



# Tracking US Coronavirus Testing Capacity

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

**349M**

March 2021

**504M**

June 2021

**700M**

September 2021

**852M**

December 2021

*No changes this week – but one development to watch: According to Business Insider, Amazon [plans to introduce a “Diagnostics” product](#) line for at-home testing including COVID-19 sexually transmitted infection diagnostics, as well as genetic testing. We will be watching this development for how it might affect capacity, test distribution and product market share.*

## What Happened Last Week

*The FDA issued two EUAs and eight amendments this week:*

- New EUAs (2)
  - Molecular Tests (1): Phosphorous Diagnostics DTC
  - Collection Kits (1): Phosphorous Diagnostics DTC Saliva Kit
- New Amendments to Existing EUAs (8)
  - Molecular Tests (5): Broad Institute | GENETWORx | Roche cobas | Phosphorous Diagnostics | Viracor Eurofins DTC
  - Collection Kits (2): EmpowerDX DTC | binx health
  - Serology Tests (1): InBios Int'l

## New & Noteworthy

*More and more breakthrough infections are documented, but are they cause for concern?*

- Commentary: As Boston Red Sox fans, it pains us to give the NY Yankees any more press than they already get, but, alas, it is relevant to COVID testing! 9 members of the New York Yankees organization have [tested positive for COVID post-vaccination](#). While seven of the nine are reportedly asymptomatic and the other two have mild symptoms, this seemingly high breakthrough infection rate might be closer to reality than the [figures reported by the CDC](#), given that testing rates in the general public have gone down.
- This is particularly relevant as the CDC is now only tracking [breakthrough infections](#) that lead to death or hospitalization.

### *Another nail in the coffin for antibody tests*

- Today the [FDA \(CDR\) issues a safety communication to](#) inform the public that antibody tests “should not be used to evaluate immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination.
- The basis for the warning is that data on which specific protein segments used in antibody tests are rarely published, so it is quite possible for neutralizing antibodies to be evoked by vaccination but be specific for an epitope not included in any specific test. The two most used US vaccines create spike protein antibodies, and although 69 of 78 FDA performance-evaluated antibody tests detect the Wuhan original spike protein (9 detect nucleocapsid only), there is no guarantee that they can detect the specific antibodies raised by vaccination without further data disclosure by manufacturers. There has been very little clinical or epidemiological value for performing antibody tests to date, but as the pandemic progresses this will change for tests with published efficacy data detecting antibodies against specific variants.

### *Trust & the public health*

- A [new NPR poll](#) showed that US government public health agencies like the CDC and FDA are trusted by only about half of Americans.
- The CDC issues [broad guidance](#) late last week and the focus of the popular press has been on the “mask on and off” policies, but little has been written about the evolving testing guidance. The CDC has said vaccinated people do not need to participate in regular screening programs or test after a known exposure.
  - *Commentary:* While the likelihood of vaccinated people contracting or spreading the virus is very low – it is not zero. For vaccinated people who regularly interact with the public and/or high-risk individuals, it may be prudent to continue testing regularly. We all want to encourage widespread vaccination but let us not abandon testing too quickly. Testing remains the only way to confirm that mitigation and vaccination is working – and it is now straightforward to find affordable tests with quick results and relatively simple for most businesses to implement and reasonably testing programs.

## Food for Thought

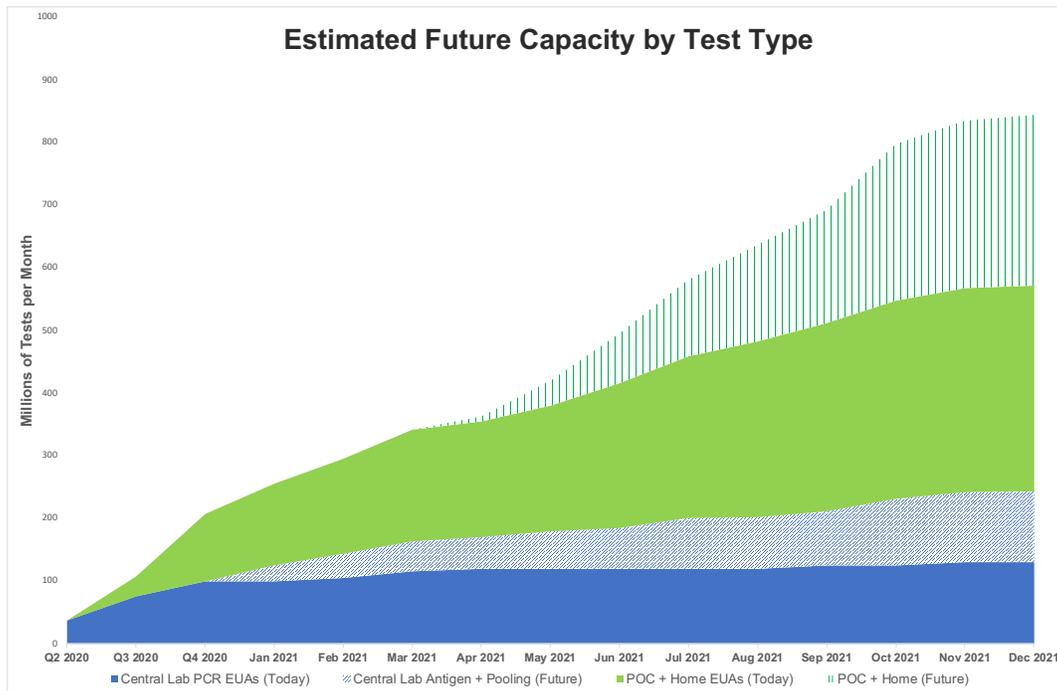
### *Focus of School Reopening Shifts to Plans for Fall Semester*

