



# 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, and one safety communication in the last week:*

- New EUAs (2):
  - Molecular Tests (1): LMSI (Lighthouse Labs) CovidNow
  - Antigen Tests (1): Xtrava Health
- New Amendments to Existing EUAs (6):
  - Molecular Tests (4): Thermo Fisher Amplitude | Thermo Fisher TaqPath | Gravity Diagnostics | Gravity Diagnostics DTC
  - Antigen Tests (2): ACON Flowflex Home Test x2 (10/15; 10/19)
- Safety Communications (1):
  - Updates (1): Abbott Alinity [Recall Classification Notice](#) and [Letter to Healthcare Providers](#); both edited to clarify that potential false positive results are due to Alinity software corrected through the associated recall

## New & Noteworthy

### *PCR vs. Antigen Debate Continues*

Fast and frequent antigen testing has been endlessly challenged for not being as sensitive as PCR. [A Clinical Epidemiology](#) paper (University College London and co-authored with Michael Mina) recalibrates data from a December 2020 Liverpool study that, when it was first published, generated headlines proclaiming that rapid antigen tests were only 40% sensitive. The new paper calculates that, measured against viral shedding potential, antigen tests are more than 80% sensitive.

Commentary: Repeated PCR testing is the right test to manage clinical care of symptomatic and high-risk infected patients. Pooled PCR is the test to manage large, regular gatherings in a cost-effective way. And lateral flow rapid antigen tests are the right tests to identify infectious individuals who transmit disease by shedding virus from the upper respiratory tract via aerosols (i.e., breathing). When we are attempting to reduce the R0 of COVID-19, what matters is getting these individuals out of circulation until they are no longer contagious. Antigen tests are the ones with the timeliness, speed, cost, and accuracy to accomplish this pandemic management objective.

### *More – and more systemic – sequencing in the US, please*

We The UK announced an impressive milestone this week: The national COG-UK sequencing consortium has uploaded [1.1 million sequences](#) to the open global [GISAID database](#), which means that the UK has contributed 24% of the sequences now available on this global variant resource. The US has dramatically increased its pace of variant sequencing over the past three months and has uploaded 1.4 million sequences (30% of the database). However, our effort still lags: With 4.9x the population and

5.3x the COVID cases as compared to the UK, we're only sequencing 3.0% of all cases, while the UK is sequencing 12%.

Commentary: The US situation is even worse than those statistics indicate: Sequence origins by state vary from 19.6% of cases in Wyoming to 0.4% in Oklahoma. Current sequencing efforts are just not large enough, not systematic enough, and not regionally distributed enough to track the emergence of clusters of new variants.

#### *Central laboratory errors in the UK emphasize the importance of QC.*

The UK Health Security Agency (previously Public Health England) [announced](#) (reported in [The Guardian](#)) that 43,000 people who tested positive with a rapid antigen test were incorrectly told that they did not have COVID after Immensa Lab's PCR test. Adding to this scandal – Immensa [wasn't even fully accredited](#). Impact – allowing this large a number of COVID positive people to spread disease might have caused up to 300,000 new primary cases (R0 of 7).

Commentary: Two issues: Lab quality counts A LOT. In the quest to get fast Results to Test Takers (RT3) we cannot go so fast that we assume that any new lab is good. The pandemic has created thousands of new PCR labs - we must ensure that they are qualified to do the work we need them to do. #2 Do we really need PCR confirmations of positive antigen tests? In this case, the confirmations allowed this incompetent lab to be exposed. And yes – Ellume had a recent false positive recall, but otherwise, OTC antigen tests have close to 99% specificity – a very, very low false positive rate.

#### *The US Provided Free At-Home Tests. Let's Say Yes to the Lessons Learned.*

A thought-provoking piece appeared in STAT News this week, looking back on the CDC/NIH [Say Yes! COVID Test](#) initiative. The program has provided millions of free at-home rapid tests to communities in Michigan, Tennessee, and North Carolina, and is ongoing in Hawaii, Georgia, and Kentucky. STAT identified [three central lessons](#) from the program:

1. Outreach and education at the *community level* are crucial. Messages about testing from on high won't get through in the same way as personal communication from trusted *local* leaders.
2. "Testing demand fluctuates – supply shouldn't." Full stop. People learned quickly that test supply was fickle and began to hoard tests instead of using them for the intended purpose: asymptomatic screening. Meanwhile, "The health-care savings associated with preventing infections would likely outweigh the costs of maintaining a surplus during cycles of low demand."
3. At-home tests hamper public health's view into the disease impact. Health departments can't contact-trace cases they don't know about, and folks who take tests at home tend not to report results. In response, boards of health must change how and when they educate about what to do for a positive test and implement other methods – like monitoring wastewater – to track case levels.

#### *Another Round of RADx Awards, This Time for Rapid Tests*

The National Institutes of Health's Rapid Acceleration of Diagnostics (RADx) program announced a [new set of grants](#) to the developers of 12 rapid diagnostic tests, for a total of \$77.7 million. The awards support "development, validation, scale-up, and manufacturing, with the goal of bringing needed tests to the market as early as this year." The lucky dozen were split between RNA detection (Detect, Palogen, Quidel, Uh-Oh Labs, UCLA) and antigen detection (Becton Dickinson, Ellume, Luminostics, LumiraDx, Princeton, BioMedtech, and Quidel again). This brings the total number of RADx grants to 45; of the previous 33 projects, 32 have received EUAs to date.

