



Tracking US Coronavirus Testing Capacity

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■ Current National Capacity Projections. (Tests / Month)

349M	379M	477M	672M
March 2021	June 2021	September 2021	December 2021

What Happened Last Week

The FDA issued no new EUAs, five amendments, one warning letter and ONE VACCINE in the last week:

- New Amendments to Existing EUAs (10)
 - Molecular Tests (4): Invites Biocore Co | Abbott Alinity | Infinity BiologiX | PlexBio IntelliPlex
 - Serology Tests (1): Beckman Coulter
- Recalls/Safety Communications (1):
 - Warning Letters (1): [Mahita, LLC dba PushMyCart](#)
- FDA [officially approved](#) the first COVID-19 Vaccine: Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as [Comirnaty](#)

New & Noteworthy

Testing comes back – early summer complacency vanquished (for now?)

In June, we had the end of the COVID epidemic in sight - vaccinations were high and rising, while cases, hospitalizations, and deaths were all down. Then came Delta, with its higher viral loads and transmissibility, and testing once again became essential. The New York Times now reports more than a million tests every day, which may seem low compared with two million a day during the January 2021 surge, BUT - current numbers [do not include widely available home or point-of-care antigen tests](#). When will we learn that testing is THE essential tool to manage health care, especially infectious disease?

The laboratory industry shared this widespread overconfidence.

In what seems in hindsight to be a classic example of unforced error, Abbott Labs earlier this summer [shut down plants and destroyed BINAXNow inventory](#) as a reaction to declining test sales. Now we find ourselves in a Delta-driven surge, with back-to-work and back-to-school [demand for tests rising](#) across the country and manufacturers of rapid tests [struggling to keep up](#).

High test positivity – evidence we are not testing enough?

Even with this higher level of testing, it seems like it's not enough. Per WHO guidelines, a nation with adequate testing should have a test positivity rate at or below 5%; Johns Hopkins' shows the current test positivity rate in the US at [over 11%](#). High numbers like these indicate that it's the symptomatic who are getting tested by data-reporting labs.

This is the cloud to the silver lining of rapid antigen / while-you-wait testing: We are losing visibility into the true positivity rate, because the at-home and point-of-care tests that are flying off the shelves allow individuals and institutions to test [without reporting the results to anyone](#).

Testing is free: but there are minefields to avoid.

Federal law stipulates that tests for COVID-19 are to be free to everyone - no out-of-pocket expenses, ever. But pockets of our complex for-profit health-care system do not understand the meaning of “free.” They do, however, seem to know all about billing people whenever they can and [a loophole in the law allows it](#).

Food for Thought

Antibody tests find a niche. The UK goes big on COVID immunity research

The very first COVID tests available in early 2020 were antibody tests. They were initially widely utilized, but the pre-symptomatic infectivity of COVID combined with the late generation of responsive antibodies rendered them irrelevant for epidemic management. Today they are relegated to limited in-hospital infection management. Antibody test quality has also been a continuous issue. To date, the FDA has revoked 167 EUAs for antibody tests, almost double the number of tests that are still authorized (87).

The single biggest unanswered COVID question is how COVID immunity evolves over time. Who needs a vaccine booster? When might they need one? Do vaccines need to evolve to match variants? Last Sunday, the [UK began a large study](#) tracking immunity in a now highly vaccinated and/or previously infected population. Up to 8,000 individuals per day who test positive on RT-PCR will be given antibody tests - one as soon as possible after the RT-PCR result, and one 28 days later. The protocol will allow researchers to track immunity in three categories: 1-vaccinated; 2- unvaccinated infected for the first time and 3-unvaccinated folks who get reinfected.

Fall brings “back to business” conferences and more testing.

While the summer brought back outdoor music festivals, concerts, and craft fairs, the fall will bring back indoor business conferences. (Adults relearning that people are 3D - not just 2D on their computer screen.) After essentially no conference season last year, event organizers are eager to restart in person. [California is the first state](#) to require vaccination or negative test for people attending indoor events of over 1,000 people - a decrease from the 5,000-person trigger CA previously had in place.

Speaking of big events, the annual Sturgis Motorcycle Rally, which brought more than 525,000 bikers to that small town, has created [its own surge](#). When riders zoomed off after the 10-day event, they left behind a hot spot they created in Meade County. Infections there are up more than 350% vs. the two weeks prior to the rally.

K-12 Metrics:

We will soon start tracking school openings and closings nationally. For now, it is interesting to look at mask policies:

- Statewide Mask Mandates: 33% / Statewide Ban on Mask Mandates: 24% / District choice: 43%

[RAND / The Rockefeller Foundation Parent Study](#):

The installment of this powerful study is out – definitely worth understanding what parents are thinking about during this Back to School season.

Higher Ed vaccine mandates:

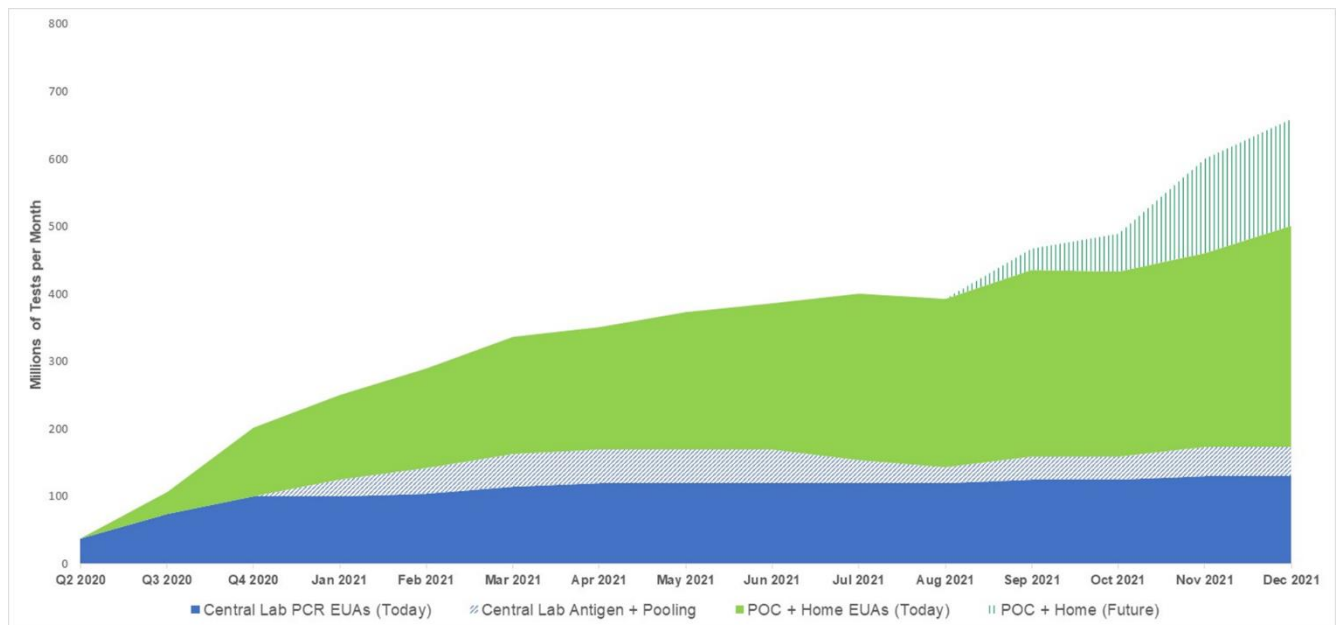
The *Chronicle of Higher Education* now counts [749 colleges and universities](#) that will require vaccines for the fall semester, up from 736 a week ago.

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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