



# Tracking US Coronavirus Testing Capacity

VOLUME 3, ISSUE 1

July 14, 2021

## ■ Current National Capacity Projections. (Tests / Month)

**349M**

March 2021

**379M**

June 2021

**590M**

September 2021

**707M**

December 2021

*No changes this week to test capacity.*

## What Happened Last Week

*The FDA issued 7 new EUAs, 8 amendments and 2 Safety-Related Notices over the last week:*

- New EUAs (7)
  - Molecular Tests (2): BioGX | Thermo Fisher
  - Antigen Tests (1): Ellume
  - Serology Tests (2): Bio-Rad | Ortho-Clinical Diagnostics
  - Collection Kits (1): Everlywell COVID & Flu
  - Flu/RSV Panels (1): Exact Sciences
- New Amendments to Existing EUAs (8)
  - Molecular Tests (6): Assurance | Assurance DTC | Rheonix | Vela Diagnostics | Havard (HUCL) | Mammoth Biosciences
  - Collection Kits (1): Everlywell DTC
  - Flu/RSV Panels (1): Abbott Alinity
- Recalls/Safety Communications (2)
  - Recalls (1): [Quidel Lyra](#) – Class I recall due to risk of false negative results
  - Other safety-related activity (1): [Johnson & Johnson vaccine](#) – Fact Sheet revised to include warning about [Guillain-Barré Syndrome \(GBS\)](#)

## New & Noteworthy

*δ wins worldwide... for now:*

In the [US](#) and the [UK](#), Delta has become the [fastest growing](#) Variant of Concern, outcompeting other variants due to its high transmissibility (about 50% higher than Alpha/B.1.1.7, which was 50% higher than the original virus). This is good and bad news: on the good side, the vaccines available in the US [work well against it](#); on the bad, it spreads like wildfire in unvaccinated communities – both in unvaccinated pockets within well-vaccinated nations and globally in countries where vaccination lags.

### *Confirmed again: Antigen tests as good as PCR for detecting infectivity:*

The University of Illinois at Urbana-Champaign [published](#) the first comprehensive longitudinal study to demonstrate the relative performance of antigen and RTqPCR tests versus the ([VeroE6TMPRSS2](#)) cell culture gold standard for SARS-CoV2 infectivity. The study of 43 COVID patients, funded by NIH, confirmed that rapid antigen tests are as good as RTqPCR at detecting patients with infective viral loads (>100,000 cp/ml), though they lose out to RTqPCR in the immediate 1-2 day pre-infective period.

Of course, RTqPCR's theoretical advantage disappears when its results take 1 - 2 days to arrive.

### *AACC pours cold water on the use of Ct counts:*

The influential laboratory American Association for Clinical Chemistry (AACC) recommended that reporting Ct values to ordering physicians "[be discouraged](#)."

Commentary: To be fair, the AACC opinion is supported by a long list of useful and accurate caveats about the lack of Ct result comparability across individuals, protocols, and assays. That being said, [Ct values are the only way](#) to calculate / estimate the all-important viral load – known to indicate relative infectivity of patients at the time of testing, used to track disease progress, and in many cases, also used to help clinicians sort out reinfection from the lingering tail of a prior infection. It is shortsighted to discourage this reporting in all circumstances. Physicians are (or should be) aware of Ct's limitations, and they need this information to make clinical and epidemiological decisions. Instead of using Ct value variability as a reason not to provide data, the laboratory industry should provide adequate data to allow comparability across assays.

## Food for Thought

### *Test, Test, Test... Commentary*

Victory over COVID has been declared prematurely in the US. Vaccines are widely available, new cases are far below the catastrophic levels of six months ago, masking has become rare, and indoor crowds are commonplace. The mRNA vaccines have been more effective than we ever thought remotely possible: [90+% effective](#) in preventing death and serious disease, a statistic that remains steady despite (expected) breakthroughs by [the most concerning current variant](#).

Yet [barely over half of the eligible US population](#) is fully vaccinated today, and vaccination rates have plateaued - 6% say they'll get vaccinated "only if required" to do so, and [14% still state that they will never accept vaccination at all](#). Meanwhile, testing companies Abbott, Quidel, and Qiagen have all [lowered their 2021 outlook](#) due to decreasing demand for COVID-19 testing.

It is foolish to reduce our vigilance against the virus while we're in the process of increasing selective evolutionary pressure on it. We've won several battles against SARS-CoV-2, but the war is still on, and testing is not only our eyes and ears against this enemy, but [can even be an active weapon against it](#). Absent community screening and surveillance, as well as increased sequencing of breakthrough cases, we will inevitably see hotspots grow out of control. The US has been luckier than it deserved to be this spring and summer, but luck is not a strategy.

### *K-12 Schools*

#### **\$15 M from NIH studies on improving testing access in underserved K-12 schools**

[Five studies recently funded by NIH](#) aim to test a range of strategies for standing up successful asymptomatic COVID-19 screening programs in underserved K-12 schools. Part of the RADx Underserved Populations program (RADxUP), the projects will focus on the under-12-year-old population that isn't yet eligible for vaccination, as well as on the ongoing issues of vaccine uptake, breakthrough infections, and the effects of the latest variants. Here's hoping that these studies will help more kids get back in school as safely as possible.

