



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

What Happened Last Week

The FDA issued 4 new EUAs, 10 amendments, and 6 warning letters in the last week:

- New EUAs (4)
 - Molecular Tests (3): Cleveland Clinic | STS Labs (Amazon) Multi-Target | STS Labs (Amazon) Multi-Target DTC
 - Collection Kits (1): Kwokman Diagnostics
- New Amendments to Existing EUAs (10)
 - Molecular Tests (4): STS Labs (Amazon) DTC | Centogene CentoFast | Centogene CentoSure | Gravity Diagnostics
 - Antigen Tests (1): Abbott BinaxNOW
 - Serology Tests (4): Siemens ADVIA | Diabetomics | Sugentech | Access Bio CareStart
 - Collection Kits (1): binx health
- Recalls/Safety Communications (6):
 - Warning Letters (6): [Secret of the Islands](#) | [Biopolygen Corp.](#) | [Lepu Medical](#) | [Vivera Pharmaceuticals, Inc.](#) | [USH Diagnostics, Inc. / covidinstanttest.net](#) | [Ome Care](#)

New & Noteworthy

Back to campus means back to screening testing at elite universities.

Several elite universities will require all students who either live on campus or come to campus regularly to participate in ongoing screening testing for COVID-19, regardless of vaccination status. The cadences for vaccinated students range from every 30 days at [Dartmouth](#) to weekly at [Stanford](#), [Brown](#), [Princeton](#), [MIT](#), [Yale](#), and [Columbia](#) (which will use random sampling to decide who actually gets tested). The schools vary as to whether they'll require vaccinated employees to be screened or not; Stanford and Yale won't, the others will.

At other schools, being unvaccinated comes with a cost.

Two small, private colleges have announced that they'll charge unvaccinated students a fee to cover the cost of screening testing. However, the fees (\$500 at [Birmingham-Southern College](#) in Alabama, \$750 at [West Virginia Wesleyan College](#)) may end up being short-lived. Alabama's attorney general immediately suggested that schools in the state can't require proof of vaccination or "fine" students for not being vaccinated, due to that state's [ban on "vaccine passports."](#) No word yet on how things will go in West Virginia.

California: Teachers must be vaccinated or get tested weekly

California has become the first state to require that all workers at both public and private K-12 schools submit [proof of vaccination or participate in PCR or antigen testing](#) at least once a week. Commentary: We're hoping that other states follow their lead. Schools are tasked to keep our kids safe - an obligation to keep students safe on their premises.

Colorado and Pennsylvania: Weekly testing for K-12 students, staff

Every kid and staff member who goes to a [Colorado](#) or [Pennsylvania](#) school can get free access to weekly COVID-19 testing this year. The Colorado voluntary program, which also includes masks, is available to all schools, whether public, private, charter, or tribal, and will use rapid antigen tests. The state is looking into the feasibility of offering financial incentives to students who participate. The Pennsylvania program, also voluntary, utilizes pooled PCR testing. Both programs are funded by each state's share of the federal coronavirus relief bill - specifically the CDC funding for K-12 testing.

Food for Thought

Crispr diagnostics closes in on PCR's 35-year lead in pathogen detection.

PCR revolutionized infectious-disease diagnostics by creating a cheap, reliable method of pathogen detection without the delays and/or costs associated with microbial culture and RNA/DNA sequencing. Now, it looks like Crispr might be ready to take the baton.

While all currently authorized Crispr diagnostics require prior PCR amplification, two recent reports demonstrate that faster, more compact versions are now ready for clinical use. [UC Berkeley's FIND-IT](#) method substitutes signal amplification for preliminary sample PCR; a team at the Broad Institute of MIT and Harvard has described a one-pot method ([miSHERLOCK](#)) with minimal instrumentation that retains prior amplification but avoids much of the handling required to create a visually read result. There is no doubt that the Crispr marriage of nucleotide selectivity (guide RNA) and CAS enzyme activity will become the go-to technique for highly specific and sensitive molecular diagnostics in the future.

Bottom line: mRNA vaccines still protect well against Delta variant family.

Real-world evidence that the mRNA vaccines retain substantial effectiveness against serious disease has been accruing steadily. The numbers vary a bit, but they all tell the same story: these vaccines still work, though not quite as well against Delta as they did against previous variants or the wild-type virus. Here are some examples.

