



# Tracking US Coronavirus Testing Capacity

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## Updated Monthly Capacity Numbers: Current EUA's

**417M**

September 2021

**484M**

October 2021

**516M**

November 2021

**601M**

December 2021

Changes to capacity numbers this week. We will add first quarter 2022 numbers next week. More importantly, we wanted to clarify: **These numbers represent our best estimate of capacity – not demand or usage.**

We do look at test usage, and while we believe the [CDC daily test estimates](#) are the best source of information on this topic, we also think that they underestimate actual test usage. For PCR, we believe that tests are under-reported by approximately 10%. For antigen tests, we believe that number is much higher, at 85 to 90%. Why so high? Because [the overwhelming majority of home / OTC antigen tests are not reported to public health authorities](#), in part because the tests provide no easy way to do it and most public health systems do not have the infrastructure to accept the data.

## What Happened Last Week

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

- New Amendments to Existing EUAs (3):
  - Molecular Tests (1): GWU SARS-CoV-2 RT-PCR Test
  - Antigen Tests (2): AccessBio CareStart (POC) | AccessBio CareStart (OTC)
- Safety/Policy Communications (1):
  - FDA Updates (1): [SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests](#) now contains lists for both:
    - Tests with Reduced Ability to Detect the SARS-CoV-2 Omicron Variant (one test – Tide Laboratories [DTPM COVID-19 RT-PCR Test](#) – and 33 lab locations listed)
    - Tests with S-Gene Drop Out – SARS-CoV-2 Detection **Should Not** Be Impacted by this factor alone (27 tests listed).

Commentary: S-gene target failure (del69/70) has been an indicator of Omicron because currently dominant Delta does not share this deletion, and Alpha (which does have it) is no longer circulating. However, sub-variants of Delta with the deletion are now registered on GISAID, and – more worryingly – a novel sub-variant of Omicron (B2) no longer carries the deletion. Sequencing is essential to be sure of VOC status.

## New & Noteworthy

### *Biden Administration's COVID-19 Winter Plan Emphasizes Testing*

President Biden laid out his administration's [latest additions](#) to its anti-COVID-19 strategy last Thursday. Three of the new initiatives aim to increase COVID-19 testing, with two targeting access within the US and one tightening testing requirements for entrance to the country:

1. If you're one of the 150M folks who has private insurance, you'll now be reimbursed by your insurer for OTC tests. (Save your receipts because details of how this will work won't come until January.)

2. To cover folks who aren't privately insured, 50M OTC tests will be sent to community sites such as Federally Qualified Health Centers, rural health clinics and food banks. (Will folks want them? The success of the [Say Yes! COVID Test](#) (SYCT) initiative - the NIH program that provides "access to free, rapid, at-home COVID-19 testing" in select communities - suggests that they do, and they will. The New Hampshire SYCT program was so popular, all of its allotted tests were snapped up in [less than 24 hours](#).)
3. All international travelers – regardless of vaccination status or nationality - must now test negative within one day of their departure.

Commentary: We applaud these measures - the global travel testing (travel bans don't work - they're porous and too late to matter) and the focus on rapid antigen tests. However, the question remains: Are they enough?

What we know:

- Vaccinations, especially without mandates, are [unlikely to rise much](#)
- Mask usage has been [stable since the end of August](#) and seems unlikely to rise significantly
- No one is willing to go back to lockdowns or physical distancing.

So, the only remaining anti-COVID measure we can increase is testing. We need every American (everyone worldwide, really) to test regularly. Can we afford it? Testing is highly cost-efficient. A [study](#) in *Annals of Internal Medicine* in March 2021 shows that broad weekly antigen testing could eliminate 24% of infections and 13% of deaths, yielding a cost-effectiveness ratio of \$7,890 per infection averted and \$1.4 million per death averted.

What do we need to make this happen? We still need more EUAs from large-volume manufacturers. We would like to see CDC update its guidance and recommend routine testing for all – not just unvaccinated or close contacts, but all of those who have regular contact with others.

With a half empty glass – we are now in the fifth surge, and little can be done to avoid it, so let's focus on containing it. With a half full glass – we have the tools we need today: vaccines and tests. Remember, at least 20% of infectious people (maybe more) have no symptoms. That means testing is the **only** way to identify these infections and stop them from spreading. Final note – Treatments to come will help reduce deaths but will not reduce infections.

