



# 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

*No changes in capacity this week but given the Biden administration's \$2 billion in advance purchasing contracts for antigen tests, plus company announcements about their own capacity, we are in the process of revising our estimates for 2021 and laying the groundwork for 2022. We expect to issue revised numbers next week, including end-of-month updates.*

## What Happened Last Week

*The FDA no new EUAs, two amendments, and one new safety communications in the last week:*

- New Amendments to Existing EUAs (2):
  - Molecular Tests (1): LetsGetChecked
  - Collection Kits (1): Color Health
- Warning Letters/Safety Communications (1):
  - Safety Communications (1): [Potential for False Positive Results with Abbott Molecular Alinity m SARS-CoV-2 AMP and Alinity m Respo-4-Plex AMP Kits](#)

## New & Noteworthy

The FDA has [amended the EUA for the Pfizer-BioNTech COVID-19 vaccine](#) to include authorization for a single additional dose at least 6 months following the initial series for certain populations:

- Anyone over 65
- Individuals 16-64:
  - High risk of severe COVID-19, or frequent occupational exposure to the virus suggesting high risk of serious complications of COVID-19.

### *Follow-Up on Biden's "Path Out of the Pandemic"*

Over the last week, the Biden administration awarded a number of contracts to purchase significant quantities of antigen tests:

OTC COVID-19 rapid antigen test kits (\$647 million total)

- Quidel - \$284.2 million; 25.6 million kits
- OraSure - \$205.2 million; 20.6 million kits
- Abbott - \$47.8 million, 3.8 million kits
- Intrivo (AccessBio US Distributor) - \$109.8 million; 10 million kits  
(Please note: Mara Aspinall is a member of the board of directors of OraSure).

Professional COVID-19 rapid antigen test kits (\$1.2 billion total)

- Abbott - \$554.4 million; 168 million kits
- Celltrion - \$626.4 million; 19 million kits

A third group of advance purchases will involve rapid antigen tests with integrated electronic (cell phone) reporting.

Delivery is expected to start next month and continue through September 2022. And not a moment too soon, as everyone from the [New York Times](#) to [school testing researcher Emily Oster](#) to our neighbors down the street have been wondering “Where are the tests?” Supply across the country appears to be widely variable, even from one county to the next, leaving some folks searching fruitlessly through 16 CVS stores for a rapid test while others find them easily on Walmart shelves. We’re also hearing disturbing stories of hoarding, with families stockpiling 100 tests at a time.

Commentary: The Good: We have to reiterate just how important this initiative is. Testing, with all technologies (but right now especially rapid antigen), needs to be broadly accessible and available. It’s impressive that the process of evaluating and selecting vendors happened so quickly - less than two weeks after the President’s speech. The Bad: Great start - but depending on the pace at which these tests actually “hit the streets,” it will be many weeks before shortages are alleviated. 240 million tests sounds like a lot, until you remember that there are 325+ million people in the US, and an effective screening program means that people should be tested once a week. Testing needs to be part of our long-term response, not just a one-time bolus.

### *Hawaii Tries Out Free Antigen Testing*

A multi-partner pilot program will provide 125,000 O’ahu residents with [eight free rapid antigen tests each](#), to be used twice a week for four weeks, regardless of symptoms. Participants may choose to report their results to their local department of health and are asked to isolate and contact their health-care provider for instructions about a confirmatory test if they come up positive. Researchers will work with CDC and NIH to see if this initiative helps slow viral spread.

Commentary: The federal government has sponsored these programs before. We don’t know how this one is structured, but we hope that results can be compiled and analyzed quickly

### *K-12 Schools – Two More States Test to Stay*

Glad to see [California](#) and [Kansas](#) joining Utah, Illinois, and Massachusetts as states with Test to Stay protocols in place. The details vary, but the concept is the same: Use rapid antigen tests to serially test close in-school contacts of positive COVID-19 cases in lieu of quarantining them.

Commentary: The CDC is not recommending this approach today, but we’re hoping they review and endorse soon, especially once additional data accumulates on this side of the Pond instead of just from [the UK](#).

## **Food for Thought**

### *Regulation of Diagnostics Tests: Western Europe (EU plus UK) and the US*

There are stark differences in the way tests are regulated in the US versus the EU. The US has a slow and thorough review process for both analytic performance and clinical utility. The EU only requires manufacturers to self-certify to CE-IVD standards of analytic performance.

