



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

These latest capacity estimates reflect the manufacturers' reactions to a more moderate outlook on demand across the country, as well as adjusted predictions as to which test features are likely to drive demand at scale. We have also "zero'ed out" June; as even if there were new high-volume manufacturers' EUAs in the next week, they are unlikely to drive any significant capacity before the end of the month.

If there is an uptick in demand in the fall, manufacturers, as well as labs, appear able to adjust their production up by 10-20%.

What Happened Last Week

The FDA issued four new EUAs, four amendments, and two safety communications over the last week:

- New EUAs (4)
 - Molecular Tests (2): Roche cobas for Liat System | WREN Laboratories DTC
 - Serology Tests (1): Siemens ADVIA Centaur
 - Collection Kits (1): WREN Labs Saliva DTC
- New Amendments to Existing EUAs (4)
 - Molecular Tests (4): MobileDetect Bio | WREN Laboratories | Kaiser KPMAS | BioFire Defense

FDA Safety Communications (2): None for tests. One [Drug Safety Communication](#) for hand sanitizer and one [warning letter](#) to the supplement company Umbrella for unproven COVID-19 claims.

New & Noteworthy

The Delta Variant – The Bad, the Ugly and the Good (a little bit of testing related good news) :

- The Delta variant continues to bring bad news: The *Times of Israel* reported on an [outbreak](#) involving at least 44 unvaccinated middle schoolers and an unspecified number of adults, some of whom were fully vaccinated. Initial analysis points to the highly transmissible [Delta variant](#). How transmissible? Well, the Alpha variant (aka B.1.1.7, first described in the UK) is about 50% more transmissible than the wild type, and Delta is 60% more transmissible than Alpha.
- Delta is already in the US, where it has caused [outbreaks among the unvaccinated](#). It is doubling every two weeks and will likely [be the most common variant here](#) by [midsummer](#). If that were not bad enough, Delta also is more likely to cause severe illness than any other variant so far, including in [kids](#). The good news is that it appears that all EUA tests - both PCR and antigen - can accurately detect infection with this variant.

- Continuing the focus on variants: Francis Collins' NIH blogs are always insightful, and [this week's subject](#) is particularly relevant. In the spotlight: [a recent paper](#) concluding that vaccination (with Moderna's mRNA vaccine, in this case) is more effective against existing variants than prior infection, and is likely to be more effective against upcoming variants, as well. (Note that the paper refers specifically to neutralizing antibodies, only a part of the overall immunity response.) Why? The receptor binding domain of the virus's spike protein binds the human ACE2 receptor under all possible mutational changes and shows that the antibody portfolio generated by vaccination is less vulnerable to immune escape than that of prior natural infection.
- Commentary: It should be obvious, but the pandemic isn't over. Let's take back control with the three tools we have to fight it:
 - #1 Vaccination
 - #2 Mitigation (through masks, improved ventilation, and handwashing)
 - #3 Confirmation (through testing)
- Thinking optimistically about the next stage of testing - outbreak control and surveillance. Number one approach: the PCR / NGS testing and analysis of wastewater. The infrastructure is in place, the cost is incredibly low, and it works. That testing strategy [proved its worth](#) in places like Guadalupe, Arizona, where it helped to save lives during 2020 pre-Easter celebrations. More on surveillance testing in coming weeks.

Food for Thought

K-12 Schools Preparing for the Fall

- Testing will continue to be available in K-12 schools this fall, funded by the Federal government. There are now three active programs:
 - CDC's direct allocation to states and territories from a \$10 billion allocation through the ELC – Epidemiology and Laboratory Capacity group. Testing partners referred to as NTAP – National Testing Action Program.
 - HHS and DoD's \$650 million Expanded Testing program through four Coordination Hubs.
 - Increasing Community Access to Testing Program (ICATT)
- Many partnerships amongst labs, manufacturers and data service providers enable these programs – see this [G2 Intelligence piece for a summary](#) of some of the larger ones.

