



Tracking US Coronavirus Testing Capacity

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MARCH 24TH, 2021

■ Current National Capacity Projections (Tests / Month)



344M

March 2021

728M

June 2021

923M

September 2021

1,064M

December 2021

There is no update to capacity numbers this week.

What Happened Last Week

The FDA issued five new EUAs and nine amendments to existing EUAs

■ New EUAs (5)

- Molecular Tests (2): Color Health DTC | Twist Bioscience NGS*
- Serology Tests (2): Beckman Coulter | Siemens Atellica
- Collection Kit (1): Color Health DTC

*there are now
5 NGS assays

■ New Amendments to Existing EUAs (8)

- Molecular Tests (5): Color Health | LetsGetChecked | SalivaDirect | Tempus | LumiraDx
- Antigen Tests (2): Ortho Clinical Diagnostics VITROS | AccessBio CareStart
- Serology Tests (1): Diazyme DZ-Lite
- Collection Kits (1): Color Health

New & Noteworthy

FDA marks some "firsts"

- FDA grants the [first EUA for COVID screening device](#) to Tiger Tech Solutions for a machine learning device that identifies COVID-19 infection through certain biomarkers. The COVID Plus Monitor is similar to a blood pressure cuff; [early data](#) indicates it can identify asymptomatic COVID with 98% accuracy.
- FDA grants [first full marketing authorization](#), not an Emergency Use Authorization, to a COVID test.
 - [BioFire Dx's Respiratory Panel 2.1](#) is a POC molecular panel able to detect 22 viruses and bacteria including SARS-CoV-2.
 - *Commentary: While this is the first test with full marketing authorization, FDA's Janet Woodcock commented, "we do not expect this to be the last". It's hard to guess after just one: What does this mean for the FDA's approach for the future of EUA's?*

Major developments in the push to reopen schools

- Decision in the 6ft vs. 3ft debate
 - Last week's newsletter covered the ongoing debate on whether students need to stay 6 ft apart.
 - Since then, [CDC updated their Operational Strategy for K-12 Schools](#) to recommend that all elementary schools with universal mask usage and middle and high schools in low, moderate, or substantial (not high) transmission areas with universal mask usage seat students 3 ft apart. Middle and high schools in high transmission areas are still recommended to maintain 6 ft.
- For the first time, more than half of K-12 students in the US attend a school offering traditional in-person/every day schools, according to [Burbio's latest data](#).
 - % US K-12 students attending "virtual-only" schools = 18.1% (from 20.8% last week)
 - % US K-12 students attending "traditional" in-person/every day" schools = 51.2% (from 49.1%)
 - % US K-12 students attending "hybrid" schools = 30.7% (from 30.1%)
- A [new preprint](#) reviews the experience of one of the first public schools in the nation to implement a weekly COVID-19 screening process (Wellesley, MA), concluding that: "A weekly COVID-19 screening program can provide critical data to inform mitigation efforts, and provides school-specific, current data to inform decisions about in-person learning models. Screening provided reassurance and identified asymptomatic cases."

Upcoming Events

- Last Call: March 25 at 12pm - 1pm EDT: Global Perspectives on Variants & Vaccines Webinar, from ASU College of Health Solutions with [Rick Bright](#), [Tamsin Berry](#), and [Alan Tenenberg](#). Register [here](#).
- March 30 from 2pm - 3pm EDT: Network for Regional Healthcare Improvement and The Rockefeller Foundation's Innovation Series: Leaders from Massachusetts, including representatives from COVID-19 Response Advisors, the [Shah Family Foundation](#), and two Massachusetts public school districts will discuss the nation's first statewide pooled COVID-19 testing program. Register [here](#).

Food for Thought

- Are 'fourth wave' fears coming true? Some states see increasing case numbers as public officials pare back restrictions and the more transmissible B.1.1.7 variant gains steam. Read more [here](#).
- FDA leaders [Jeffrey Shuren](#) and [Timothy Stenzel](#) penned a [blog post in Health Affairs](#) on five key steps to "rapidly expand access to accurate and reliable tests" in the future, based on their learnings on the arc of diagnostic COVID-19 development.

Commentary: Why is SARS-CoV-2 generating so many damaging variants now?

