



Tracking US Coronavirus Testing Capacity

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■ Current National Capacity Projections. (Tests / Month)

349M

March 2021

379M

June 2021

477M

September 2021

672M

December 2021

A comprehensive review of the capacity numbers this week. The total estimated capacity dropped a bit as the pace of new EUA's, especially for large capacity manufacturers, has been slower than we expected. In summary, our view of the landscape:

Late Based Molecular / PCR: Broad snapshot - stable overall but many labs decommissioned PCR lines and cut back staffing in early summer when demand was declining. It can take one to two weeks to validate systems and bring back staff. We believe that many are doing so now and that unlike nine months ago - supply chains are stronger and more diverse, so we don't expect to see long wait times for results that occurred last year. (RT3 - Results to Test Takers). Capacity is down for pooled testing. With test positivity rates above 10%, pooled testing has little utility except in school settings with much lower positive rates.

Point-of-Care Tests - Molecular and Antigen: Overall POC capacity has declined as manufacturers shift focus to their OTC / Home tests. However, we expect an increase in both demand and capacity for COVID+Flu+RSV panels (especially in physician offices) as the 2021/22 flu season approaches. We predict more EUAs will be granted for these panel tests by Thanksgiving.

Antigen Home / OTC / Self Tests: This is currently the fastest-growing market, with supply from existing manufacturers ramping up again and new players receiving EUAs. Most recently, OraSure's IntelliSwab and AccessBio's CareStart were authorized for home use without Rx. We had previously anticipated Innova to have a high-capacity test but now highly unlikely given their FDA warning letter. Manufacturers who might change the future capacity picture: Roche with SDBiosensor test / Siemens / LumiraDx / Cellex. Technology that might change the picture is a Home / OTC combination COVID+Flu test.

What Happened Last Week

The FDA issued one new EUA, 5 amendments, and one warning letter in the last week:

- New EUAs (1)
 - Antigen Tests (1): QIAGEN QIAreach
- New Amendments to Existing EUAs (5)
 - Serology Tests (2): AccessBio | ACON Laboratories
 - Fli/RSV Combo Tests (2): CDC | Thermo Fisher TaqPath
 - Collection Kits (1): Spectrum Solutions
- Recalls/Safety Communications (1):
 - Warning Letters (1): [Blue Willow Biologics](#)

New & Noteworthy

Fauci Hints at Big Testing Ramp-Up.

At an event hosted last week at the Center for Strategic and International Studies, Dr. Anthony Fauci warned that as 2021 moves into fall, the US will need to [drastically ramp up testing](#) to distinguish COVID-19 from seasonal respiratory diseases such as flu, RSV, and other viruses. But he indicated that the US does have plans to do that, and also suggested that the NIH RADx program might have the COVID-testing moonshot in the pipeline: a test that's "easily administered, highly sensitive, and highly accurate." We're crossing our fingers, but at this point we'll also believe it when we see it.

ELC Guidance Follows the Science.

The [ELC Reopening Schools program](#) enters the 2021 - 22 school year with a few important updates, having learned from 18 months of research and return-to-school experiences at the end of the 2020-21 year. Now explicitly funded: diagnostic testing (not just asymptomatic screening); testing events that include family and community members as well as students and staff; PPE; and portable HEPA units and fans for classrooms. Here's hoping they have lots of takers.

"Test to Stay" programs Gaining Traction.

Illinois and Massachusetts are the latest states implementing "test to stay" programs aimed at helping keep kids in classrooms in the fall. Based on Utah's successful [Test to Play/Test to Stay](#) of 2020-21, both states will allow asymptomatic close contacts of a COVID-19 case to avoid quarantine, provided that they undergo serial testing. The details differ - [Illinois](#) requires either rapid or PCR testing on days one, three, five, and seven, and participation in the program is contingent upon mask use, while [Massachusetts'](#) initial overview simply stipulates five days' worth of daily negative results using BinaxNOW. Will be interesting to see if other states follow suit. These programs are similar to the one in the UK study we shared in this Newsletter two weeks ago, which showed that five days of daily testing reduces days lost for students by 40% and staff by 60% compared to quarantine.

Physical distancing at schools adds little if any benefit.

