



# Tracking US Coronavirus Testing Capacity

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## Updated Monthly Capacity Numbers: Current EUA's

<b>417M</b>	<b>484M</b>	<b>516M</b>	<b>645M</b>
September 2021	October 2021	November 2021	December 2021

## What Happened Last Week

The FDA issued two new EUAs, 14 amendments to existing EUAs and two safety/policy communications in the last two weeks:

- New EUAs (2):
  - Antigen Tests (1): [InBios International SCoV-2 Ag Detect Self-Test \(OTC\)\\*](#)
  - Collection Kits (1): [Audere HealthPulse@home](#)
- New Amendments to Existing EUAs (14):
  - Molecular Tests (6): RCA Labs GENETWORx | MiraDx | Aeon Global Health | Abbott RealTime | MD Anderson | LumiraDx
  - Antigen Tests (5): PHASE Scientific INDICAID | Ortho Clinical Diagnostics VITROS | GenBody | AccessBio *CareStart* Home Test (OTC)\* | BD Veritor At-Home (OTC)\*
  - Serology Tests (2): Healgen Scientific IgG/IgM | Sugentech SGTi-flex IgG
  - Collection Kits (1): Kwokman Diagnostics
- \* InBios, AccessBio, and BD's OTC Antigen tests were [all authorized](#) for self-collected home nasal swabs for all individuals over age 14, or collection by an adult for ages 2 and over. Serial testing is indicated for asymptomatic individuals. Single tests are authorized for symptomatic individuals.
- Safety/Policy Communications (2):
  - Recalls (1): [Select Philips Respironics Ventilators, BiPAP, and CPAP Machines](#)
  - FDA Press Releases (1): [FDA Actively Working to Investigate Impact of Omicron](#)
    - [Industry guidance](#) addressing variants for device developers
    - [Ongoing communication](#) regarding tests impacted by viral mutations
    - "On preliminary review, we believe ... widely used [PCR and Antigen tests] in the U.S. show low likelihood of being impacted and continue to work."

## New & Noteworthy

*Omicron underlines the importance of genomic sequencing and the need to double down*

As we've said before, the US genomic sequencing is under-resourced and not as systematic as it needs to be ([some states](#) have sequenced >20% of cumulative cases, while others have sequenced <1%).

We believe the best way to look at the percentage of sequenced cases in context is to look at the sequences submitted to [GISAID](#), which is the primary source for international comparisons of genomes sequenced. Why? Because the point of sequencing is to let policy makers and scientists know what variants are where, and in what proportion. If a sequence is not uploaded to a public database where others can easily find it, it might as well not have been performed.

According to GISAID, the US has sequenced 3.6% of its cases since the start of the pandemic, and 2.7% of its cases over the last 30 days. (Compare that to the UK's 12.7% and 11.0%, respectively.) The

US actually has more sequencing data than that: CDC data shows 258,000 sequences performed over the past 30 days, yielding a rate of 14.7%. But unless it all gets submitted to GISAID, the rest of the world doesn't have access to this data (setting aside the question of how systematically it was gathered). Let's ramp up sequencing and reporting. Omicron has just been reported in the US - a week after we first learned about it. Do we still need to emphasize how this is a global issue?

### *Odds Are, Rapid Tests Can Handle Omicron*

We know that most PCR tests can detect Omicron - and not only that, but they can alert testers to the new variant's presence without the need for full sequencing. (Although creating a system to report tests for Omicron is still elusive.)

So, what about rapid antigen tests?

We're still waiting for official, evidence-based words, but [test manufacturers](#) and testing experts are making uniformly soothing noises thus far. According to 360Dx, NIH's Bruce Tromberg noted that out of the four mutations that could potentially confuse rapid antigen tests, three were present in the [Lambda variant](#) - and the tests managed Lambda without difficulty. Abbott, BD, Ellume, and Quidel have all issued statements indicating that their rapid tests should pick up Omicron, a sentiment the [FDA](#) echoed. We're hoping that lab and real-world data will confirm quickly.

