Tracking US Coronavirus Testing Capacity

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Current National Capacity Projections. (Tests / Month)

349M	470M	595M	713M
March 2021	June 2021	September 2021	December 2021

Much discussion about test capacity this week with Abbott and Quidel's statements concerning the lack of demand for COVID tests in general and over-the-counter tests in particular. The decline in cases overall, coupled with the CDC's relaxed guidelines for vaccinated individuals and broad testing fatigue has clearly reduced demand. This news is consistent with this newsletter's recent reductions to capacity estimates. Does this mean testing numbers will continue to fall? Not necessarily. The Wall Street Journal reports on the potential of a "testing heavy future" and substantial investment in testing should vaccination rates fail to rise to herd immunity levels.

What Happened Last Week

The FDA issued five EUAs and fifteen amendments over the last two weeks:

- New EUAs (5)
  - Molecular Tests (1): Thermo Fisher TagPath for Pooling
  - Antigen Tests (3): OraSure InteliSwab OTC | OraSure InteliSwab Pro | OraSure InteliSwab Rx
  - Serology Tests (1): Diabetomics CovAb
- New Amendments to Existing EUAs (15)
  - Molecular Tests (12): Quidel Lyra | Infinity TagPath | Amazon (STS Labs Holdco) | Amazon DTC | ProLab Diagnostics | BioTNS | 3B Blackbio | SynergyDx | Synergy Dx DTC | Gravity Diagnostics | SalivaDirect | Assurance
  - Collection Kits (2): GetMyDNA DTC | Everlywell
  - Serology Tests (1): Siemens Atellica

New & Noteworthy

- WHO announces new naming convention for Variants of Concern (VOCs): The new names – Alpha, Beta, Gamma, and Delta, from the Greek alphabet – are designed to be easier to remember than the scientific names. The WHO is also aiming to avoid stigmatizing the location where variants are first detected (α: B.1.1.7/UK; β: B.1.351/South Africa; γ: P1/Brazil; δ: B.1.617.2/ India).
- In good news: Evidence continues to mount that vaccines (especially mRNA-based ones) are effective against all four WHO VOCs, albeit with somewhat lower levels of neutralizing antibodies (Nab). The Lancet reported substantial Nab titers against even the newest novel variant, δ/B.1.617.2, but only after a second dose of mRNA vaccine.
  - Commentary: Even a minimally detectable level of NAb should be adequate for protection against severe disease. In theory, a single memory B cell is protective.

- How do the current tests work against these variants? Antigen tests: A University of Geneva preprint evaluated nine commercially available rapid antigen tests and found that they were each 10x more sensitive to the first three VOCs than to the original strain (δ/B.1.617.2 was not evaluated). PCR tests: The FDA warned that the performance of four PCR tests could be negatively impacted by viral mutations, but since all four are multi-gene tests, they should still return accurate results.
    - Commentary: While sequencing is the gold standard, we need to identify faster and cheaper tests to aggressively monitor variant spread. PCR tests can and should be adapted with targeted primer and probe design to identify specific variants. A few are available for research only or as Laboratory Developed Tests, but none have EUAs. At a time when mRNA vaccines were authorized at what seemed to be lightning speed, the exact opposite has been true for diagnostics. Accuracy needs to reign - but how can we speed up diagnostic test authorizations?

