Tracking US Coronavirus Testing Capacity

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Current National Capacity Projections (Tests / Month)

March 2021	June 2021	September 2021	December 2021
593M	977M	1,176M	1,259M

No significant updates this week. Testing capacity estimates are now projected through December 2021 as we expect the need for COVID-19 active virus testing through at least the end of 2021. However, it is critical to note that at least 50% of the future capacity estimates are dependent on EUAs not yet issued. This includes large capacity rapid antigen manufacturers such as Roche, Innova, Cellex and E25Bio.

What Happened Last Week

The FDA issued five new EUAs and twelve amendments to existing EUAs:

- New EUAs (5)
  - Molecular Tests (4): Bio-Rad Laboratories Reliance SARS-CoV-2/FluA/FluB | Becton, Dickinson (BD) SARS-CoV-2/Flu for BD MAX System | Thermo Fisher Scientific TaqPath COVID-19, FluA, FluB | Grifols Procleix
  - Serology Test (1): Ortho-Clinical Diagnostics IDS IgG
- New Amendments to Existing EUAs (12
  - Molecular Tests (7): PerkinElmer | SalivaDirect (Yale) | QDx Pathology | GENETWORx | Seasun U-TOP | DxTerity | LumiraDx RNA STAR
  - Antigen tests (3): Ortho Clinical Diagnostics VITROS | Access Bio CareStart | Ellume
  - Serology tests (2) : Nirmidas MidaSpot | Ortho-Clinical Diagnostics VITROS IgG

What to Watch for this Week

02/15/2021

- Continued field studies show that vaccines offer a much better chance of avoiding future infection by novel variants than prior COVID recovery, but only after both required doses. A published preprint provides an excellent summary of what is known about invoked immunity and evaluates the Pfizer/BNT vaccine in close to real-world conditions versus prior in-vitro studies. The data, albeit in relatively few samples, shows both T-cell and antibody responses against convalescent patient and vaccinated individual serum.

- With the focus on new mutations / strains / variants, we wanted to be sure that we all have our terminology straight: What is the difference between a variant, a mutation, and a strain? A new JAMA editorial helps us define the different terms.
    - "*When specific **mutations**, or sets of mutations, are selected through numerous rounds of viral replication, a new **variant** can emerge. If the sequence variation produces a virus with distinctly different phenotypic characteristics, the variant is co-termed a **strain**. When through genetic sequencing and phylogenetic (Family tree) analysis a new variant is detected as a distinct branch on a phylogenetic tree, a new **lineage** is born."*

New & Noteworthy

- **A new image of the pandemic's causal virus shows unparalleled detail.** Nature's News in Brief shows the first 3D image of the SARS-CoV2 virus using Cryo-Electron Tomography. The abundance of the spike protein (in pink) clearly shows why the spike protein is so prominent in the infection cascade and the focus of vaccine design.

- Serology tests have not been used as aggressively as once anticipated but still play an important role in COVID patient management. FDA's Jeff Shuren and Timothy Stenzel shared a thoughtful piece on lessons learned from emergency approvals of serology tests.

Food for Thought

All eyes are on new school reopening guidance from CDC released Friday

- The CDC's guidance was a welcome addition to the conversation, providing a clear and coherent strategy for how to safely reopen schools under different conditions. The guidance suggests that elementary schools should be open in hybrid models no matter the community prevalence rates but that middle and high schools in the CDC defined red zone (more than 100 cases new cases per 100,000 population in the last 7 days or a test positivity rate of more than 10%) should be closed unless strict mitigation measures are taken and case counts are kept low or they can implement a regular, weekly COVID-19 screening program. In addtion to the guidance itself, we recommend two op-eds in response by Joseph Allen and Helen Jenkins and Emily Oster.

  Commentary: four key points emerged as we reviewed the guidance and expert opinions.