Six feet of distance was always an old and arbitrary measure with little scientific validity, plus now we know about COVID-19's airborne transmission. The [ABC Science Collaborative final report](#), published June 30 and [summarized in the NYT](#) on August 10, confirms this in a study of 1.3 million North Carolina students during the last half of the 2020-21 school year. Schools were required to mask, then adopted one of two protocols: Plan A (full in-person schooling and no physical distancing in classrooms or buses) or Plan B (hybrid schooling and enforcement of six-foot distancing in classrooms and buses). Bottom line - adding physical distancing provided no benefit.

Food for Thought

Back to School Commentary.

There are three components to safety:

A. Vaccination: All who can - should!

B. Mitigation: Masking and handwashing. Yes, a small piece of cloth works. It is literally the best offense and defense packaged together. To those who say kids lose their identity, the most profound portrait photographers have always said, "It is all about the eyes."

C. Confirmation: Test. Why? The only way to be sure that there is no COVID in the classroom is to test regularly. Why not? The money is available (universally available federal / state funds for school testing), the tests are simple to use, results are available in either 24 minutes or 24 hours, and action can be taken before the infection spreads.

Higher ed vaccine mandates:

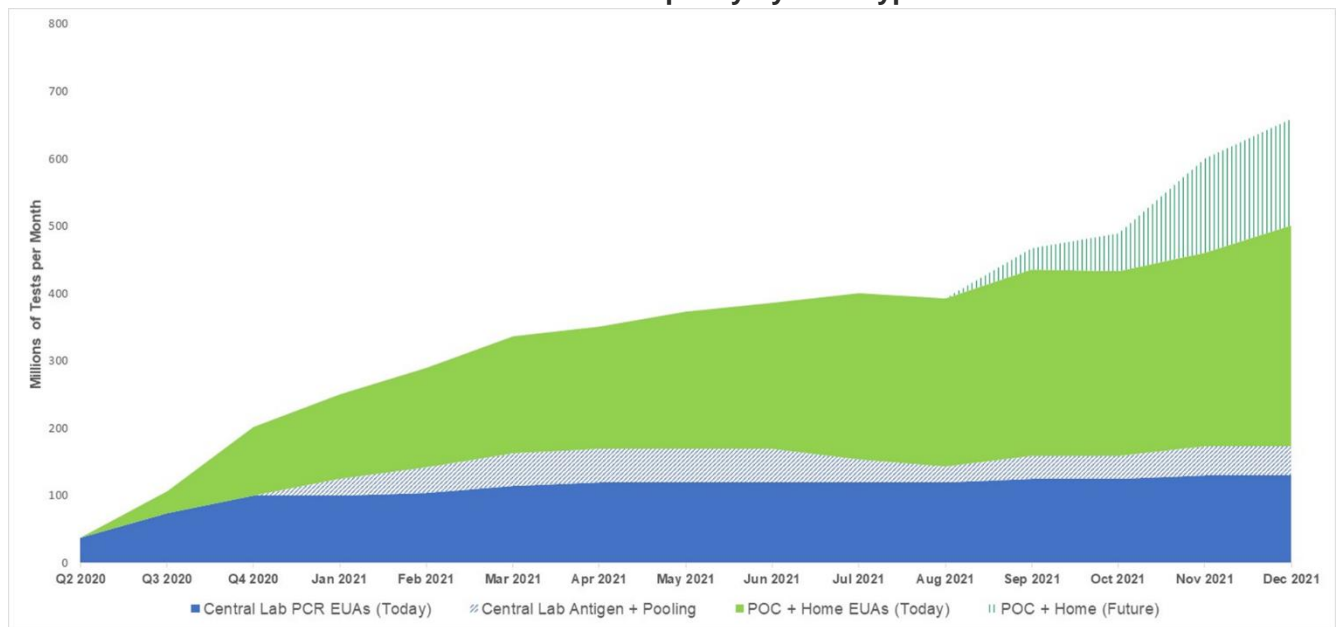
The *Chronicle of Higher Education* now counts [681 colleges and universities](#) that will require vaccines for the fall semester, up from 631 a week ago.

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
Subtotal POC & Home EUA Today	32	103	125	147	174	181	203	216	247	249	277	275	288	328
<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
Subtotal POC & Home Future	0	0	0	0	0	0	0	0	0	0	31	56	139	158
Total POC & Home	32	103	125	147	174	181	203	216	247	249	308	331	427	486
<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
Total Central Lab	75	100	128	150	170	178	178	172	162	154	169	169	186	186
Total Current & Future	107	203	253	297	344	360	381	389	409	403	477	500	613	672

Estimated Future Capacity by Test Type



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