



# Tracking US Coronavirus Testing Capacity

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## Updated Monthly Capacity Numbers: Current and Future EUA's

**417M**

September 2021

**479M**

October 2021

**537M**

November 2021

**601M**

December 2021

## What Happened Last Week

*The FDA issued two new EUAs, six amendments, no safety communications and two EUA template updates in the last week:*

- New EUAs (2):
  - Antigen Tests (1): Celltrion DiaTrust (OTC Home Test)
  - Serology Tests (1): InBios Int'l Total Ab
- New Amendments to Existing EUAs (6):
  - Molecular Tests (3): Roche cobas | Cleveland Clinic SelfCheck (cobas) | Life Technologies (Thermo Fisher TaqPath)
  - Antigen Tests (1): Quidel QuickVue (Home Test) Re-authorized for OTC single-use test for symptomatic individuals without a prescription.
  - Flu/RSV Panels (2): Roche cobas | Cepheid Xpert Xpress
- EUA Protocol Changes (2):
  - Template Updates (2): [Molecular and Antigen Test Home Use](#) | [Molecular and Antigen Test Serial Screening](#)  
These updates are part of the FDA's efforts to "support authorization of [more COVID-19 tests for use without a health care provider prescription.](#)"

## New & Noteworthy

### *Full-Court Press from HHS*

It was a two-press-release week for HHS in the ongoing effort to increase access to COVID tests in the US - especially OTC tests.

#### [Announcement #1:](#)

- A \$560 million injection of funding to help thirteen manufacturers of testing supplies (pipette tips, protective packaging, swabs, and reagents) keep up with current and anticipated future demand - particularly for OTC tests.

#### [Announcement #2:](#)

- NIH, in coordination with the FDA, is investing \$70 million from the American Rescue Plan to establish a new Independent Test Assessment Program (ITAP), an accelerated pathway to support FDA evaluation of tests with potential for large-scale manufacturing - quickly.
- The program is an extension of the NIH Rapid Acceleration of Diagnostics (RADx) initiative.

- As part of this new program, “NIH, FDA, and other CDC and HHS experts will assess and conduct studies on OTC tests and work with companies to compile proper data, work towards the right benchmarks for performance, and support other needs that will help ensure they are providing the best submissions possible for FDA’s regulatory review. NIH will provide reliable, independent laboratory and clinical data to FDA for test manufacturers that can scale up quickly. If tests meet FDA’s performance and quality standards, FDA will use this information to grant emergency use authorization (EUA).”
- The FDA is also making it easier for developers of tests that have EUA for serial testing to get add-on authorization for single-use testing in symptomatic people. The goal - get “more individual tests for sale, potentially at a lower price.”

### *An Apple a Day Becomes: A Test a Day at Apple – and Elsewhere*

This week saw businesses in multiple industries increase their required COVID testing. [Apple was the most aggressive](#) - requiring daily testing for unvaccinated employees who come into the office and weekly testing for those who are vaccinated. We are also seeing some universities testing more frequently, even if they have a vaccine mandate. [University of Wyoming started the semester](#) with testing for all students and staff and is now testing weekly on a random 3% sample. [At Duke University](#), unvaccinated students are required to complete surveillance testing two times per week, and vaccinated students required to complete surveillance testing at least once per week.

## Food for Thought

### *Should we worry about post-delta emerging variants? AY.4.2? Something else?*

We are optimistic that we will not see a new surge from [AY.4.2](#) in the US, at least not at Alpha- or Delta-level scale. AY.4.2 (aka Delta Plus) is [Delta plus a spike mutation \(A222V\)](#) at a location targeted by antibodies (i.e., it may enhance immune escape). It has become 9.3% of current UK cases, but has died out in Spain, Germany, and Ireland. While its level of transmissibility [may be 10 - 15% higher](#) than Delta, that difference doesn’t appear to be big enough for it to overtake the current Goliath here.

