



Tracking US Coronavirus Testing Capacity

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■ Current National Capacity Projections. (Tests / Month)

349M

March 2021

379M

June 2021

590M

September 2021

707M

December 2021

No changes this week to test capacity.

What Happened Last Week

The FDA issued 2 new EUAs, 4 amendments, 2 revocations and 1 warning letter in the last week:

This was an unusual week for safety communications. It is important to clarify what these communications mean:

- *The CDC independently notified labs that it will withdraw its COVID test EUA at the end of the year and encourage labs to consider multi-analyte (i.e. Flu/RSV combination) tests.*
- *Curative and Gravity's revocations were also at the companies' request as they are redirecting customers towards their other proprietary EUA-approved tests.*
- New EUAs (2)
 - Serology Tests (1): Ortho-Clinical Diagnostics Total Ab
 - IVDs for Management of COVID-19 Patients (1): [BD Vacutainer](#) Plus Citrate Plasma Tubes (UK Manufacturing Site)* This is a COVID EUA, but it's a bit of an "odd man out" since it is granted for all uses including COVID patient testing and is in response to "a shortage of this type of tube at present" ([FDA](#)).
- New Amendments to Existing EUAs (4)
 - Molecular Tests (4): Applied DNA Sciences | CDC | DiaSorin Simplexa | Hologic
- Recalls/Safety Communications (3) See above
 - Withdrawal (upcoming): [CDC](#) announced plans to withdraw December 31
 - Revocations (2): [Gravity Diagnostics](#) | [Curative](#)
 - Warning Letters (1): [Jordan's Crossing Herbal Connections](#)

New & Noteworthy

High-level vaccine mandates made big news this week:

It was widely expected that federal agencies would institute them, but not until at least one vaccine was fully approved. Turns out, the feds aren't waiting: on July 26, the Veterans Administration became [the first federal agency to require vaccination](#) for its 115,000 frontline healthcare-related employees.

On the coasts, we're also seeing big decisions at the state and municipal level: the [state of California](#), [New York State](#) and the [New York City](#) are now requiring proof of vaccination for their employees (California is also requiring for public & private health-care workers). Those not vaccinated must get tested at least once a week.

Supporting these decisions, 58 different healthcare associations including the American Nurses Association and the Infectious Disease Society of America have issued a [joint statement](#) urging health-care facilities to require vaccination for their employees.

Commentary:

This recommendation will not be popular in some circles, but given the aggressive march of the Delta variant and the increase in vaccine breakthrough cases, shouldn't we also be testing those who are vaccinated? We know, we know - there has to be a benefit to being vaccinated. But - consistent with the [JAMA Viewpoint](#) we reported on last week - could random testing be a workable compromise? Or testing for all those exposed, even if vaccinated?

Federal funding continues to back testing and mitigation:

The US Department of Health and Human Services (HHS) is channeling \$1.6 billion toward COVID mitigation and testing in "[high-risk congregate settings](#)," including prisons and shelters for those experiencing homelessness or escaping domestic or dating violence.

δ continues to spread and spread and spread:

Sadly, no new news here. How does Delta move so fast? Estimates indicate that people infected with Delta carry [1000 times more virus](#) than those infected with the wild-type virus. They also appear to reach detectable levels of infection faster - in four days instead of six.

Food for Thought

UK Daily Testing Study: Used properly, rapid antigen does the job:

A large (215,000 staff & students), recent (March - June 2021) and *relevant* (δ surging to dominance) [UK high-school study](#) published this week provides compelling support for daily rapid antigen testing programs both in schools and, potentially, workplaces. It compared two approaches to COVID management after a positive case was identified:

#1 - Send all contacts home for a 10-day quarantine (control arm)

#2 - Test all contacts at the beginning of each day and send antigen positives for PCR referral. Confirmed cases quarantine for 10 days (intervention arm).

Intervention-arm students lost 40% fewer school days, and COVID-related staff absence dropped by 61%. COVID incidence at the intervention and control schools was equal, showing that even the 53% sensitive antigen test ([antigen tests have higher sensitivity](#) when [viral load is higher](#)) used in a systematic, frequent testing program can effectively prevent onward transmission.

Commentary: Since we are going to be living with COVID variants and some level of breakthrough infections for the foreseeable future, schools, universities, and workplaces should adopt a suitable rapid testing program ASAP.