- A large study from [Mayo](#) began in December 2020, and continued through July 2021, by which time Delta was widespread. Prevention of hospitalization: 75% efficacy for Pfizer/BNT, 81% for Moderna). Prevention of death: 100% for both vaccines. Infection prevention declined over time: 76% (Pfizer/BNT) and 86% (Moderna) efficacy from December through April to 42% (Pfizer/BNT) and 76% (Moderna) in July.
- Recent CDC MMWR data:
 - In [NYC](#) from May to July: Vaccines were consistently 95% effective at preventing hospitalization, but declined to 80% effectiveness in preventing infection.
 - Infection prevention [nursing homes](#) was 75% pre-Delta, declined to 53% with Delta.
 - An [IVY](#) hospital network study as Delta became dominant showed sustained 90% prevention of hospitalization.

Commentary: Let's put these percentages in context. Just a year ago, as we awaited the results of clinical trials of these new vaccines, 50% effectiveness would have been considered a miracle of speed and success. [Flu vaccine efficacy](#) for the last five years has been below 40%. We were spoiled by the unexpectedly outstanding results - 95% efficacy for the Pfizer/BNT and 94% for Moderna vaccine with equally impressive real-world results.

Since that time, the variant landscape has changed dramatically. These vaccines were designed to protect against the wild-type virus (original Wuhan strain), and since their roll-out they've had to face multiple variants, including Delta. While it's become clear that [boosters are necessary](#) to maintain the immunity that they have admirably provided, so far, the vaccines are holding the line. [See HHS joint statement on boosters](#) for all eight months after full vaccination - issued today - August 18th.

Higher ed vaccine mandates:

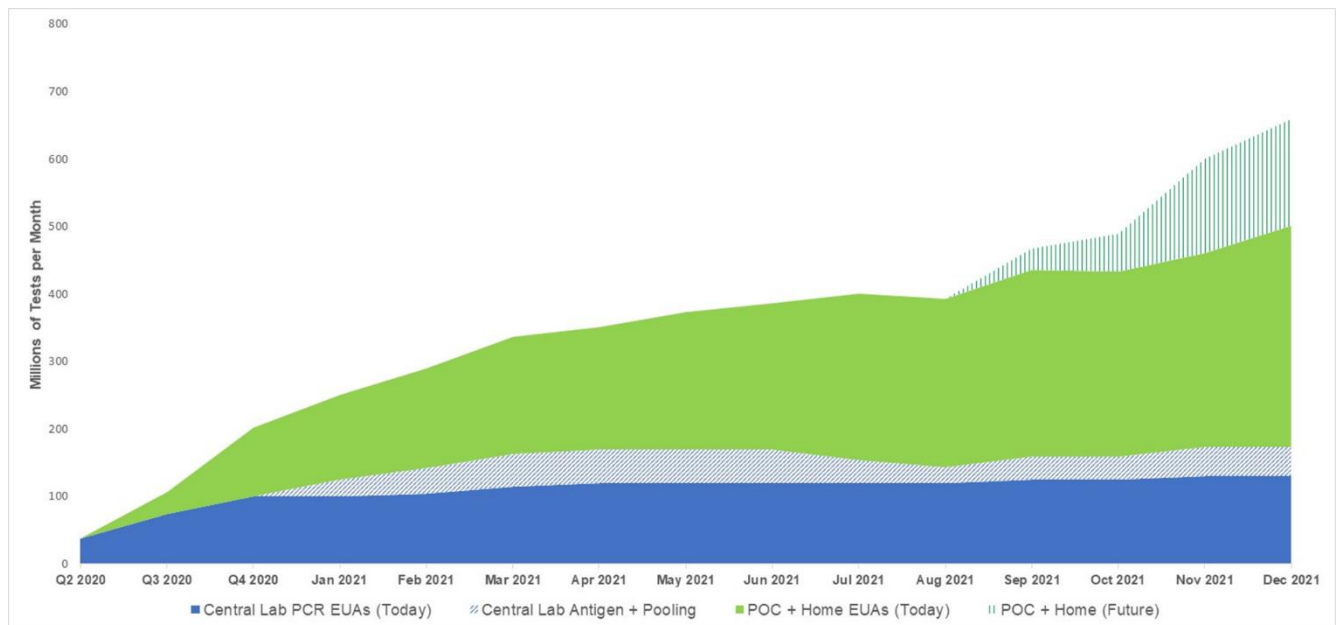
The *Chronicle of Higher Education* now counts [736 colleges and universities](#) that will require vaccines for the fall semester, up from 681 a week ago.

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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