



Tracking US Coronavirus Testing Capacity

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MARCH 31ST, 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 three new EUAs and five amendments to existing EUAs

- New EUAs (5)
 - Molecular Tests (2): NeuMoDx | STS Lab (Amazon)
 - Antigen Tests (1): BD Veritor (Respiratory Panel)
- New Amendments to Existing EUAs (5)
 - Molecular Tests (3): Hologic | Quidel | Tempus iC
 - Serology Tests (2): Beckman Coulter | InBios

New & Noteworthy

Amazon enters COVID testing market

- [Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2](#), was developed by Amazon subsidiary, STS Lab Holdco. The EUA includes up to five pooled samples for symptomatic and asymptomatic individuals for use with the Amazon Collection kit. It is a modification of a rapid test from [BGI Genomics](#).
- Employee testing at Amazon will be voluntary, but the company will schedule employees to be tested [every two weeks](#).
- This is yet another move for Amazon in the healthcare arena. No surprise that the question is whether Amazon plans to use this test for the “outside world” in conjunction with their [recently announced](#) expansion of their [Amazon Care](#) telehealth initiative.

Disclaimer and Commentary from Mara

I had the privilege of being the lead author of this program but none of it would have been possible without the guidance, support and active debate of so many others. The NTAP partner companies were instrumental in creating and refining the plan, I have to call out Rockefeller Foundation President Raj Shah and Managing Director Andrew Sweet, as well as Rockefeller advisor and Section 32 Managing Partner, Mike Pellini, for their inspiration and push to get this done right. Now to the Program!

- [The K-12 National Testing Action Program \(NTAP\): Connecting Schools with the Nation's Leading Testing Companies to Safely Reopen](#) synthesizes findings from school leaders, parents, advocates, labs, and manufacturers into an integrated and detailed operational program that demonstrates how to implement regular testing in schools nationwide. NTAP makes the case that reopening schools is both an economic and a social imperative, shows a myriad of schools that have safely reopened with testing, and proves that the country has enough testing capacity to provide schools with predictable supply without impacting the testing supply for the rest of the nation.
- The program is enabled by the [Biden administration's allocation of \\$10 billion](#) to 64 states, jurisdictions, and cities for K12 testing this spring. It is a comprehensive program from initiation testing to screening to deconvolution of positive pools if pooling is used. The testing technology and choice of vendor is up to the school / district to choose the combination that best suits their community. To support schools, NTAP includes step-by-step operational guidance, a [checklist](#) to help schools select testing vendors, and a contact list of testing vendors. Read the report.
- [Burbio's latest data](#) shows continued return to in-person school.
 - % US K-12 students attending "virtual-only" schools = 16.3% (from 18.1% last week)
 - % US K-12 students attending "traditional" in-person/every day" schools = 53.1% (from 51.2%)
 - % US K-12 students attending "hybrid" schools = 30.6% (from 30.7%)

Food for Thought

- [New real world CDC study](#) confirms protective benefits of mRNA COVID-19 vaccines - that shows significant (90%) reductions in infection among fully vaccinated individuals. How does that compare to immunity from a prior infection? A recent [commentary](#) and [paper](#) in The Lancet quantifies that prior infection was 80.5% protective on average, and only 47.1% in those over 65. This is compounded with growing evidence that increasingly widespread variants further reduce levels of vaccine protection.

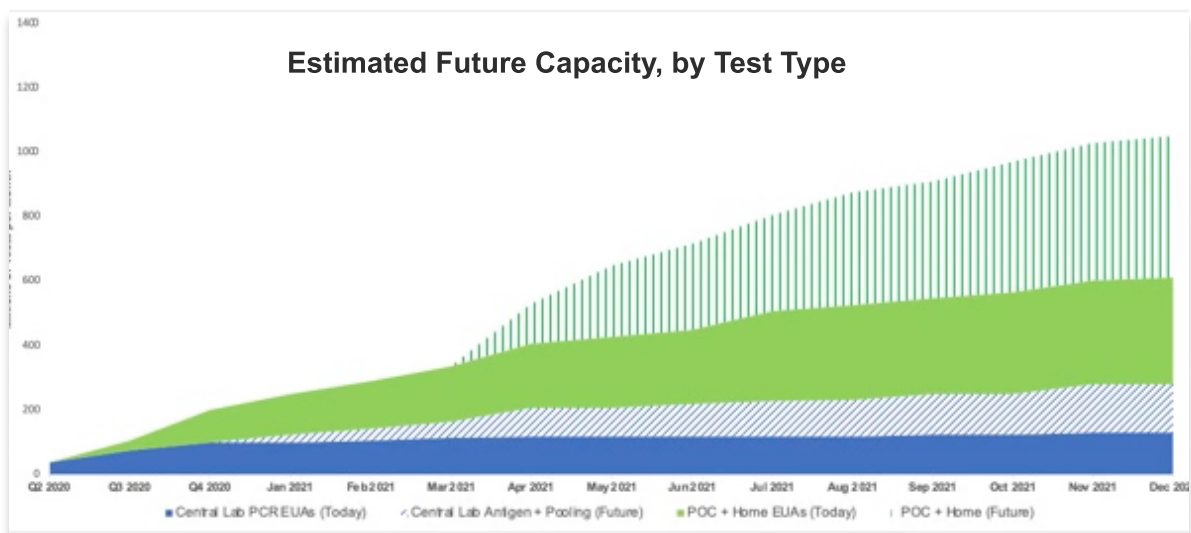
Commentary: A [survey](#) of 77 epidemiologists from academic institutions globally showed that 66% predicted the world has a year or less before variants make current vaccines ineffective. The faster current vaccination levels rise, the less opportunity exists for the virus to mutate further. Current studies that suggest lower effectiveness are all "worst case" since it is likely that even at lower effectiveness there is sufficient in-vivo immunity generated to suppress symptomatic infection. To be on the safe side, mRNA vaccine manufacturers have designed and are currently testing new versions designed to counter the main variants of concern, to be available in late 2021. It would be a tragedy if surveys like this expressing concerns become self-fulfilling prophecies by increasing reluctance to accept current vaccines.

- Likely because of data showing that emerging mutations might inadvertently block monoclonal antibody (Mab) therapies, [FDA guidance](#) for effective therapy appears to be favoring cocktails of multiple antibodies over individual MABs (e.g. [Lilly's Bamlanivimab](#)).
- Fueling conspiracy-like theories of when and how SARS-CoV-2 jumped from its evident bat host to humans, a [very important paper in Science](#) tracks the date of this jump to mid-October to mid-November 2020 – a full 6-8 weeks prior to the [first official acknowledgement](#) of the emerging spread of a "viral pneumonia" on an obscure Wuhan Municipal Health Commission website on December 31st, 2019.

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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