- [Randi Weingarten](#), President of the American Federation of Teachers (AFT), spoke extensively this week on the importance of ALL kids being back to school in person in the fall.
- CDC [recommends](#) continued use of prevention measures in schools for the 2020-2021 school year. Current recommendations include the use of asymptomatic screening testing for unvaccinated individuals in most areas of the US.
- [Burbio's](#) data this week continue to show that there are very few virtual-only schools, calling for a shift in focus to the 28.8% of kids who are in schools with hybrid schedules, meaning that many students are still spending substantial time outside of the physical classroom and families are faced with complex and often-changing schedules.
  - % US K-12 students attending “virtual-only” schools = 2.6% (from 2.8% last week)
  - % US K-12 students attending “traditional in-person/every day” schools = 68.8% (from 67.9%)
  - % US K-12 students attending “hybrid” schools = 28.8% (from 29.3%)
- US colleges and universities are deciding vaccination policy for the fall semester. The [Chronicle of Higher Education](#) published a list of the 361 colleges identified so far that will be *requiring* vaccines for the fall semester. We will continue to monitor this.

# 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	99	116	136	150	160	167	181	193	205	218	220	226	226
Home / Self Tests EUA Today	0	2	6	7	17	12	21	38	45	55	63	75	77	80
Molecular Point of Care EUA Today	4	5	8	10	12	12	12	13	20	20	20	21	22	22
<b>Subtotal POC &amp; Home EUA Today</b>	<b>32</b>	<b>107</b>	<b>130</b>	<b>152</b>	<b>179</b>	<b>184</b>	<b>201</b>	<b>232</b>	<b>258</b>	<b>280</b>	<b>301</b>	<b>316</b>	<b>325</b>	<b>328</b>
Antigen Point of Care Future	0	0	0	0	0	0	18	41	81	106	119	144	152	152
Home / Self Tests Future	0	0	0	0	0	0	11.4	28	29	37	47	93	101	107
Molecular Point of Care Future	0	0	0	0	0	8	10	10	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>8</b>	<b>39</b>	<b>79</b>	<b>122</b>	<b>155</b>	<b>180</b>	<b>251</b>	<b>267</b>	<b>273</b>
<b>Total POC &amp; Home</b>	<b>32</b>	<b>107</b>	<b>130</b>	<b>152</b>	<b>179</b>	<b>192</b>	<b>240</b>	<b>311</b>	<b>381</b>	<b>435</b>	<b>481</b>	<b>567</b>	<b>592</b>	<b>601</b>
Antigen Central Lab Today	0	0	3	7	7	8	8	8	8	8	8	8	8	8
Antigen Central Lab Future	0	0	0	0	0	0	9	14	22	23	25	26	29	30
Lab Based PCR Today	75	100	100	105	115	120	120	120	120	120	125	125	130	130
Add'l Lab Based PCR with Pooling	0	0	25	38	48	50	50	50	59	59	61	80	83	83
<b>Total Central Lab</b>	<b>75</b>	<b>100</b>	<b>128</b>	<b>150</b>	<b>170</b>	<b>178</b>	<b>187</b>	<b>192</b>	<b>209</b>	<b>210</b>	<b>219</b>	<b>239</b>	<b>250</b>	<b>251</b>
<b>Grand Total</b>	<b>107</b>	<b>207</b>	<b>258</b>	<b>302</b>	<b>349</b>	<b>371</b>	<b>427</b>	<b>504</b>	<b>589</b>	<b>645</b>	<b>700</b>	<b>806</b>	<b>842</b>	<b>852</b>



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