



# Tracking US Coronavirus Testing Capacity

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



**205M**

December 2020

**258M**

January 2021

**686M**

March 2021

**1,075M**

June 2021

Another week with no major new EUA's - this week we only saw amendments - see below.

Please note that 32% of the future capacity in March and 42% in June are dependent on the FDA issuing new EUAs from large capacity manufacturers including Roche, Innova, Siemens, Cellex and E25Bio. All of these are no-instrument lateral flow rapid antigen tests.

## What Happened Last Week

- The FDA issued:
  - 12 amendments to IVD molecular tests
  - 2 amendments to Laboratory Developed (LDT) molecular testing labs
  - 1 amendment to antigen tests
  - 2 amendments to serology tests

## What to Watch for this Week



02/01/2021

*All signs point to increased investment in at-home tests*

- The US signed a [\\$231.8 million contract](#) to purchase 8.5 million Ellume at-home, over the counter, rapid antigen tests before the end of the year. To fulfill the contract, Ellume will be establishing a US-based manufacturing operation capable of producing 19 million tests each month.
  - *Commentary: While it's great to see investment in at-home tests, the impact of this capacity will not be available until Q3 and Q4 of 2021 and into 2022. As reported in The Washington Post, the updated Ellume U.S. capacity of 100,000 tests a month from February to July is actually lower than [previously announced](#) by Ellume of 1 million tests per day by June.*

- Surgeon General nominee [Vivek Murthy](#) touts at home tests in interview with The New York Times' Ezra Klein, saying the administration is interested in "investing in the production of better tests, of more accurate, more mobile... tests that could be performed at home, where we can both get samples and deliver results ideally in the home setting."
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## New & Noteworthy

### *Support for school reopening at federal level face local resistance*

- New [CDC study](#) shows that school transmission in 17 rural Wisconsin's schools was not a major driver of spread and that school transmission rates were low, fueling calls to reopen schools from CDC officials and leaders at all levels of government.
- [Dr. Anthony Fauci](#) clearly stated his support for reopening schools and backing for CDC recommendations.

### *Large urban school districts attempt to reopen multiple challenges*

- In New York City and in other cities around the country, [distrust in institutions](#) has led black families to keeping their children home and learning remotely at higher rates than white families.
- [Chicago](#) Mayor Lori Lightfoot and Chicago Public Schools CEO Dr. Janice Jackson have insisted that teachers return to the classroom in-person, but the date continues to be pushed back as the schools and Chicago Teachers Union are unable to reach an agreement about safe reopening.
- [Washington, D.C.](#) schools were set to open Monday after an arbiter ruled Saturday night that the Washington Teachers' Union's concerns about safety were not valid reasons to delay reopening. The snow, however, kept everyone learning remotely on Monday.

### *New insights on COVID-19 Variants*

- The UK [reported](#) that a limited number of B.1.1.7 genomes have developed the concerning E484K mutation also observed in the South African and Brazil variants, highlighting the need for widespread genomic testing to monitor the rapidly evolving virus.
  - Cases of the South African variant B.1.351 have been detected in multiple states across the US, including in [Maryland](#) and [South Carolina](#).
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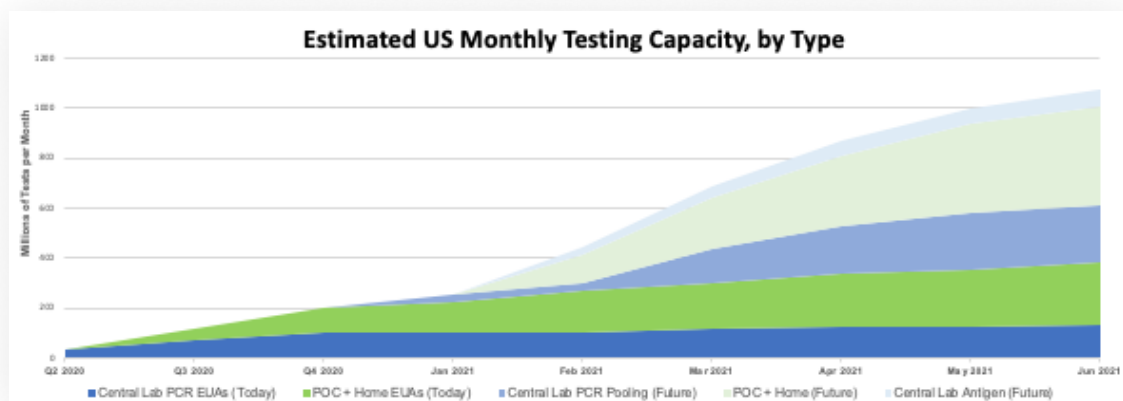
## Food for Thought

- Initial data from multiple asymptomatic school screening programs suggest that prevalence rates in schools are generally lower than 0.5%, even in schools in communities where the community test positivity rates are between 6% and 10%. (Sources include: [CIC Health](#), [JCM Analytics](#), [Ginkgo Bioworks](#), and [United Health Group](#).)
- The new variants are becoming increasingly relevant and concerning. Need a primer? [Try this one!](#)

# Latest Monthly Capacity Estimates

No significant changes from last week. Please note that 32% of the future capacity in March and 42% in June are dependent on the FDA issuing new EUAs from large capacity manufacturers including Roche, Innova, Siemens, Cellex and E25Bio. All of these are no-instrument lateral flow rapid antigen tests.

Estimated Monthly Capacity of All Tests (M)								
Test Type	Sep 2020	Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	Jun 2021
Antigen Point of Care EUA Today	36	95	111	138	155	167	181	196
Home DIY EUA Today	0	2	7	11	14	35	36	40
Molecular Point of Care EUA Today	5	6	9	11	13	13	13	15
<b>Subtotal POC &amp; Home EUA Today</b>	<b>41</b>	<b>104</b>	<b>127</b>	<b>161</b>	<b>181</b>	<b>215</b>	<b>230</b>	<b>250</b>
Antigen Point of Care Future	0	0	0	78	115	160	207	225
Home DIY Future	0	0	3	28	83	114	139	154
Molecular Point of Care Future	0	0	0	4	8	10	11	12
<b>Subtotal POC &amp; Home Future</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>110</b>	<b>206</b>	<b>284</b>	<b>357</b>	<b>391</b>
<b>Total POC &amp; Home</b>	<b>41</b>	<b>104</b>	<b>130</b>	<b>271</b>	<b>387</b>	<b>499</b>	<b>587</b>	<b>641</b>
Total Antigen Central Lab Today	N/A	N/A	3	7	7	10	10	11
Lab Based PCR Today	75	100	100	105	115	125	125	130
Total Antigen Central Lab Future	0	0	0	22	39	52	52	59
Add'l Lab Based PCR with Pooling	0	0	25	38	138	188	225	234
<b>Total Central Lab</b>	<b>75</b>	<b>100</b>	<b>128</b>	<b>172</b>	<b>299</b>	<b>375</b>	<b>412</b>	<b>434</b>
<b>Grand Total</b>	<b>116</b>	<b>204</b>	<b>258</b>	<b>442</b>	<b>686</b>	<b>874</b>	<b>999</b>	<b>1075</b>



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