



Tracking US Coronavirus Testing Capacity

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■ Current National Capacity Projections (Tests / Month)



344M

March 2021

721M

June 2021

910M

September 2021

1,031M

December 2021

We have updated the capacity numbers this week to reflect recent EUAs and manufacturing updates.

What Happened Last Week

The FDA issued two new EUAs and 18 amendments to existing EUAs

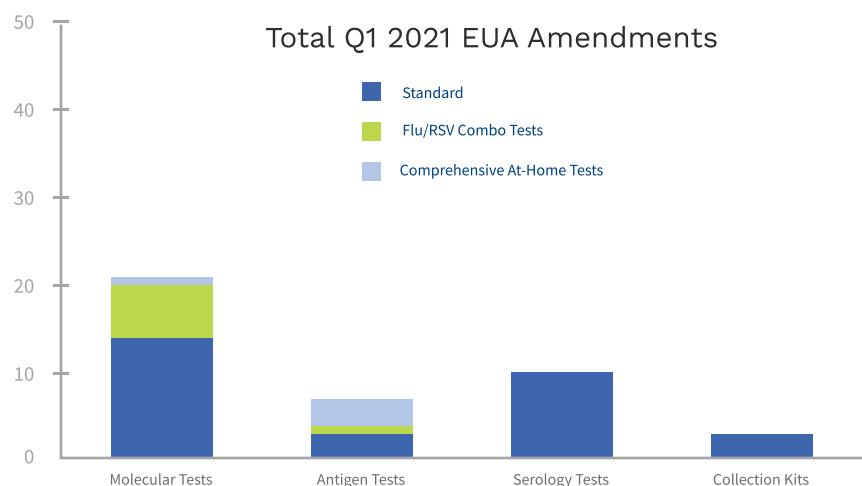
■ New EUAs (2)

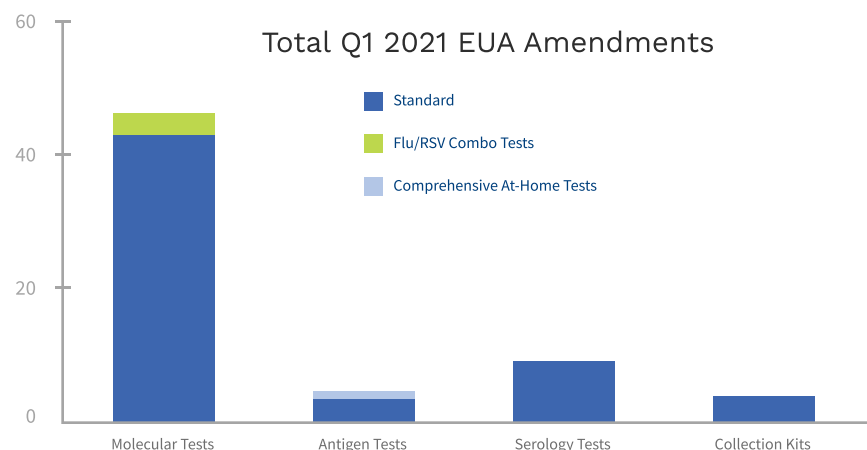
- Antigen Tests (1): DiaSorin Liaison
- Serology (1): Symbiotica Self-Collected Antibody Test

■ New Amendments to Existing EUAs (18)

- Molecular Tests (11): LumiraDx | DxTerity | BGI Genomics | Kaiser Permanente | Gravity Diagnostics | P23 TaqPath | PerkinElmer | DiaSorin Simplexa | covidSHIELD | Trax PhoenixDx | Fast Track Diagnostics
- Serology Tests (4): Siemens Atellica | Ortho Clinical Diagnostics Vitros | Siemens Dimension Vista | Siemens Dimension EXL
- Antigen Tests (2): Quidel Sofia | Abbott BinaxNOW POC
- Flu/RSV Panels (1): Roche cobas

Special Q1 FDA Testing Roundup





Commentary and Takeaways from FDA Activities in Q1 2021

- The FDA issued 41 new EUAs and amended 65 existing EUAs in Q1. There were 14 new molecular tests including 6 molecular Flu / RSV panels and one Comprehensive At-Home test.
- The biggest shift was that the FDA seemed to become more comfortable with both OTC and antigen tests (mostly together) as long as they are used in a serial manner, in accordance with new guidance. It is also good to see 4 EUAs for what we are calling Comprehensive At-Home - or DIY - Tests.
- However, we were still surprised that there were not additional EUAs for rapid antigen or central lab / high throughput antigen tests.
- Serology tests continue to be authorized (10 EUAs for a total of 74 tests) but were of less focus in Q1, perhaps unsurprisingly given challenges with early tests and lack of clear use cases despite post-vaccine immunity questions.