Higher Ed Preparing for the Fall

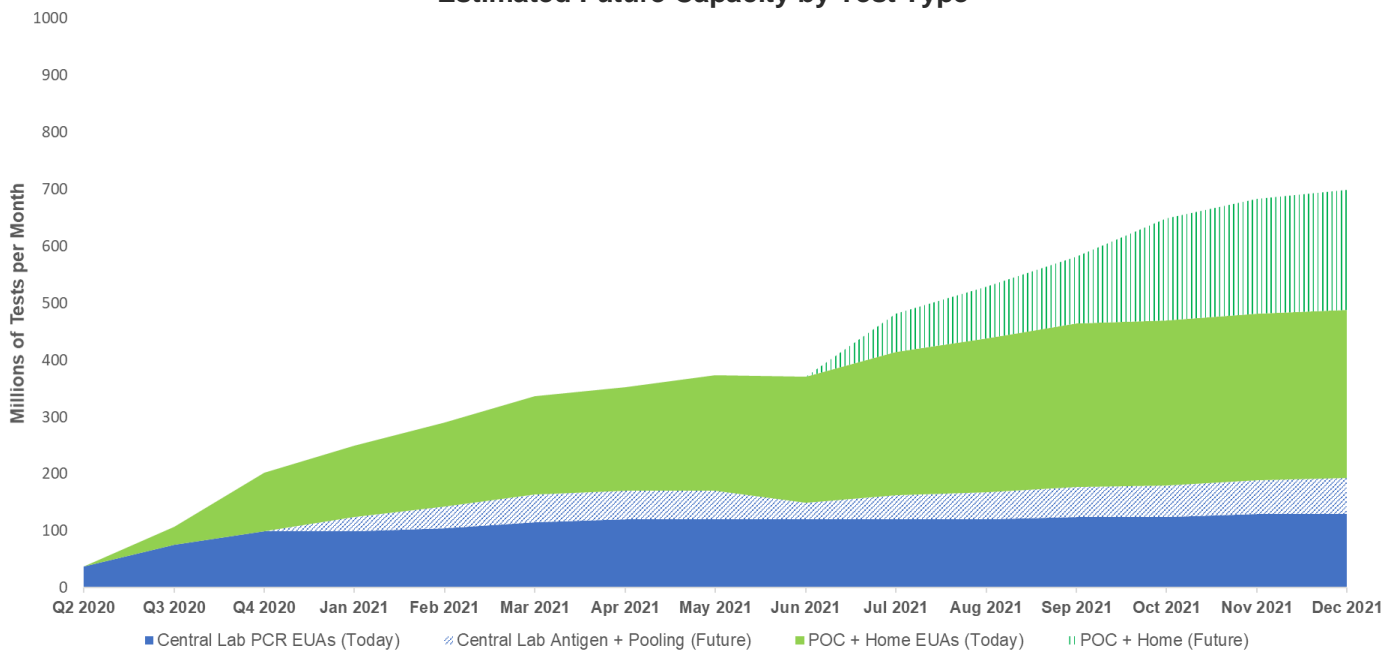
- *The Chronicle of Higher Education* now counts 537 universities that will require vaccines for the fall semester, up from 510 last week.
- The [first lawsuit against these vaccine mandates](#) has been filed against Indiana University by eight of their students. According to *The Chronicle*, in the only court decision to date on vaccine requirements, a federal judge dismissed the complaint against Methodist Hospital in Houston.

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
Antigen Point of Care Future	0	0	0	0	0	0	0	0	43	61	74	89	102	102
Home / Self Tests Future	0	0	0	0	0	0	0	0	12	18	30	75	85	95
Molecular Point of Care Future	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
Antigen Central Lab Today	0	0	3	7	7	8	8	8	8	8	8	8	8	8
Antigen Central Lab Future	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
Add'l Lab Based PCR with Pooling	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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