### *If You're Vaccinated, Isolation Needn't Be Such a Tall Order*

An interesting [analysis](#) of data from the NBA's COVID testing program appeared in the *New England Journal of Medicine* last week. Key findings: peak viral load in the infected didn't vary significantly either between (pre-Omicron) variants or by vaccination status, implying that vaccination does not eliminate the possibility of onward transmission when breakthrough infections do occur. Other details:

1. Viral load increases and declines in a log linear manner, with the ramp up twice as quick as the clearance phase: First PCR-detectable disease was 3 - 4 days before peak viral load, with last PCR positive test 6 - 8 days later, ~11 days overall.
2. The vaccinated cleared virus 2.3 days quicker than the unvaccinated, for an 8.7-day total PCR-detectable infection period.
3. There was far more variation in length of infection among the unvaccinated, implying even longer isolation is needed beyond the additional two-day average infection difference. Some unvaccinated individuals still shed PCR-detectable virus for up to 30 days.

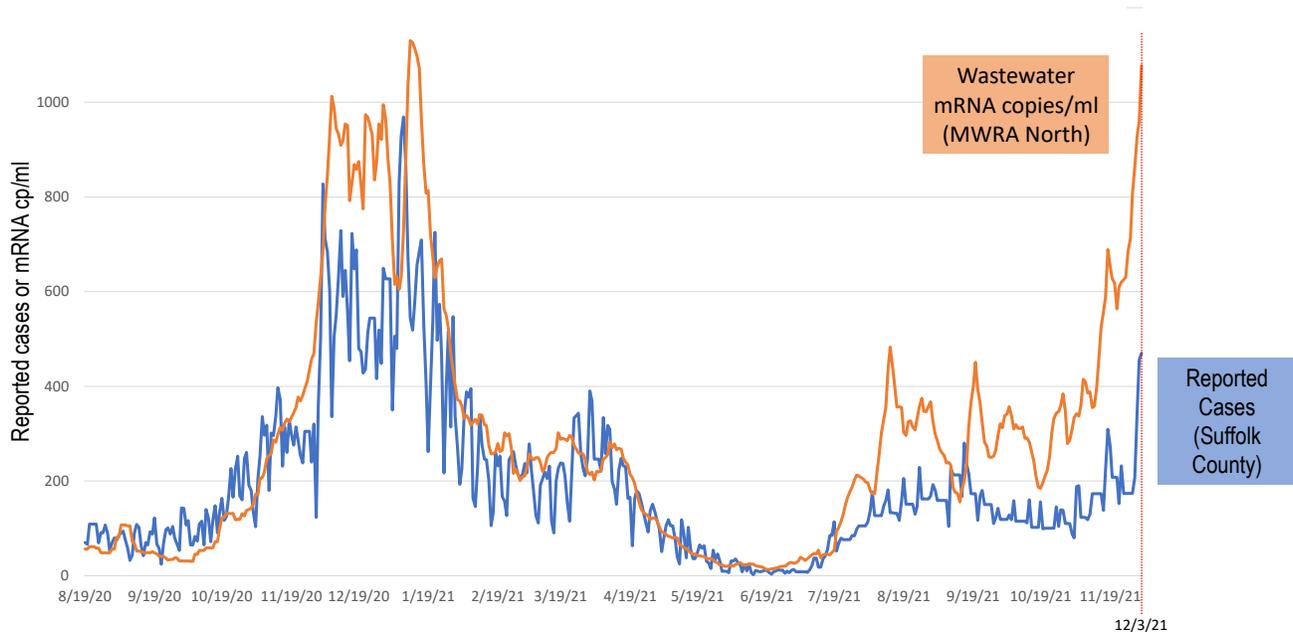
Commentary: The PCR test used for this data (Roche Cobas) has a very low limit of detection, at 25 cp/ml. Viral cultivation studies indicate that infection could be transmitted if viral load exceeds 100,000 cp/ml - well above the sensitivity of all approved rapid antigen tests. This suggests that the transmissible infection period lasts for only half of the PCR-positive days: i.e., 4 - 5 days in total for the vaccinated (1 - 2 days before peak illness and 2 - 3 days after). As discussed in *The Atlantic* this week, it's time to change the isolation protocol for vaccinated folks who test positive: [seven days is sufficient](#).