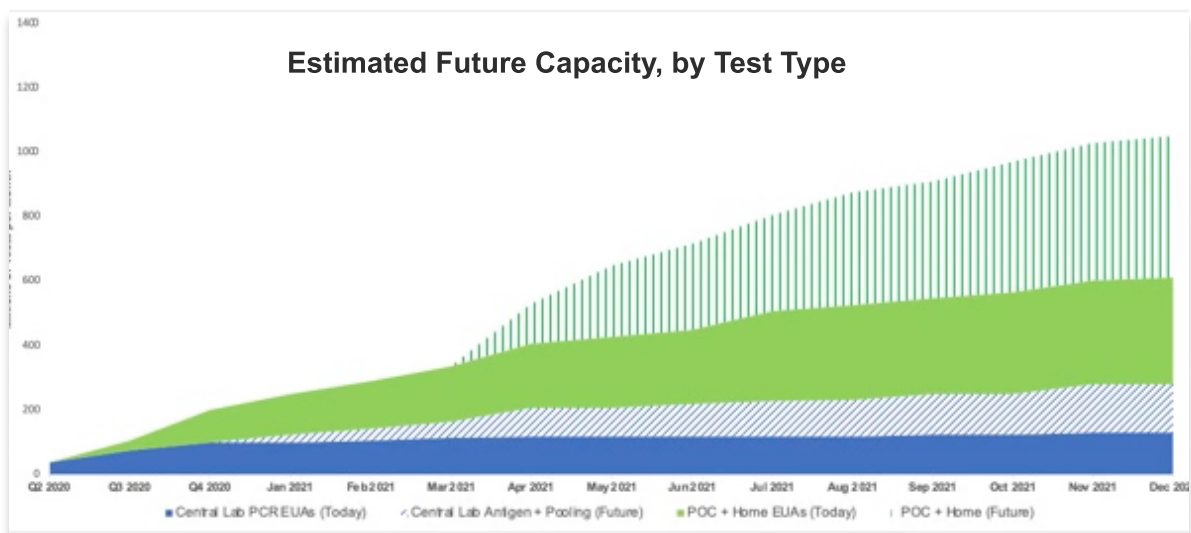
Our current vaccines were all designed to counter the initial virus identified in Wuhan, China, in early January 2020 - the Wuhan-Hu1 strain. Viral mutation occurs randomly, at a steady rate, but when a particular mutation confers an advantage it becomes fixed in the viral genome. Advantage is specific to whatever host context the virus finds itself at that point in time. When that environment includes immune adaptations to resist infection, the strains that prosper are those with a set of mutations that enable escape from counter-attacks. Immune compromised individuals provide an especially favorable viral learning environment to perfect immune escape.

But the treatments deployed to date have been ineffective or limited in use; and vaccines have only been very recently deployed. None of the current variants of concern could have evolved in response to our attempts at treatment and vaccination. So, why are they occurring? One simple answer – SARS-CoV-2 was a bat virus (likely RaTG13/2019) until late 2019, all subsequent mutations causing so much anxiety have been "housekeeping" mutations required of the virus to be successful in the late 2019 human immune environment. If we do not bring the virus under control globally this year, we can be sure that the next wave of mutations will be exquisitely tailored to escape ways our vaccines have changed that environment.

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	176	178	202	210	215	230	234	239
Home / Self Tests EUA Today	0	2	6	7	17	27	27	37	52	57	60	62	64	67
Molecular Point of Care EUA Today	4	5	8	10	12	16	16	17	25	25	25	26	27	27
Subtotal POC & Home EUA Today	32	103	125	147	174	200	220	232	279	292	300	318	325	333
Antigen Point of Care Future	0	0	0	0	0	65	132	157	172	207	217	245	255	255
Home / Self Tests Future	0	0	0	0	0	50	80	100	116	131	131	146	156	171
Molecular Point of Care Future	0	0	0	0	0	8	10	10	12	12	14	14	14	14
Subtotal POC & Home Future	0	0	0	0	0	123	222	267	300	350	362	405	425	440
Total POC & Home	32	103	125	147	174	323	442	499	579	642	662	723	750	773
Antigen Central Lab Today	0	0	3	7	7	10	10	10	10	10	11	11	11	11
Antigen Central Lab Future	0	0	0	0	0	28	30	32	32	37	45	45	45	45
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	59	59	67	77	77	80	80	105	105
Total Central Lab	75	100	128	150	170	217	219	229	239	244	261	261	291	291
Grand Total	107	203	253	297	344	540	660	728	818	886	923	984	1041	1064



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