Food for Thought

School Testing

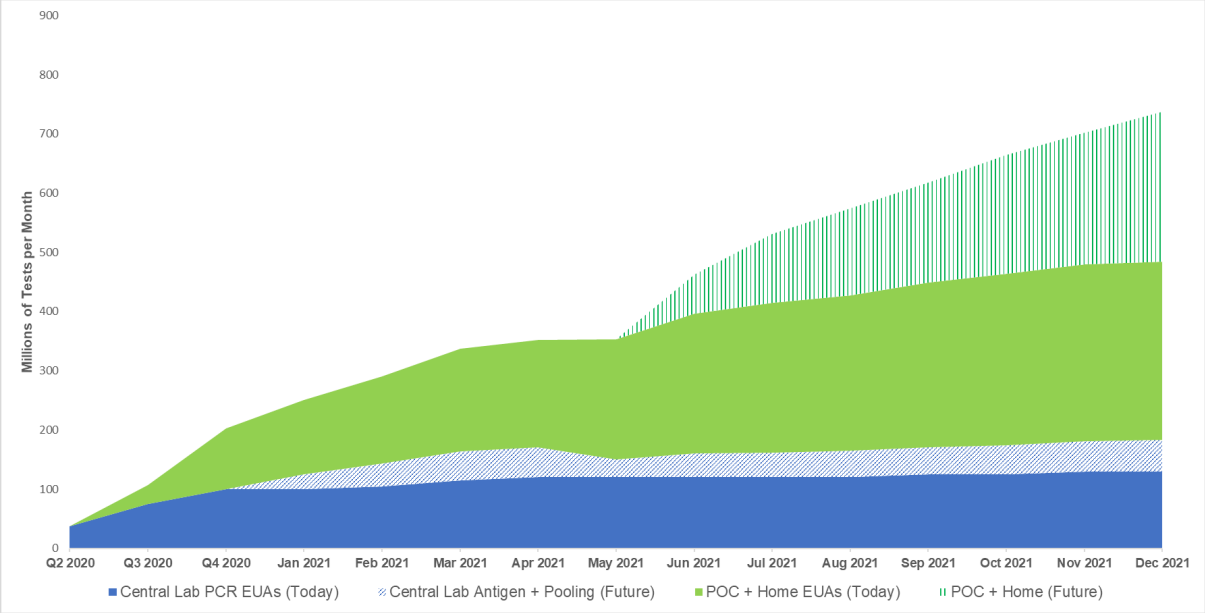
- The focus of school testing has been K-12 and higher education. But this leaves out our youngest learners - those in early education and child-care centers. To correct that, Massachusetts announced a new weekly COVID-19 pooled testing program at no cost to these programs. Created and administered by Boston nonprofit Neighborhood Villages in partnership with Veritas, it's one of the few programs of its kind nationwide.
- K-12: Burbio reports no changes in K-12 school status this past week. In-person schools remain at 69%, hybrid at 28%, and virtual-only at 2%. Since we're at the end of the current semester, we will stop reporting on K-12 testing until August, when we hope to have visibility into schools' plans for the fall.
- Higher Ed: The Chronicle now counts 483 universities, up from 404 last week, that will require vaccines for the fall semester.

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	180	189	191	201	201	207	207
Home / Self Tests EUA Today	0	2	6	7	17	12	24	43	50	58	63	75	77	80
Molecular Point of Care EUA Today	4	5	8	10	12	12	13	13	14	14	14	14	14	14
Subtotal POC & Home EUA Today	**32**	**103**	**125**	**147**	**174**	**181**	**203**	**236**	**253**	**263**	**278**	**290**	**298**	**301**
Antigen Point of Care Future	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*33*	*75*	*100*	*110*	*135*	*135*	*135*
Home / Self Tests Future	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*23*	*29*	*35*	*45*	*51*	*73*	*104*
Molecular Point of Care Future	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*10*	*12*	*12*	*14*	*14*	*14*	*14*
Subtotal POC & Home Future	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**66**	**116**	**147**	**169**	**200**	**222**	**253**
Total POC & Home	**32**	**103**	**125**	**147**	**174**	**181**	**203**	**302**	**369**	**410**	**447**	**490**	**520**	**554**
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*	*10*	*12*	*15*	*15*	*18*	*19*	*21*
Lab Based PCR Today	75	100	100	105	115	120	120	120	120	120	125	125	130	130
Addt'l Lab Based PCR with Pooling	*0*	*0*	*25*	*38*	*48*	*50*	*30*	*30*	*30*	*30*	*31*	*31*	*33*	*33*
Total Central Lab	**75**	**100**	**128**	**150**	**170**	**178**	**158**	**168**	**170**	**173**	**179**	**182**	**190**	**192**
Grand Total	**107**	**203**	**253**	**297**	**344**	**360**	**361**	**470**	**539**	**583**	**626**	**672**	**710**	**746**

Estimated Future Capacity by Test Type



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Based on published reports, company interviews, and proprietary analysis

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