



# 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

*Tough calls this week on capacity. Pre-Omicron, we expected PCR lab capacity to shrink at least 15% - likely more - in 2022. While that did not happen in Q1, we still expect the number of active PCR labs and PCR capacity to contract significantly this year starting in Q2. For antigen testing, we are "zeroing out" the Central Lab Antigen category and adding the small remaining volume to the Antigen Professional category. While companies are still performing tests, the market never materialized outside of research. For POC test capacity, modest reductions in the short term, as the instrument-based systems have a large installed base, and Test to Treat opportunities will help justify physician offices maintaining demand. The big question is OTC test capacity. No question - it will shrink. The largest companies are setting expectations of 50% reductions in sales for the rest of the year. The smaller companies will likely find niche markets and maintain close to their maximum production. Of course, a new variant or new surge will change everything!*

## What Happened Last Week

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

- New Amendments to Existing EUAs (5):
  - Molecular Tests (4): Yale SalivaDirect 92 | Assurance Scientific Laboratories (2)
  - Antigen Tests (1): Phase Scientific INDICAID
- Safety/Policy Communications (4):
  - Warning Letters (1): [My Natural Treatment](#)
  - Safety Communications (3): [Celltrion DiaTrust](#) | [SD Biosensor STANDARD Q Ag Home Tests](#) | [ACON Flowflex](#)

## New & Noteworthy

### *The State of the Union – Testing Highlights*

President Biden's State of the Union provided a new roadmap for how we can safely manage life with COVID-19 without kowtowing to the virus. In addition to a continued commitment to keeping schools open by leveraging ventilation improvements, testing, and continued surveillance for emergent variants, he highlighted these key testing-related points:

### *Free Tests: You can get a second helping*

We were surprised to see that [almost half](#) of the Feds' first 500 million free rapid tests still haven't been claimed. Perhaps that's the reason why, starting next week, folks who want [a second set of tests](#) can go ahead and order them. Commentary: Maybe we shouldn't have been surprised - after all, the most recent [KFF poll](#) found that over 60% of people feel that "the worst [of the pandemic] is behind us." Here's hoping they're right.

### *Tests: Now with a side of treatment*

For the individual being tested, testing in some ways has had no upside. Either you test negative, in which case nothing has changed, or you test positive, and you're stuck isolating in your room with your cat and hoping you don't get super sick. That will change by the end of this month, with the Administration's new [Test to Treat](#) program. The plan: Folks get rapid tested (for free) at a pharmacy, and if they test positive, they can immediately get antiviral medication (also for free). As has been the case throughout the pandemic, implementation will be dependent on supply, education, and access.

*We were unprepared twice. HHS is trying to prevent a third time.*

The nation's supply of tests was inadequate when COVID first arrived, and then again when Delta hit. One key aspect of the President's SOTU discussion about producing more goods in the US was a commitment to improve the supply chain for COVID tests today and tomorrow. To that end, [HHS has outlined plans to invest in US based infrastructure](#) for test manufacturing and testing component equipment. As part of this effort, HHS has issued a [Request for Information: Preservation and Expansion of Current Domestic Capacities for Lab-Based Testing and Manufacturing of OTC Rapid Antigen and POC Nucleic Acid Amplification Tests](#).

### *Those darned deer*

Well, it's finally been documented. SARS-CoV-2, the virus that causes COVID, has mutated significantly in deer, according to a recent [preprint](#) out of Canada, and may have been transmitted from deer to at least one [human](#). Don't say we didn't warn you.

### *Workplace testing works*

*Science Advances* published a Canadian study on the feasibility, effectiveness, and acceptance of [twice-weekly asymptomatic COVID screening](#) using rapid antigen tests in the workplace. The object of the game: limit transmission and minimize sick days and quarantines that cripple productivity. The paper, which involved workplaces ranging from under 100 to over 10,000 employees, is primarily a "how to," with a detailed playbook on implementation. Over 300K total tests yielded 473 true positives, and surveys (71% responding) showed that 96% of respondents would recommend the program to others. The authors also point out that the program yielded only 75 false positives (one out of every 4,300 positives), which should relieve anxiety about one of the most frequently cited concerns. Unfortunately, there is no comparison to a default (control) group of companies. A more in-depth explanation of results is enthusiastically anticipated.

## **Food for Thought**

### *Applying the Lessons of the Pandemic: Testing Edition, Episode 4*

The president of the American Medical Association spoke about the [five actions](#) that we as a society need to take in order to truly learn from our successes and failures during the pandemic. Core message: Rebuild trust and better respond to the next public health crisis.

1. Enhance state and federal stockpiles of medically necessary supplies and improve the system for acquiring and distributing them.
2. Increase funding to bolster our diminished public health infrastructure.
3. Learn from the process that led to the rapid-scale development of vaccines.
4. Continue expanding access to telehealth.
5. Address clinician burnout.

Commentary: We don't say "love" a lot - but we love these actions. They are a clear and simple compilation of necessary actions that are necessary to Protect, Prepare, and Prevent in both the short and long term.

## K-12 Round Up:

The masks are definitively coming off in schools. Burbio noted that “For the first time, the number of Top 500 districts that are mask-optional exceeds the number that are mask-required.” As it stands today, the only state that will still have a school mask mandate after March 31 is Hawaii.

## The Good News is...

OTC COVID tests are now generally available in retail stores and online, yet vulnerable communities continue to face barriers to access - the biggest one being price. Even at \$7 a test, a family of five needs \$140 a month for regular testing. So, the good news is that community health workers in these areas are [hand-delivering](#) not only free tests, but education on the use and reliability of at-home testing.

Note - Mara is involved with the Rockefeller program mentioned in this story.

# Latest Monthly Capacity Estimates

## Estimated Monthly Capacity of All Tests (M)

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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