### *Vaccine Passports Without Testing Miss Asymptomatic COVID Cases*

According to this [Israeli study](#) (done at Ben Gurion airport and reported by [Reuters](#)), the use of vaccine passports that exempt people from COVID testing has a significant negative impact - it allows many asymptomatic or presymptomatic active infections to be missed. BUT - the definition of "unvaccinated" has changed in Israel: It now includes both folks who have never been vaccinated and those who received their most recent shot more than six months prior. Commentary: Yet another study and reason to prioritize both vaccination and testing - not vaccination alone.

## Food for Thought

### *Why bother vaccinating kids? Because the alternative is Omicron ... and its successors*

Commentary: The many parents who've been chewing their nails since last spring, waiting for the opportunity to get their elementary-school kids vaccinated, are flooding their Facebook feeds with proud pictures of small Band-Aided arms. The rest of the nation's parents . . . aren't. The most recent Kaiser Family Foundation [vaccine survey](#) indicated that about 2/3 of parents either won't vaccinate their 5- to 11-year-olds (33%) or will "wait and see" (30%).

Most young kids who get COVID-19 have either mild or asymptomatic cases, it's true. (Though [not all](#) - in the US alone, where 5- to 11-year-olds represent 10% of cases, over 500 kids in this age group have been hospitalized, and, tragically, more than 60 have died, putting COVID-19 on the list of the 10 most common causes of death in this age group.) So, if your kid is at relatively low risk of being seriously harmed by this virus, why bother to vaccinate?

Omicron is why.

As NPR reported yesterday, the [genetic ancestry](#) of this variant indicates that it evolved from a strain that was around in mid-2020. That means it either evolved in a place where none of the more recent variants ever showed up (not impossible, but unlikely), or (probably more likely) it evolved in a single person. Someone immunosuppressed, who was unable to clear the virus from their body, unknowingly gave it a place to hang out and gather [mutations](#) over time.

What does this have to do with vaccinating kids? The answer is that the overwhelming majority of kids can be successfully vaccinated, while immunosuppressed people like Omicron's original host cannot. Since these folks' immune systems can't respond properly to vaccination, the only way to protect them from infection is to surround them with successfully immunized people so that the virus has fewer places in which it can circulate - that's the whole concept behind [herd immunity](#). While true herd immunity is, sadly, now beyond our grasp, every successfully fully vaccinated person means that there's one less place for the virus to go - and makes it just a tiny bit less likely that someone like Omicron's host will unintentionally harbor the next Variant of Concern.

So – as with so many infection-prevention measures in this pandemic - the reason to vaccinate one person isn't only about lowering one person's individual risk. It's about lowering the risk to all of us. It's public health, not private health.

And that, as has become abundantly clear over the past year and a half, is a much harder sell.

### K-12 Metrics:

School closures continue apace, per Burbio's 2021/2022 [School Disruptions Tracker](#). Total closures to date: 916 districts (up from 769 two weeks ago), and 9,313 schools, up from 7,001. Mental-health breaks bracketing Veteran's Day and Thanksgiving caused a recent spike; some schools are now starting to announce similar closures leading up to winter break.

### Higher Ed vaccine mandates:

*The Chronicle of Higher Education* now counts [1,142 colleges and universities](#) that require vaccines, up from 1,132 two weeks ago.

## Latest Monthly Capacity Estimates

### Estimated Monthly Capacity of All Tests (M)

Test Type	Sep '21	Oct '21	Nov '21	Dec '21
<b>ANTIGEN</b>				
Antigen Professional + Point of Care EUA Today	149	163	174	197
Antigen OTC: Home/Self EUA Today	81	130	141	242
Antigen Central Lab Today	10	11	11	11
<b>Antigen Total</b>	<b>239M</b>	<b>304M</b>	<b>326M</b>	<b>450M</b>
<b>MOLECULAR</b>				
Molecular Professional, Point of Care, OTC EUA Today	28	31	32	37
Lab Based PCR Today	125	125	130	130
Add'l Lab Based PCR with Pooling	25	25	29	29
<b>Molecular Total</b>	<b>178M</b>	<b>181M</b>	<b>190M</b>	<b>195M</b>
<b>Total Test Capacity</b>	<b>417M</b>	<b>484M</b>	<b>516M</b>	<b>645M</b>

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