



Tracking US Coronavirus Testing Capacity

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■ Current National Capacity Projections (Tests/ Month)



344M

March 2021

716M

June 2021

950M

September 2021

1,076M

December 2021

Changes this week reflect new approvals and refined capacity projections from company announcements.

What Happened Last Week

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

- New EUAs (6)
 - Molecular Tests (4): Thermo Fisher Amplitude Solution (for TaqPath) | LGC, Biosearch Technologies | SynergyDx | SynergyDx DTC
 - Collection Kits (1): Color Health
 - Antigen Tests (1): Celltrion DiaTrust
- New Amendments to Existing EUAs (9)
 - Molecular Tests (3): Color Health | Seegene Allplex | STS Labs (Amazon)
 - Antigen Tests (4): Abbott BinaxNOW Ag Card | BD Veritor | Access Bio CareStart | LumiraDx
 - Serology Tests (1): Quanterix Simoa
 - Collection Kits (1): Color Health (Amended EUA from above)

New & Noteworthy

- The [Biden administration stepped up its commitment](#) to detect and monitor new variants with additional funding to increase sequencing in every state, create six Centers of Excellence in Genomic Epidemiology and build a National Bioinformatics Infrastructure. *Commentary:* Bioinformatics is critically important to ensure we have the necessary data systems and connectively to actually use the genomic data.
- Speaking of variants, confidence in existing and future tests' ability to effectively detect positive cases regardless of variants is critical. Today, [tests work well](#) but test manufacturers need to stay vigilant to ensure that remains true as new variants arise.

- In a development that could have dramatic impact on the availability and affordability of COVID-19 tests, the FDA announced a new, streamlined approach to add pooled serial screening claims to certain molecular tests. Under the new amendment, a test developer can self-certify that it has validated its test (anterior nasal swabs only) for pooling and get added to a new FDA list of authorized tests for serial testing programs.
- Following on previous warnings and at the [request](#) of manufacturer Eli Lilly and Co, the [FDA revoked the EUA](#) for the monoclonal antibody treatment bamlanivimab when administered alone due to concern about effectiveness against new variants.