Higher ed: Vaccine mandates turning out to be a regional thing:

The Chronicle of Higher Education now counts [607 universities](#) that will require vaccines for the fall semester, up from 586 a week ago. While this might seem like a large number, the vast majority of these schools are in New England, the mid-Atlantic, and California.

K-12 schools moving to broader testing in the fall?

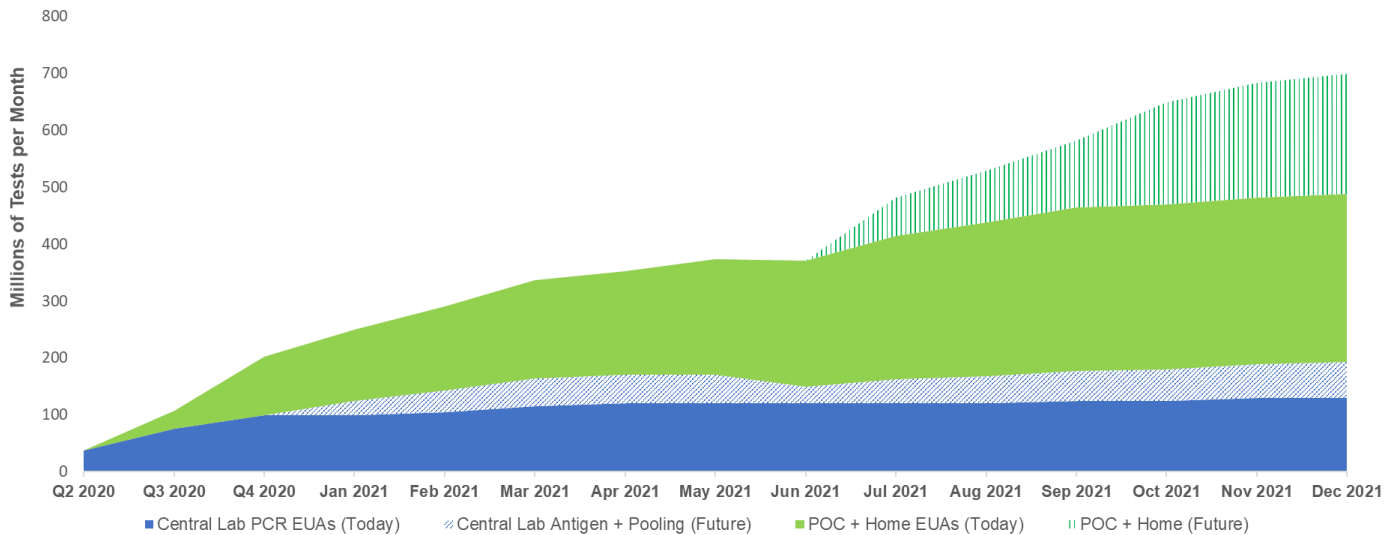
Too early to say if this is a sustainable trend, but we are hearing that more school districts are recommending or [mandating](#) weekly testing. Another model that's getting attention: Utah's [Test to Play/Test to Stay](#), instituted last fall, may be picked up elsewhere this fall. We will be watching this closely.

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	163	178	190	204	206	206	206
Home / Self Tests EUA Today	0	2	6	7	17	12	24	44	56	61	63	64	66	69
Molecular Point of Care EUA Today	4	5	8	10	12	12	13	14	19	19	20	20	20	20
Subtotal POC & Home EUA Today	32	103	125	147	174	181	203	221	253	270	287	290	292	295
<i>Antigen Point of Care Future</i>	0	0	0	0	0	0	0	0	43	61	74	89	102	102
<i>Home / Self Tests Future</i>	0	0	0	0	0	0	0	0	12	18	30	75	85	95
<i>Molecular Point of Care Future</i>	0	0	0	0	0	0	0	0	12	12	14	14	14	14
Subtotal POC & Home Future	0	0	0	0	0	0	0	0	67	91	118	178	201	211
Total POC & Home	32	103	125	147	174	181	203	221	320	361	405	468	493	506
<i>Antigen Central Lab Today</i>	0	0	3	7	7	8	8	8	8	8	8	8	8	8
<i>Antigen Central Lab Future</i>	0	0	0	0	0	0	0	0	12	18	21	24	27	30
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	30	30	30	31	31	33	33
Total Central Lab	75	100	128	150	170	178	178	158	170	176	185	188	198	201

Estimated Future Capacity by Test Type



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