



# Tracking US Coronavirus Testing Capacity

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



**593M**

March 2021

**977M**

June 2021

**1,176M**

September 2021

**1,259M**

December 2021

Significant update this week as we have extended testing capacity estimates through December 2021 and updated projections based on new company estimates. This is important as we anticipate the need for COVID-19 active virus testing to continue through at least the end of 2021.

*However, it is critical to note that at least 50% of the future capacity estimates are dependent on EUAs not yet issued. This includes large capacity rapid antigen manufacturers such as Roche, Innova, Cellex and E25Bio.*

## What Happened Last Week

The FDA issued two new EUAs and seven EUA amendments:

- New EUAs (2)
  - One point of care antigen test: Princeton BioMeditech Status COVID-19 / Influenza A/B test. Lateral Flow test with NP swab
  - One in lab molecular test: Clinomics USA TrioDx RT-PCR test
- New Amendments to Existing EUAs (7)
  - Six amendments to IVD molecular tests: Quidel Lyra | Mesa Biotech Inc. Accula | DiaCarta QuantiVirus | PlexBio IntelliPlex | Access Bio CareStart MDx | BGI Genomics RT Fluorescent
  - One amendment to Laboratory Developed (LDT) molecular testing labs: Corneum

# What to Watch for this Week



02/08/2021

We're following major research developments on the degree to which the current generation of vaccines will protect against emerging strains, especially B.1.1.7 (UK) and B.1.351 (South Africa). All eyes are on Israel and Brazil, see details in the most recent [ASU blog](#) on variants.

- **Good news:** Israel is the most advanced real-world test of Pfizer/BNT vaccine effectiveness against the B.1.1.7 strain. By February 2, 89% of over 60 year olds had either recovered or been vaccinated. Early returns show [41% fewer cases](#) and [~50% lower mortality](#) in that age group. This is lower than clinical trial results but still encouraging, demonstrating effectiveness away from highly optimized trial conditions.
- **Too early to tell:** Yesterday, South Africa's [Wits University announced](#) reduced effectiveness of the Oxford/AZ vaccine against the locally dominant B.1.351 strain. In response, South Africa halted its vaccination program. The data leading to the announcement has not yet been published as pre-print, so we do not know how much of the reduced effectiveness is due to unique aspects of the Oxford/AZ vaccine or whether it would apply to any of the other vaccines. All available vaccines were designed to counter the same original January 12, 2020 Wuhan-identified strain.
- **Bad news:** Reinfection by mutated strains is possible. Manaus, an isolated 2 million person community in Brazil, is facing a widespread and more lethal second wave despite that an estimated [76% of the population had been previously infected](#) and presumably COVID-immune. [Preliminary data](#) and [case investigations](#) suggest a more transmissible and virulent strain (P.1, a derivative of the B.1.1.28 Brazil strain containing the headline mutations of the South African strain) as the dominant cause.

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## New & Noteworthy

- Innova Medical Group recently opened [new production facilities](#) in Southern California to produce their rapid antigen test kits with a reported ["initial capacity of 5 million test kits per day and continuing to increase to 50 million per day"](#). Innova has delivered more than 400 million COVID-19 test kits for public use in 20 countries, but their antigen test does not yet have an EUA in the US.
- Quidel also announced [plans to open a Southern California manufacturing facility](#) capable of manufacturing 50 million QuickVue rapid antigen tests per month by end of 2021.
- [Lucira Health completed its Initial Public Offering](#), raising \$150 million. In November, the Lucira COVID-19 All-in-One Test Kit became the first rapid, at-home, molecular test to be issued an EUA. It is an isothermal LAMP test available by prescription that runs on a single use handheld battery-powered device.