Food for Thought

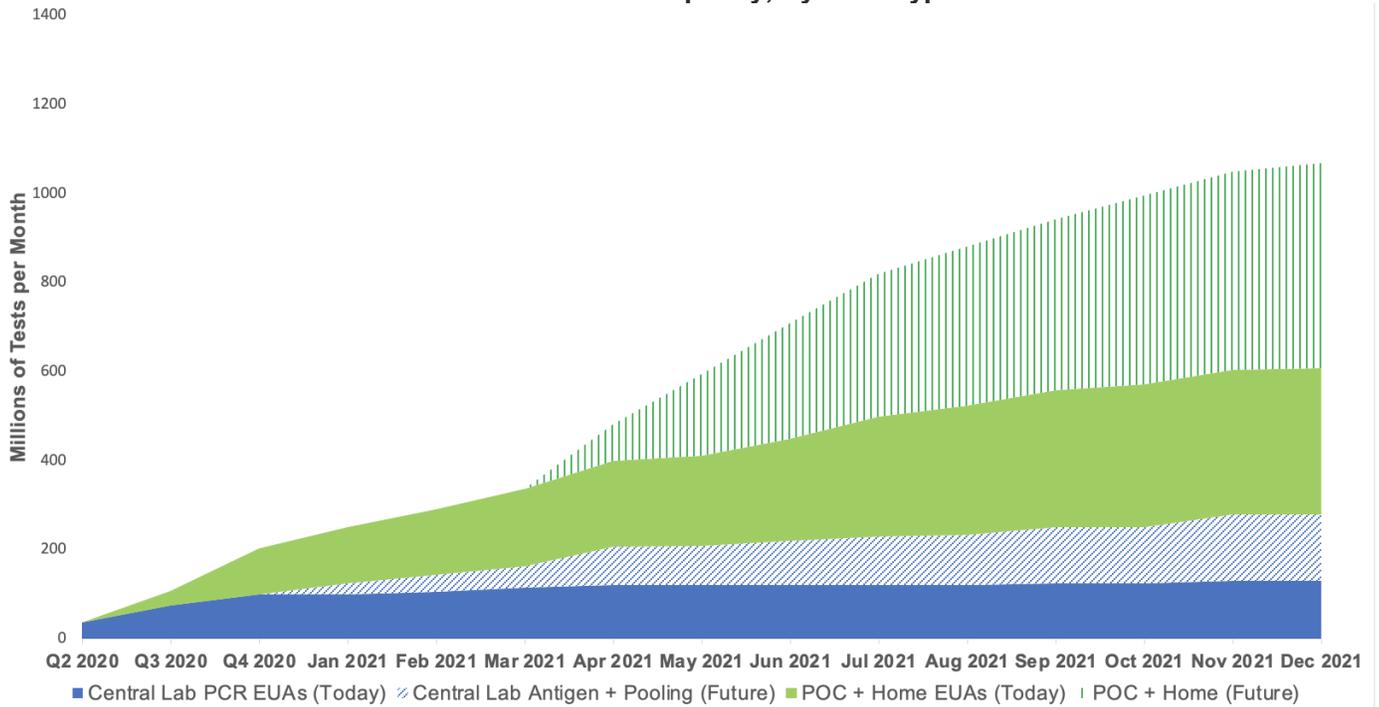
- On the lighter, or maybe higher note... In the past, we have discussed Covid multiplex panels. Our readers likely assumed we meant COVID plus FLU and RSV, but now there is a different multiplex: COVID plus Cannabis! Yes - [RICOVR Healthcare raised \\$1.5M to commercialize a rapid point-of-care testing device for Cannabis & COVID-19](#). Will this kill two birds with one stone or just help us identify a stoned person?
- Over the Counter (OTC) test availability was one of the week's highlights with Abbott's announcement of "tens of millions" of their BINEX rapid antigen self-tests at retail locations. Current pricing:
 - [Abbott BinaxNOW COVID-19 Ag Self Test - \\$23.99 at CVS / Walgreens and \\$19.88 at Walmart](#)
- A study of SARS-CoV-2 transmission in a Georgia school district, published in Clinical Infectious Diseases, concluded that [indoor sports carried the highest risk of transmission](#) compared to other school activities
- K-12 students continue to move to in-person learning - now at 62.4% according to [Burbio's latest data](#):
 - % US K-12 students attending "virtual-only" schools= 9.4% (from 12.2% last week)
 - % US K-12 students attending "traditional" in-person/every day" schools= 62.4% (from 59.4%)
 - % US K-12 students attending "hybrid" schools= 28.2% (from 28.4%)

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	161	168	180	205	215	225	225	225	225
Home / Self Tests EUA Today	0	2	6	7	17	19	21	38	45	55	63	75	77	80
Molecular Point of Care EUA Today	4	5	8	10	12	12	12	13	20	20	20	21	22	22
Subtotal POC & Home EUA Today	32	103	125	147	174	192	202	231	270	290	308	321	324	327
<i>Antigen Point of Care Future</i>	0	0	0	0	0	25	87	130	165	185	200	225	245	255
<i>Home / Self Tests Future</i>	0	0	0	0	0	50	86.4	118	144	160	170	186	186	192
<i>Molecular Point of Care Future</i>	0	0	0	0	0	8	10	10	12	12	14	14	14	14
Subtotal POC & Home Future	0	0	0	0	0	83	183	258	321	357	384	425	445	461
Total POC & Home	32	103	125	147	174	275	385	489	592	647	692	746	769	788
<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	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
<i>Add'l Lab Based PCR with Pooling</i>	0	0	25	38	48	59	59	67	77	77	80	80	105	105
Total Central Lab	75	100	128	150	170	215	217	227	237	242	258	258	288	288
Grand Total	107	203	253	297	344	490	602	716	828	889	950	1004	1057	1076

Estimated Future Capacity, by Test Type



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