# Food for Thought

## The Scoop on Poop

Until relatively recently, the correlation of wastewater mRNA levels with reported cases has been high. For example, the Massachusetts Water Resource Authority wastewater viral loads for the Northern sector are shown below in orange, while the reported cases in Suffolk County (city of Boston) are shown in blue.

## Boston area COVID cases and wastewater viral loads



These two measures follow the same trajectory until July 2021, but start to diverge in August - why? Three major possibilities:

- The Delta variant was dominant in the area starting in [mid-July](#), and folks infected with that variant carry more virus (while the NBA study above didn't find a difference in viral load among variants, [others have](#)).
- The Delta surge was the first one to affect a relatively well vaccinated population (61% of Suffolk County residents were [fully vaccinated](#) by July 29, 2021), so more cases in this surge could have been asymptomatic and therefore gone untested.
- More cases are going unreported due to self-testing.

Commentary: As unreported self-testing grows, wastewater testing will become more essential and will ultimately become the single most important measure of COVID trends at the community, town, regional, and state levels.

### K-12 Metrics:

The Thanksgiving surge of school closures has ebbed, per Burbio's 2021/2022 [School Disruptions Tracker](#). Total closures to date: 948 districts (up from 916 last week), and 9,606 schools, up from 9,313.

### 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

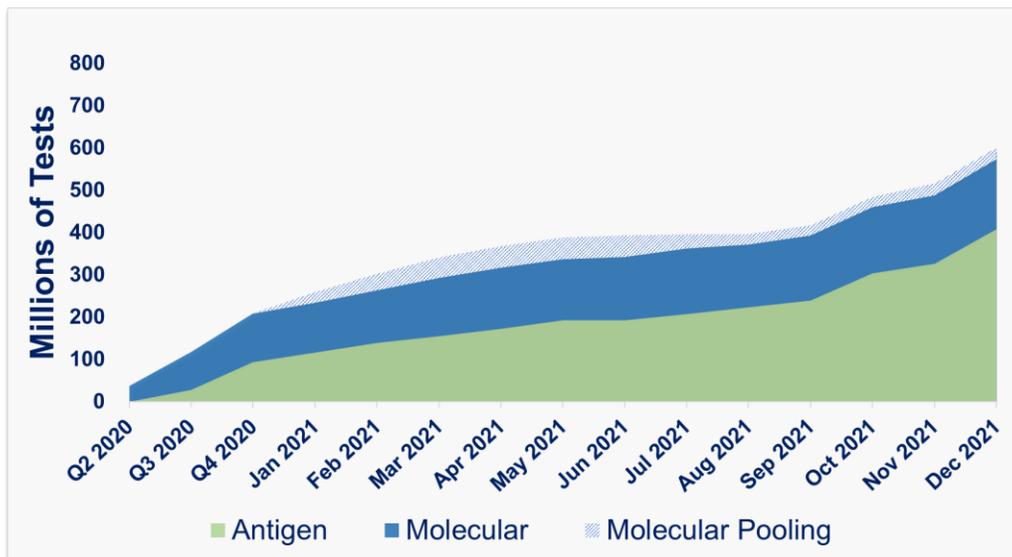
## Estimated Monthly Capacity of All Tests (M)

Test Type	Sep '21	Oct '21	Nov '21	Dec '21
<b>ANTIGEN</b>				
Antigen Professional + Point of Care EUA Today	149	163	174	185
Antigen OTC: Home/Self EUA Today	81	130	141	216
Antigen Central Lab Today	10	11	11	7
<b>Antigen Total</b>	<b>239M</b>	<b>304M</b>	<b>326M</b>	<b>408M</b>

<b>MOLECULAR</b>				
Molecular Professional, Point of Care, OTC EUA Today	28	31	32	36
Lab Based PCR Today	125	125	130	130
Add'l Lab Based PCR with Pooling	25	25	29	27
<b>Molecular Total</b>	<b>178M</b>	<b>181M</b>	<b>190M</b>	<b>193M</b>

<b>Total Test Capacity</b>	<b>417M</b>	<b>484M</b>	<b>516M</b>	<b>601M</b>
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## Manufacturing Capacity by Test Type Over Time



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