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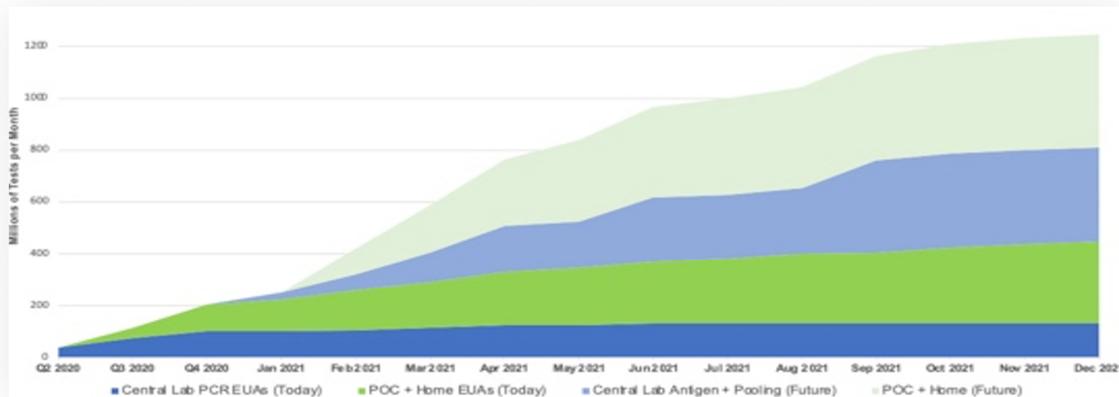
## Food for Thought

- The Biden Administration plans a [big bet on at home tests](#), promising contracts to six more at-home test manufacturers.
- A growing body of evidence can inform strategies to safely reopen schools & other community organizations, and much of it is tracked and compiled by top researchers and clinicians at [Mass General Hospital's School and Community Resource Covid-19 Library](#), which is updated on a regular basis. While it may feel like we never catch up with the virus, resources like this show that know a lot more about how the virus spreads and how to keep our communities safe than we did a year ago.

# Latest Monthly Capacity Estimates

It is critical to note that 50-60% of future capacity estimates continue to be dependent on EUAs not yet issued from potentially large capacity manufacturers such as Roche, Innova, Siemens, Cellex and E25Bio.

Estimated Monthly Capacity of All Tests (M)														
Test Type	Sep 2020	Dec 2020	Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Antigen Point of Care EUA Today	36	95	111	135	152	162	179	194	199	209	209	224	234	239
Home DIY EUA Today	0	2	6	11	11	31	31	32	32	37	40	42	44	48
Molecular Point of Care EUA Today	5	6	9	11	13	13	13	15	22	27	27	30	31	32
<b>Subtotal POC &amp; Home EUA Today</b>	<b>41</b>	<b>104</b>	<b>126</b>	<b>157</b>	<b>176</b>	<b>206</b>	<b>223</b>	<b>241</b>	<b>253</b>	<b>273</b>	<b>275</b>	<b>296</b>	<b>309</b>	<b>319</b>
<i>Antigen Point of Care Future</i>	0	0	0	78	115	150	177	195	205	225	235	255	265	265
<i>Home DIY Future</i>	0	0	0	19	64	97	129	144	154	154	154	155	155	155
<i>Molecular Point of Care Future</i>	0	0	0	2	4	8	10	10	12	14	14	14	14	14
<b>Subtotal POC &amp; Home Future</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>99</b>	<b>183</b>	<b>255</b>	<b>316</b>	<b>349</b>	<b>371</b>	<b>391</b>	<b>403</b>	<b>424</b>	<b>434</b>	<b>434</b>
<b>Total POC &amp; Home</b>	<b>41</b>	<b>104</b>	<b>126</b>	<b>256</b>	<b>359</b>	<b>461</b>	<b>539</b>	<b>590</b>	<b>624</b>	<b>664</b>	<b>678</b>	<b>720</b>	<b>743</b>	<b>753</b>
Total Antigen Central Lab Today	0	0	3	7	7	10	10	11	11	11	12	12	12	13
Lab Based PCR Today	75	100	100	105	115	125	125	130	130	130	130	130	130	130
Total Antigen Central Lab Future	0	0	0	22	39	52	52	59	59	63	63	68	68	70
Add'l Lab Based PCR with Pooling	0	0	25	38	73.6	125	125	187	187	187	293	293	293	293
<b>Total Central Lab</b>	<b>75</b>	<b>100</b>	<b>128</b>	<b>172</b>	<b>235</b>	<b>312</b>	<b>312</b>	<b>387</b>	<b>387</b>	<b>391</b>	<b>498</b>	<b>503</b>	<b>503</b>	<b>506</b>
<b>Grand Total</b>	<b>116</b>	<b>204</b>	<b>254</b>	<b>427</b>	<b>593</b>	<b>773</b>	<b>851</b>	<b>977</b>	<b>1011</b>	<b>1055</b>	<b>1176</b>	<b>1223</b>	<b>1246</b>	<b>1259</b>



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*Based on published reports, company interviews, and proprietary analysis*

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