUA	141	216	260	535	462	415	399
<b>Antigen Total</b>	<b>315M</b>	<b>401M</b>	<b>447M</b>	<b>722M</b>	<b>643M</b>	<b>580M</b>	<b>555M</b>
<b>MOLECULAR</b>							
Molecular Professional, Point of Care, OTC EUA	32	36	36	36	34	33	32
Lab Based PCR	130	130	125	130	124	108	90
Add'l Lab Based PCR with Pooling	29	20	16	16	12	11	7
<b>Molecular Total</b>	<b>190M</b>	<b>185M</b>	<b>177M</b>	<b>182M</b>	<b>171M</b>	<b>151M</b>	<b>128M</b>
<b>Total Test Capacity</b>	<b>505M</b>	<b>586M</b>	<b>624M</b>	<b>904M</b>	<b>814M</b>	<b>731M</b>	<b>683M</b>

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