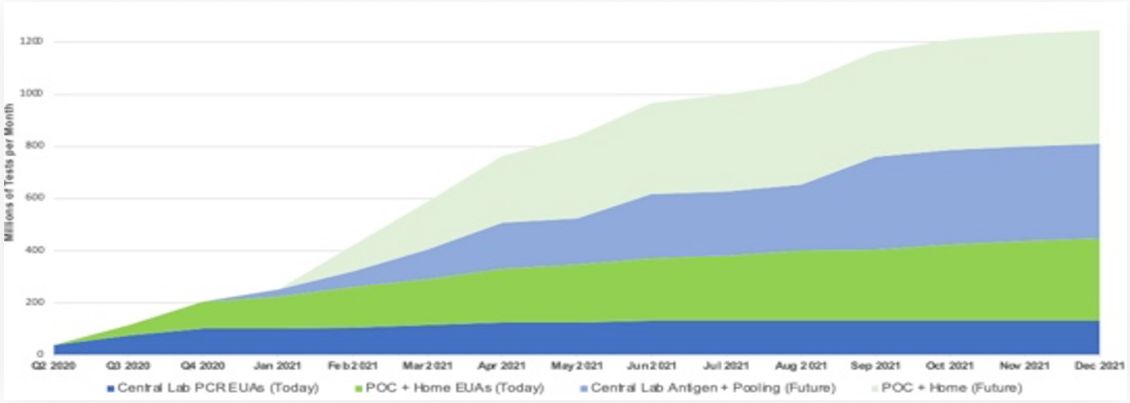
    - First, the thresholds themselves. Based on two indicators used, 90% of US counties are in the high transmission Red Zone. Critics highlight that community prevalence and test positivity rates are not always direct indicators of in-school risk.
    - Second, the CDC holds firm on 6 ft of distance in all but very low prevalence communities (fewer than 49 cases per 100,000 people over the last 7 days). The challenge is that this means almost every school in America will lack the physical space to serve all kids until the pandemic is effectively over.
    - Third, ventilation is not a central theme in the document though experts believe there are highly effective means to reduce in-school risk through improved ventilation.
    - Fourth, and most relevant to the topic of our newsletter, weekly screening testing is offered as a solution to help schools reopen. The guidance discusses both rapid antigen testing and pooled PCR testing as effective options, although cautions against pooled testing in the red zone. Our experience implementing testing programs on the ground has shown pooled testing to be feasible and cost effective in communities with prevalence rates well into the red zone.

Latest Monthly Capacity Estimates

It is critical to note that at least 50% of future capacity estimates continue to be dependent on EUAs not yet issued from potentially large capacity manufacturers such as Roche, Innova, Cellex and E25Bio.

Estimated Monthly Capacity of All Tests (M)

Test Type	Sep 2020	Dec 2020	Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Antigen Point of Care EUA Today	36	95	111	135	152	162	179	194	199	209	209	224	234	239
Home DIY EUA Today	0	2	6	11	11	31	31	32	32	37	40	42	44	48
Molecular Point of Care EUA Today	5	6	9	11	13	13	13	15	22	27	27	30	31	32
Subtotal POC & Home EUA Today	**41**	**104**	**126**	**157**	**176**	**206**	**223**	**241**	**253**	**273**	**275**	**296**	**309**	**319**
Antigen Point of Care Future	*0*	*0*	*0*	*78*	*115*	*150*	*177*	*195*	*205*	*225*	*235*	*255*	*265*	*265*
Home DIY Future	*0*	*0*	*0*	*19*	*64*	*97*	*129*	*144*	*154*	*154*	*154*	*155*	*155*	*155*
Molecular Point of Care Future	*0*	*0*	*0*	*2*	*4*	*8*	*10*	*10*	*12*	*12*	*14*	*14*	*14*	*14*
Subtotal POC & Home Future	**0**	**0**	**0**	**99**	**183**	**255**	**316**	**349**	**371**	**391**	**403**	**424**	**434**	**434**
Total POC & Home	**41**	**104**	**126**	**256**	**359**	**461**	**539**	**590**	**624**	**664**	**678**	**720**	**743**	**753**
Total Antigen Central Lab Today	*0*	*0*	*3*	*7*	*7*	*10*	*10*	*11*	*11*	*11*	*12*	*12*	*12*	*13*
Lab Based PCR Today	75	100	100	105	115	125	125	130	130	130	130	130	130	130
Total Antigen Central Lab Future	*0*	*0*	*0*	*22*	*39*	*52*	*52*	*59*	*59*	*63*	*63*	*68*	*68*	*70*
Addt'l Lab Based PCR with Pooling	*0*	*0*	*25*	*38*	*73.6*	*125*	*125*	*187*	*187*	*187*	*293*	*293*	*293*	*293*
Total Central Lab	**75**	**100**	**128**	**172**	**235**	**312**	**312**	**387**	**387**	**391**	**498**	**503**	**503**	**506**
Grand Total	**116**	**204**	**254**	**427**	**593**	**773**	**851**	**977**	**1011**	**1055**	**1176**	**1223**	**1246**	**1259**



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