



# Tracking US Coronavirus Testing Capacity

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

<b>349M</b>	<b>379M</b>	<b>477M</b>	<b>672M</b>
March 2021	June 2021	September 2021	December 2021

## What Happened Last Week

*The FDA issued 7 EUAs, 17 amendments, and 4 safety communications in the last two weeks:*

- New EUAs (7)
  - Molecular Tests (4): Mount Sinai Hospital | Empire City Laboratories (2 EUA's) | SalivaDirect DTC (Yale)
  - Antigen Tests (1): BD Veritor Home Test
  - Serology Tests (1): InBios Int'l IgG Rapid Test
  - Collection Kits (1): SalivaDirect DTC (Yale)
- New Amendments to Existing EUAs (17):
  - Molecular Tests (9): Univ. of Illinois covidSHIELD | Gencurix | Abbott ID NOW | TBG Biotechnology Corp. | Visby Medical | Thermo Fisher TaqPath Combo Kit 2.0 | Assurance Scientific Labs | Roche cobas | Color Health DTC
  - Antigen Tests (3): Access Bio CareStart Home Test | InBios Int'l Ag Rapid Test | Celltrion DiaTrust Ag Rapid Test
  - Serology Tests (2): Siemens Atellica IgG | Abbott AdviseDx IgM
  - T-Cell Tests (1): Adaptive Biotechnologies T-Detect
  - Flu/RSV Panels (1): BioFire Resp-4-Plex
  - Collection Kits (1): Color Health DTC
- Recalls/Safety Communications (4):
  - Warning Letters (3): [Shanghai Dasheng](#) | [Invisi Smart Technologies](#) | [Kaleido Biosciences, Inc.](#)
  - Safety Communications (1): [Letter to Veterinarians and Animal Retailers re: misuse of animal Ivermectin](#)

## New & Noteworthy

*The WHO Variant of Interest: Mu*

The WHO named a new Variant of Interest last week: [Mu](#), first identified in Colombia in January and now responsible for nearly 40% of cases there and rising. While Mu sports some potentially immune-evading mutations, its level of transmission outside of Colombia and Ecuador [doesn't seem to be able to hold a candle to Delta](#). We'll keep you posted.

*Vaccinated and asymptomatic? You could still be spreading Delta*

We already know that both vaccinated and unvaccinated individuals can develop high viral loads when infected with the Delta variant. A preprint from University of Wisconsin has now demonstrated that both [symptomatic and asymptomatic](#) patients infected with Delta can shed similar levels of virus, whether vaccinated or not. An important side note was that among asymptomatic cases, [the vaccinated had](#)

[higher viral loads than the unvaccinated](#) – suggesting that vaccination can allow hidden onward transmission after contact.

Commentary: The CDC's reimposition of universal masking in close quarters is fully supported by the data. Although Delta's surge is so recent that we have no direct data, it is reasonable that its greater transmissibility is because of higher shedding of virus in aerosols from the upper respiratory tract.

[Masking is our best-known defense](#) against the resulting aerosols. Frequent testing remains essential to identify these "silent but potentially deadly" cases, and sadly, it cannot be reserved for the unvaccinated alone.

### *CE-IVD rules in the UK : Closing the stable door after the horse has bolted?*

The light hand of the Europe-wide CE-IVD rules is going to be tightened up in the UK, at least for [point-of-care lateral flow devices](#). The Department of Health and Social Care has set new validation criteria for these tests, including lab confirmation of performance for asymptomatic screening.

Commentary: The change seems to come at least partly as response to the UK's aggressive early purchases of antigen tests that failed to meet their stated claims. Some of these tests truly did not perform adequately. However, many failed because the distinction between antigen tests' ability to detect those who are infectious vs. those who are infected was not acknowledged. The US FDA's serial-testing approach (two Ag tests in 24 to 48 hours) for home / OTC / no prescription antigen tests is a clever way to do both.

## Food for Thought

### *From epidemic to endemic*

McKinsey updated their analysis, "[When will the COVID-19 pandemic end?](#)" They segment countries into three groups: High Vaccination (eg, US and UK), for which normalcy will return late 2021 to early 2022; Case Controllers (eg, Singapore and Australia), which are rapidly vaccinating and will return to normalcy in mid/late 2022; and At Risk (the less developed world), whose return will come in late 2022 / 2023.

Commentary: We need to redefine "return to normalcy." Normalcy is likely to be managing COVID as an endemic disease, not eradicating it. Nature published a more comprehensive and technical examination of [the pandemic's trajectory](#), comparing prior pandemics to this one and discussing the success of all 17 viral disease vaccines available in the US across various diseases; their conclusions were consistent with ours.

### *Vaccines still work very well - Moderna even more so than Pfizer*

Data continues to confirm that even against Delta, vaccines retain effectiveness where it counts. Real-world experience varies but confirms 40-60% protection from Delta infection and about 90% protection against death. How do the different vaccines compare? A 50,000-person [Mayo study](#) found that Moderna retained almost 2x the infection protection of Pfizer (76% vs 42%). Moderna also provided a bit more protection against hospitalization - 81% to Pfizer's 75% - which likely reflects antibody levels generated. Per dose, Moderna contains 3.3x the mRNA that Pfizer does, and two recent studies (from [Belgium](#) and [Wisconsin](#)) report corresponding antibody generation differences.