New & Noteworthy

- England is offering [free twice weekly rapid COVID-19 tests](#) to the entire population, a move heralded by the government as a way to quash outbreaks as reopening begins but criticized by some as a waste of money and [likely to yield incorrect test results](#).
- Ortho Clinical Diagnostics expects to triple test production after a [\\$54.7 million deal](#) with the U.S. government. By April 2022, Ortho plans to produce 6.7 million antigen and antibody tests each month.

Impact of the P.1 Variant

- Brazil continues to suffer from unprecedented COVID-19 morbidity and mortality following the emergence of P.1 variant. A [new report](#) analyzing data from the largest province in southern Brazil found the mortality rate in young and middle aged adults had nearly tripled from January 2021 to February 2021, after emergence of the novel strain.
- Outside Brazil, an outbreak of P.1 has struck [British Columbia](#), while in the USA, the state of [Massachusetts](#) leads the US in cases with 58 reported to-date.

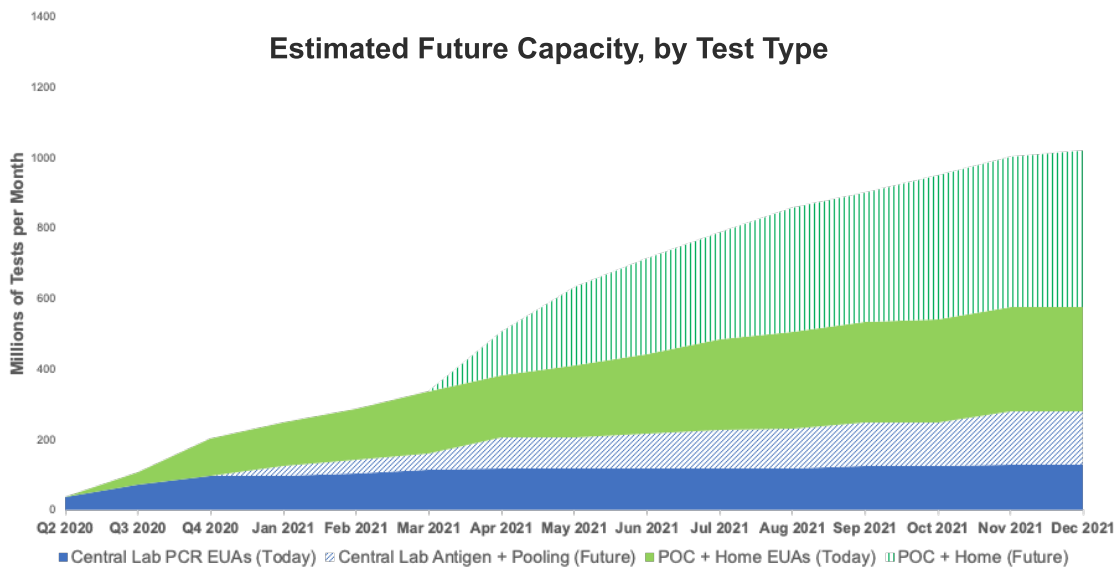
Food for Thought

- K-12 students continue to be moving back to in-person schools - now at 55.3% according to [Burbio's latest data](#):
 - % US K-12 students attending "virtual-only" schools = 14.4% (from 16.3% last week)
 - % US K-12 students attending "traditional" in-person/every day" schools = 55.3% (from 53.1%)
 - % US K-12 students attending "hybrid" schools = 30.3% (from 30.6%)
- The New York Times had a significant focus on testing from several perspectives including the [dangers of a decline in testing](#), [insights from behavioral economics](#) on improving school and workplace screening programs, [why testing still matters](#), and [how screening testing prevents outbreaks](#) in school settings.

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	126	148	155	175	185	190	190	190	190
Home / Self Tests EUA Today	0	2	6	7	17	34	39	52	57	62	70	77	79	82
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	176	204	224	257	272	285	293	296	299
Antigen Point of Care Future	0	0	0	0	0	65	132	160	175	210	220	245	255	255
Home / Self Tests Future	0	0	0	0	0	50	80	100	116	131	133	148	160	175
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	270	303	353	367	407	429	444
Total POC & Home	32	103	125	147	174	299	426	494	560	625	652	700	725	743
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	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	215	217	227	237	242	258	258	288	288
Grand Total	107	203	253	297	344	514	642	721	797	867	910	958	1013	1031



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