# Food for Thought

## *Test to Stay Update: Schools Need Staff to Make it Work*

More than 2,200 K-12 schools in Massachusetts have signed up for one or more of the state's [COVID-19 testing programs](#), but staffing has continued to be a critical barrier to some schools' ability to get testing off the ground. This week members of the Massachusetts [National Guard](#) were deployed to fill the gap - a role they'd also filled in nursing homes in 2020. (National Guard members are also helping to alleviate an ongoing [school bus-driver shortage](#) in 13 Massachusetts districts.)

Commentary: The good news is that there is broad excitement and parental buy-in about Test to Stay to do exactly what the name implies - keep kids in school. The bad news is that executing it effectively takes a lot of additional staff. While the National Guard routinely responds to emergencies of all kinds, it is unsettling to some to see them working in schools.

### *K-12 Metrics:*

Burbio's 2021/2022 [School Disruptions](#) showed a slight increase in the number of closures over last week, but the current number of closed districts (28) remains low by comparison to the late-August peak (238). The count to date: 2,319 closures across 605 districts (up from 580 last week).

Burbio also noted a new trend: Some districts starting to remove mask mandates not due to political pressure but as a response to improving COVID-19 metrics. *Higher Ed vaccine mandates:*

### *Higher Ed vaccine mandates:*

*The Chronicle of Higher Education* now counts [1,069 colleges and universities](#) that require vaccines, up from 1,061 a week ago. While the official number of higher-ed institutions with vaccine mandates has not increased much in the last month, actual vaccination requirements are beginning to change as campuses leverage [President Biden's vaccine mandates for federal contractors](#). Why? Many colleges and universities receive substantial grants from the US government, effectively making them large federal contractors.

## *The Professional Version of Test to Play – Women's Professional Leagues*

<b>Sports League</b>	<b>Player Vaccine Requirements</b>	<b>Spectator Vaccine Requirement</b>
Women's National Basketball Association (WNBA)	Full vaccine requirements for all players and staff. All teams considered fully vaccinated.	Many teams requiring proof of vaccination or recent negative PCR test to enter arenas. Local/state vaccine rules apply.
Women's Football Alliance (WFA)	No league mandated vaccine requirements. Local/state vaccine rules apply.	No league mandated spectator vaccine requirement. Local/state vaccine rules apply.
Premiere Hockey Federation (PHF) (previously National Women's Hockey League)	Full vaccine requirements for all players, staff, volunteers, and rink partners. Weekly PCR testing required. Temperature checks prior to practice/games. Mask mandate where social distancing cannot be achieved except on-ice.	No league mandated spectator vaccine requirement. Local/state vaccine rules apply.
National Pro Fastpitch (NPF)	NPF suspended operations in 2020 due to "an inability to access testing" and uncertainty of testing costs; lack of access to venues; and decreased infrastructure for travel in order for players to practice and compete while maintaining good health and safety.	N/A

# Latest Monthly Capacity Estimates

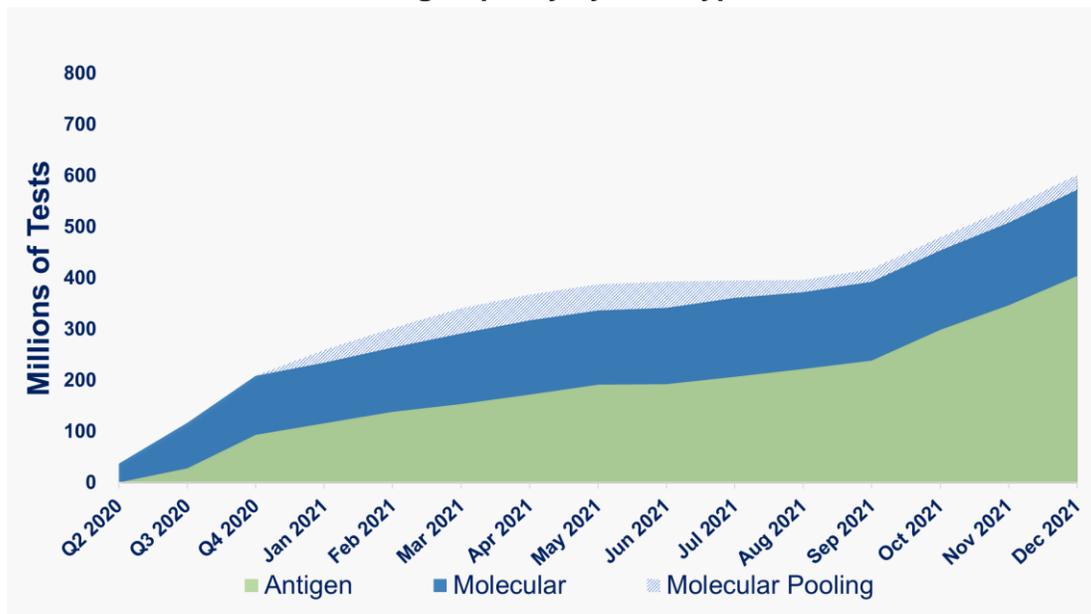
## Estimated Monthly Capacity of All Tests (M)

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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