Will a novel vaccine-escaping variant emerge? It is certainly possible, but mRNA vaccines present an entire spike protein to the immune system, making it hard for any single mutation to completely evade vaccine-evoked (or even natural) immunity. That said, vaccine makers are in clinical trials of Delta-tailored vaccines, just in case. The problem is that many variants have appeared and declined as Delta emerged - so greater tailoring of the vaccine to Delta might allow a dormant variant to re-emerge. If this were to happen, it would do so in a place where systematic selection pressure is highest - i.e., in a high-vaccination country (US, UK, or Israel). The [UK tracking system](#) will be the “canary in a coal mine” for us on this front.

Commentary: There are two ways to identify dangerous new variants that require renewed intervention, both of which require sequencing: 1) Look for mutations in the genome known to be important for viral function; and 2) Examine cases in regional outbreak clusters. As we pointed out last week, the US is not doing nearly enough sequencing for us to have confidence that we will spot the next explosive variant early enough to react. The US must create a scaled, systematic sequencing process at least as good as the UK’s and preferably better – in other words, we have to up our genomic profiling game 10-fold.

### *K-12 Metrics:*

Burbio’s 2021/2022 [School Disruptions](#) shows that closures have plateaued in the 20s to 30s. To date: 2,359 closures across 624 districts (up from 605 last week).

### *Higher Ed vaccine mandates:*

*The Chronicle of Higher Education* now counts [1,091 colleges and universities](#) that require vaccines, up from 1,069 last week.

# Latest Monthly Capacity Estimates

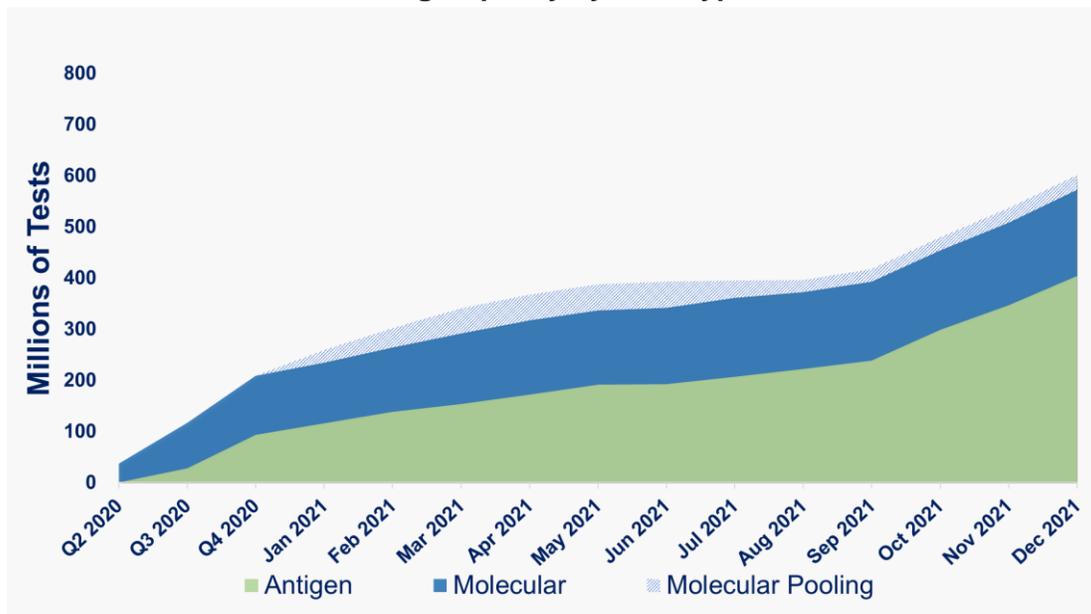
## Estimated Monthly Capacity of All Tests (M)

Test Type	Sep '21	Oct '21	Nov '21	Dec '21
<b>ANTIGEN</b>				
Antigen Professional + Point of Care EUA Today	149	158	172	197
Antigen OTC: Home/Self EUA Today	81	130	162	194
Antigen Central Lab Today	10	11	13	14
<b>Antigen Total</b>	<b>239M</b>	<b>299M</b>	<b>346M</b>	<b>404M</b>

<b>MOLECULAR</b>				
Molecular Professional, Point of Care, OTC EUA Today	28	31	32	39
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>198M</b>

<b>Total Test Capacity</b>	<b>417M</b>	<b>479M</b>	<b>537M</b>	<b>601M</b>
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## Manufacturing Capacity by Test Type Over Time



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