



# 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

*As described below – the biggest impact on capacity this week was the announcement of ACON Labs' EUA for an OTC rapid antigen test. We added ACON into our estimates, with a bit of skepticism/realism. Why? A company's estimate of capacity does not always meet expectations as they ramp up in a new market. But since ACON has been manufacturing COVID tests for many months, we assume that they will come close to the announced numbers very soon.*

## What Happened Last Week

*The FDA three new EUAs, one amendment, and one new safety communications in the last week:*

- New EUAs (3):
  - Antigen Tests (1): [ACON Laboratories Home OTC](#)
  - Serology Tests (1): Euroimmun IgG
  - Flu/RSV Panels (1): LabCorp
- New Amendments to Existing EUAs (1):
  - Serology Tests (1): Abbott AdviseDx IgM
- Safety Communications (1):
  - Safety Alert (1): Ellume COVID-19 Home Test ([Company recall announcement](#); [FDA Letter](#))

## New & Noteworthy

*ACON Laboratories Flowflex Home Test: Why is this EUA unique?*

#1 – The EUA is for an OTC rapid antigen test and [doesn't require serial testing](#).

#2 – The FDA's [press release](#) specifically states that this test will double availability of rapid at-home tests in the next several weeks, making this EUA not just about safety and efficacy but about scale.

Commentary: Over the last few weeks we've seen many calls to make more rapid tests available, both from voices who've been beating this drum for a year ([Michael Mina](#)) and from new quarters (businesses and states now faced with the task of [testing unvaccinated staff](#) as part of compliance with a vaccine mandate, whether their own or the feds'). As far as we can tell, this is the first FDA EUA announcement mentioning manufacturing capacity, suggesting that they're not only hearing, but listening.

*Vaccine mandates work*

Workplace vaccine mandates are [accomplishing what they were intended to do](#). Vaccination rates are up as many – often at the last minute – are choosing to get vaccinated rather than leave their jobs. Teachers are now among the highest vaccinated groups, with approximately 87% fully vaxxed nationwide. The most high-profile groups of holdouts: [police officers](#) and [firefighters](#). Commentary: We owe so much gratitude to first responders. Appropriately, they got vaccine access first, so it is surprising and disappointing that many are choosing not to be vaccinated. Given their critical role interacting with the public, it is essential that they not spread disease to those they are dedicated to protect. Importantly,

the vaccines are also there to protect them and their families too - COVID-19 was the leading cause of death for law enforcement officers in 2021.

### *Vaccine won't prevent every case – treatment matters too*

... which is why it's such good news to hear about not just one, but two new potential options for COVID-19 treatment. One is an [oral antiviral](#) that Merck and Ridgeback Biotherapeutics say reduces the chance of hospitalization with COVID-19 by [about 50%](#) if given early in the course of the disease. (Another reason that regular testing is important.) The other: AstraZeneca's [injectable antibody cocktail](#), which is used as post-exposure prophylaxis and can last for three months, according to the company. While our number-one defense against COVID-19 remains vaccination, we now know that this virus isn't going away. It is best to prevent, but important to better treat as well.

## Food for Thought

### *Pandemic, Epidemic, Endemic: How many COVID-19 tests will we need in 2022 and beyond?*

A key question: How long does infection and/or vaccine-induced immunity last? If it is years, then testing needs will drop precipitously; if it is months, then widespread testing will continue to be required. This issue is complicated by virus mutagenesis (how well does infection or vaccination against earlier variants protect against new variants?) and by individual variability in induced immunity. Laboratory evidence shows that antibody levels decline in 6-12 months. But – How much of what type of immunity is enough, and how long will it last? We don't really know. A [recent study](#) attempts to answer the second part of this question by modeling viral evolution and infectivity of other coronaviruses. Its answer: 16 months, with a range from 3 months to 5 years. If that's right, we should be prepared for the need for COVID-19 testing to continue at least through 2022, probably beyond. More to come on this.