### *Higher Ed Preparing for the Fall*

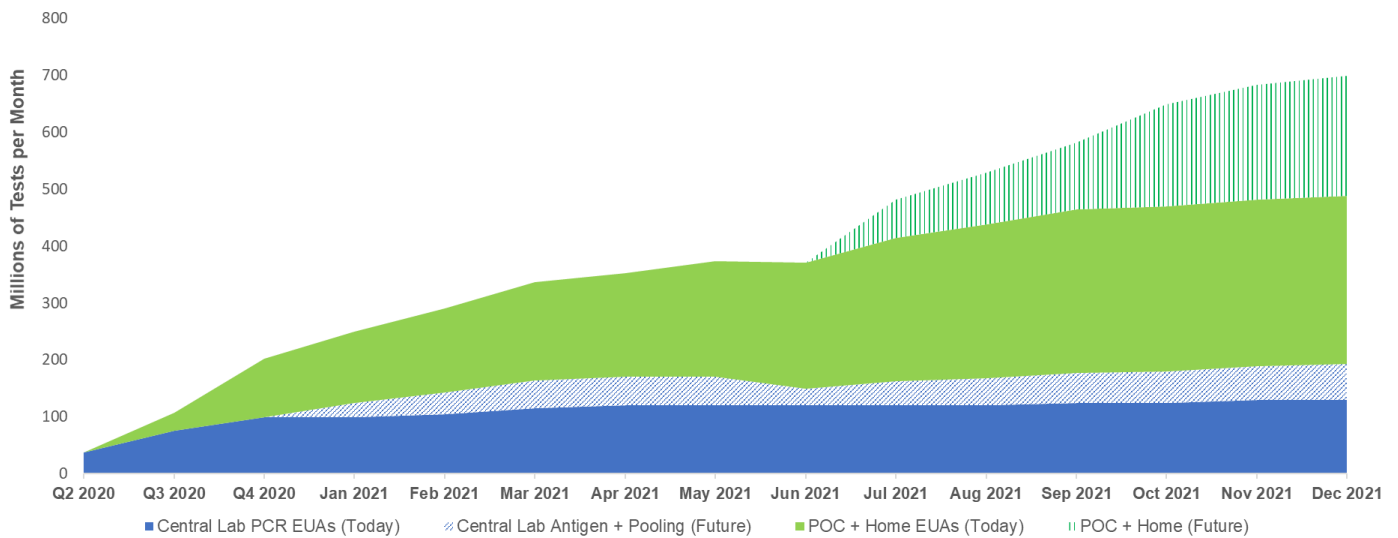
*The Chronicle of Higher Education* now counts [578 universities](#) that will require vaccines for the fall semester, up from 544 two weeks ago.

# Latest Monthly Capacity Estimates

## Estimated Monthly Capacity of All Tests (M)

Test Type	Sep '20	Dec '20	Jan '21	Feb '21	Mar '21	Apr '21	May '21	Jun '21	Jul '21	Aug '21	Sep '21	Oct '21	Nov '21	Dec '21
Antigen Point of Care EUA Today	28	95	111	131	145	157	166	163	178	190	204	206	206	206
Home / Self Tests EUA Today	0	2	6	7	17	12	24	44	56	61	63	64	66	69
Molecular Point of Care EUA Today	4	5	8	10	12	12	13	14	19	19	20	20	20	20
<b>Subtotal POC &amp; Home EUA Today</b>	<b>32</b>	<b>103</b>	<b>125</b>	<b>147</b>	<b>174</b>	<b>181</b>	<b>203</b>	<b>221</b>	<b>253</b>	<b>270</b>	<b>287</b>	<b>290</b>	<b>292</b>	<b>295</b>
<i>Antigen Point of Care Future</i>	0	0	0	0	0	0	0	0	43	61	74	89	102	102
<i>Home / Self Tests Future</i>	0	0	0	0	0	0	0	0	12	18	30	75	85	95
<i>Molecular Point of Care Future</i>	0	0	0	0	0	0	0	0	12	12	14	14	14	14
<b>Subtotal POC &amp; Home Future</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>67</b>	<b>91</b>	<b>118</b>	<b>178</b>	<b>201</b>	<b>211</b>
<b>Total POC &amp; Home</b>	<b>32</b>	<b>103</b>	<b>125</b>	<b>147</b>	<b>174</b>	<b>181</b>	<b>203</b>	<b>221</b>	<b>320</b>	<b>361</b>	<b>405</b>	<b>468</b>	<b>493</b>	<b>506</b>
<i>Antigen Central Lab Today</i>	0	0	3	7	7	8	8	8	8	8	8	8	8	8
<i>Antigen Central Lab Future</i>	0	0	0	0	0	0	0	0	12	18	21	24	27	30
Lab Based PCR Today	75	100	100	105	115	120	120	120	120	120	125	125	130	130
<i>Add'l Lab Based PCR with Pooling</i>	0	0	25	38	48	50	50	30	30	30	31	31	33	33
<b>Total Central Lab</b>	<b>75</b>	<b>100</b>	<b>128</b>	<b>150</b>	<b>170</b>	<b>178</b>	<b>178</b>	<b>158</b>	<b>170</b>	<b>176</b>	<b>185</b>	<b>188</b>	<b>198</b>	<b>201</b>

## Estimated Future Capacity by Test Type



### Editors

Mara G. Aspinall, Arizona State University  
Liz Ruark, COVID-19 Response Advisors

### Contributors

Simon Johnson, Massachusetts Institute of Technology  
Sarah Igoe, MD, Arizona State University

### Designer

Fer Sagastume, COVID-19 Response Advisors

Based on published reports, company interviews, and proprietary analysis  
A collaboration between COVID-19 Response Advisors & Health Catalysts Group

[www.covidresponseadvisors.org](http://www.covidresponseadvisors.org) & [www.healthcatalysts.com](http://www.healthcatalysts.com)