### *K-12 Metrics:*

Burbio's School Opening Tracker has transformed into a tracker of [school disruptions](#). Thus far in the nascent 2021-2022 school year, they've "identified over 1,400 in-person school closures (up from 698 last week) across 278 districts (from 158) in 35 states (from 25)," with about 90% of US schools now in session. Disruptions are spread across Indiana, Ohio, and nearly all of the South, including eastern Texas and Oklahoma, with closures fewer and farther between elsewhere in the nation.

### *Higher Ed vaccine mandates:*

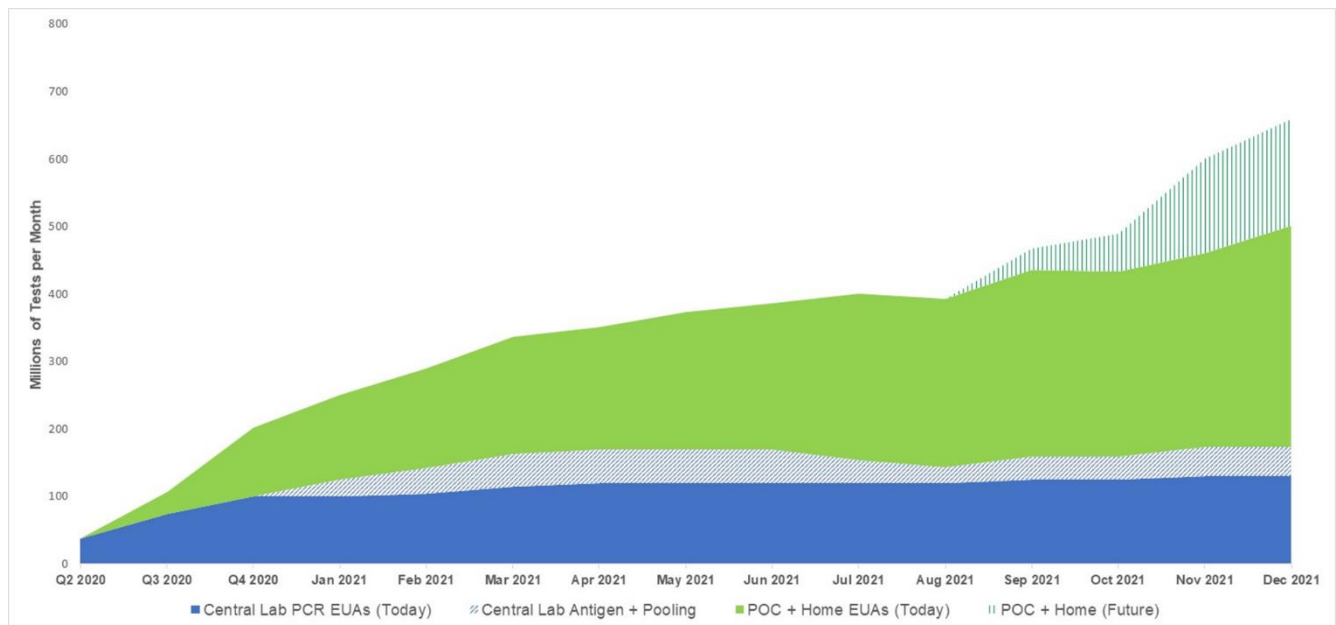
The *Chronicle of Higher Education* now counts [1,014 colleges and universities](#) that will require vaccines for the fall semester, up from 749 two weeks ago. This 36% increase is not just because two weeks have passed since our last update. The reality of re-opening campuses in person and early outbreaks seem to have moved more new institutions to new vaccine mandates, especially in Indiana, Louisiana, North Carolina, and Ohio.

# 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	168	183	159	168	165	167.5	172.5
Home / Self Tests EUA Today	0	2	6	7	17	12	24	34	45	76	93	94	102	127
Molecular Point of Care EUA Today	4	5	8	10	12	12	13	14	19	14	16	16	18	28
<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>216</b>	<b>247</b>	<b>249</b>	<b>277</b>	<b>275</b>	<b>288</b>	<b>328</b>
<i>Antigen Point of Care Future</i>	0	0	0	0	0	0	0	0	0	0	11	16	69	74
<i>Home / Self Tests Future</i>	0	0	0	0	0	0	0	0	0	0	15	35	60	70
<i>Molecular Point of Care Future</i>	0	0	0	0	0	0	0	0	0	0	5	5	10	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>0</b>	<b>0</b>	<b>31</b>	<b>56</b>	<b>139</b>	<b>158</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>216</b>	<b>247</b>	<b>249</b>	<b>308</b>	<b>331</b>	<b>427</b>	<b>486</b>
<i>Antigen Central Lab Today</i>	0	0	3	7	7	8	8	2	8	10	10	10	13	13
<i>Antigen Central Lab Future</i>	0	0	0	0	0	0	0	0	0	0	9	9	15	15
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	50	34	24	25	25	29	29
<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>172</b>	<b>162</b>	<b>154</b>	<b>169</b>	<b>169</b>	<b>186</b>	<b>186</b>
<b>Total Current &amp; Future</b>	<b>107</b>	<b>203</b>	<b>253</b>	<b>297</b>	<b>344</b>	<b>360</b>	<b>381</b>	<b>389</b>	<b>409</b>	<b>403</b>	<b>477</b>	<b>500</b>	<b>613</b>	<b>672</b>

## Estimated Future Capacity by Test Type



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