As a result, both the US and EU suffered different early pandemic problems: in the US, very few tests were available for the first 6 months of the pandemic until the EUA process gained steam, costing thousands of lives – while in the EU, individual governments moved very quickly to buy available tests, only to be embarrassed by wasting millions of Euros on tests that had inadequate analytic accuracy (primarily rapid tests of antibodies and antigens).

EU systems will become more onerous starting in May 2022 ([the 1998 In Vitro Diagnostic Regulation](#)), when 90% of IVDs will require independent review of manufacturer claims in the test’s clinical environment. Brexit adds another layer of complexity, as this past week the UK MHRA published a [191-page proposal](#) to be implemented from July 2023. It applies broadly to all devices, including diagnostics, but for the latter it is largely consistent with EU regulations, with a greater focus on performance in clinical use ([Ch 7](#)) and post-market surveillance ([Ch 8](#)).

### *K-12 Metrics:*

Burbio’s 2021/2022 [School Disruptions](#) tracker has thus far logged just over 2,000 in-person school closures (up from just under 1,700 last week) across 469 districts (from 386) in 39 states (from 38).

### *Higher Ed vaccine mandates:*

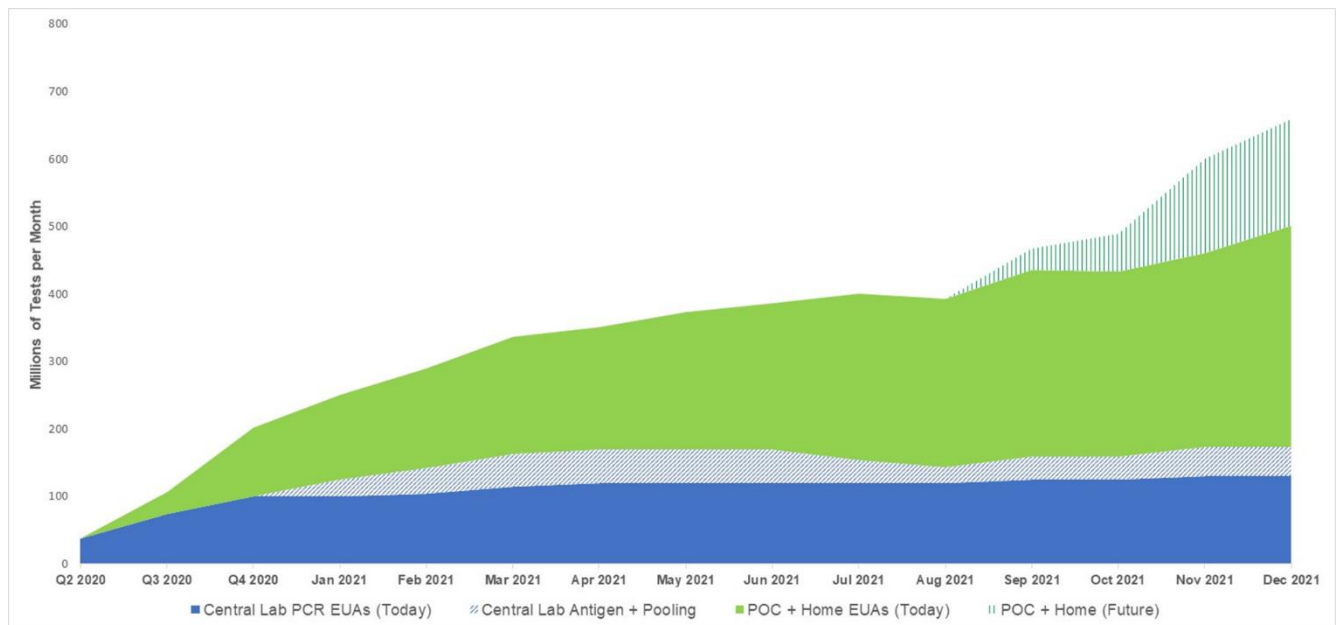
The Chronicle of Higher Education shows [1,033 colleges and universities](#) that require vaccines, up from 1,030 a week ago. Clearly, with school well underway, there are few new institutions adding mandates.

# 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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