### [Say Yes to Test](#)

Over the course of the pandemic, testing has improved tremendously – from the pain and discomfort of those “tickle the brain” nasopharyngeal swabs processed in central labs over several days to the front of the nose samples and results at home in 15 minutes. Getting people comfortable with testing often requires them to try the test themselves. Say Yes to Test is an answer to that - a cooperative effort from state & local health departments, the NIH and the CDC. The first three cities in the spring were [Ann Arbor/Ypsilanti, MI](#); [Chattanooga, TN](#); [Pitt County, NC](#). Current cities are [Fulton County, GA](#) and [O'ahu, HI](#).

### [Testing Commons.com](#) Q3 Review

Testing Commons now logs 2,657 COVID tests worldwide including those authorized for clinical use in the US and abroad, available for research, or in the development pipeline. [Q3 Pandemic Review](#) highlights an uptick in interest in serology testing overseas that has not yet seemed to materialize domestically, and strong efforts by the FDA to authorize assays that address a broader scope of respiratory infections (i.e., Flu/RSV Panels). There were 28 new US FDA EUAs in Q3 compared to 45 and 41 in Q2 and Q1 respectively.

### *K-12 Metrics:*

Burbio's 2021/2022 [School Disruptions](#) shows that new closures continue to occur at a much slower pace than at the start of the school year. New this week: at least two districts have halted in-person learning for the second time this semester (one in [Kentucky](#) and one in [Georgia](#), where the closure was prompted as a result of cases discovered by the district's testing program). The cumulative count: 2,238 school closures across 561 districts (up from 549 last week) across 45 states (up from 43).

Burbio has also started tracking vaccination requirements, but only for the nation's 200 largest districts. The big news there is [California's](#) recent announcement of a vaccine mandate for students (to be phased in as vaccines receive full FDA approval). As of now, 61 of the 200 districts have put vaccine mandates in place for teachers and staff.

### *Higher Ed vaccine mandates:*

*The Chronicle of Higher Education* now counts [1,058 colleges and universities](#) that will require vaccines for the fall semester, up from 1,053 a week ago.

# Latest Monthly Capacity Estimates

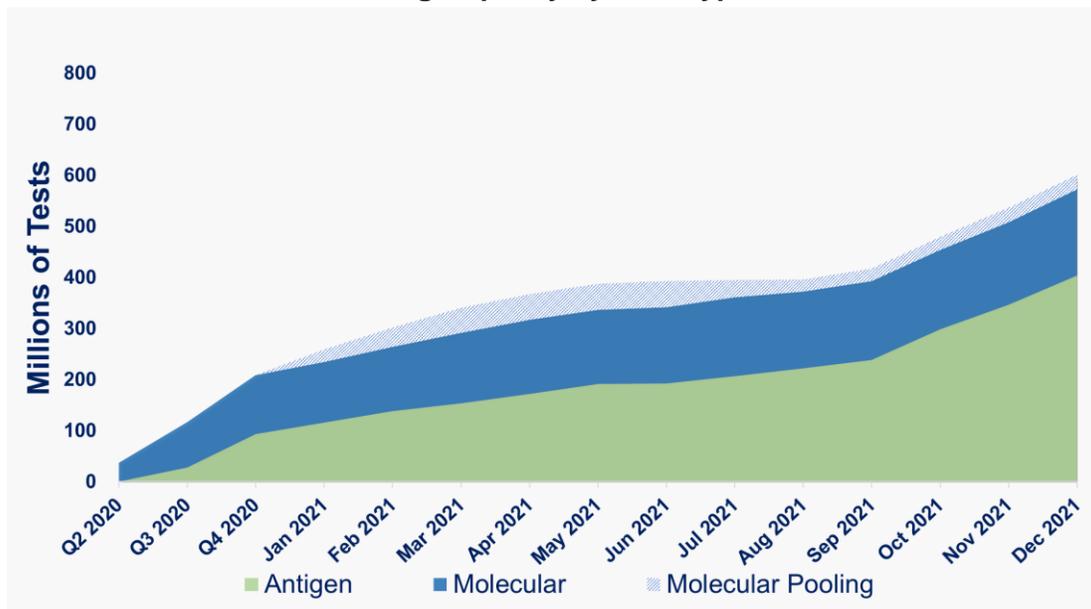
## Estimated Monthly Capacity of All Tests (M)

Test Type	Sep '21	Oct '21	Nov '21	Dec '21
<b>ANTIGEN</b>				
Antigen Professional + Point of Care EUA Today	149	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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