Tracking US Coronavirus Testing Capacity

VOLUME 1, ISSUE 03 | JANUARY 12TH, 2021

Current National Capacity Projections (Tests / Month)

205M	258M	686M	1,075M
December 2020	January 2021	March 2021	June 2021

Please note that 2%, 32, and 42% of the future capacity in January, March and June are dependent on the FDA issuing new EUAs from large capacity manufacturers including Roche, Innova, Siemens, Cellex, and E25Bio. All of these are no-instrument lateral flow rapid antigen tests.

What Happened Last Week

- FDA Issued three new Emergency Use Authorizations (EUAs), including two new serology tests and one new central lab antigen test from Quanterix.
- The FDA has recently advised that mutations in the coronavirus's genetic code could trigger false negative results in PCR tests.
- CDC is collaborating with Illumina and Helix to use Next Generation Sequencing (NGS) to detect emerging variants of SARS-CoV-2.

What to Watch for this Week 01/11/2021

- Massachusetts announced plans to implement pooled PCR surveillance testing in K-12 schools, the first program of its kind in the US. This builds on individual town pilots and a statewide deployment Abbott BinaxNOW tests. This effort could drive continued expansion of pooled PCR testing products and the operational and software services necessary to implement school testing programs. This follows California Governor Newsom's proposal for a $2 billion incentive package for CA elementary schools to reopen.

- Current major providers of pooled testing include:
  - Broad Institute - Pooled AN Swabs
  - Concentric by Ginkgo - Pooled AN Swab
  - Mirimus Clinical Labs - Pooled saliva with automatic reflex
  - Poplar Health - Pooled AN Swabs

New & Noteworthy

Increased focus on monitoring new SARS-CoV-2 variants

- Genomic analysis of community wastewater samples was able to detect mutations characteristic of SARS-CoV-2 variants (B.1.1.7 and 501.V2), demonstrating that this technique may serve as a tool to detect and monitor the circulation of diverse viral lineages.

- The new variant is a serious threat. Mara Aspinall and Dr. Jonathan Quick describe five key questions that need to be considered to determine how the new variant will impact public health response.

More field studies emerge measuring test quality

- An investigation from Yale demonstrated that saliva viral load was superior to nasopharyngeal viral load as a predictor of COVID-19 severity and mortality.

- A newly published study found that several high-throughput commercial antibody tests are significantly less accurate than reference lab tests and should not be used to assess if a person has antibodies that protect them from COVID-19.

Food for Thought

- The Vermont Department of Health confirmed CDC's recommendation for shortened quarantine for anyone exposed to SARS-CoV-2 who tests negative on a RT-PCR test 7 days after exposure after an assessment found that no asymptomatic individuals who tested RT-PCR negative at day 7 post-exposure later tested positive.

- In 2020, the FDA authorized 19% of commercially available tests worldwide, authorizing significantly fewer antigen and antibody tests than other nations. The Testing Commons Year in Review provides details on last year's authorizations.

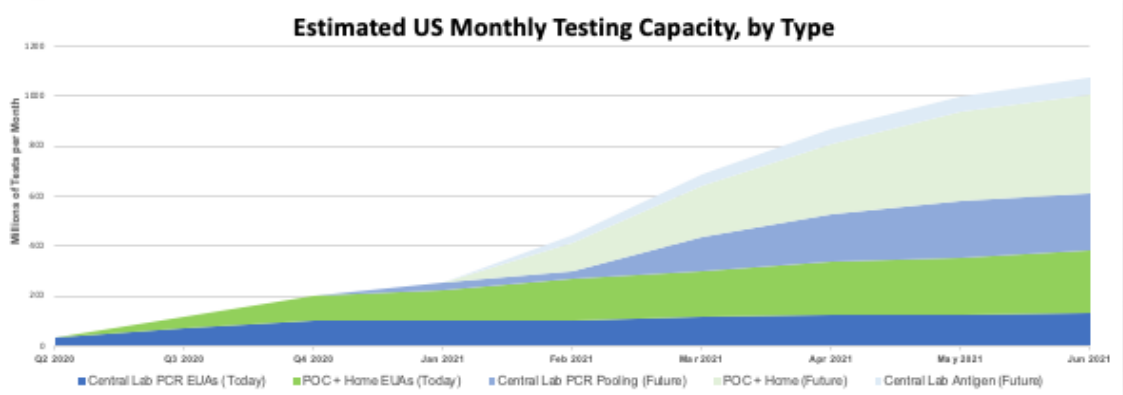
- In response to the CMS reimbursement change that incentivizes 48-hour turnaround, one industry source reports that 76% of PCR tests and 92% of labs will meet the 48 hour turnaround.

Latest Monthly Capacity Estimates

Please note that 2%, 32, and 42% of the future capacity in January, March, and June are dependent on the FDA issuing new EUAs from large capacity manufacturers including Roche, Innova, Siemens, Cellex and E25Bio. All of these are no-instrument lateral flow rapid antigen tests.

Estimated Monthly Capacity of All Tests (M)

Test Type	Sep 2020	Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	Jun 2021
Antigen Point of Care EUA Today	36	95	111	138	155	167	181	196
Home DIY EUA Today	0	2	7	11	14	35	36	40
PCR Point of Care EUA Today	5	6	9	11	13	13	13	15
Subtotal POC & Home EUA Today	**41**	**104**	**127**	**161**	**181**	**215**	**230**	**250**
Antigen Point of Care Future	*0*	*0*	*0*	*78*	*115*	*160*	*207*	*225*
Home DIY Future	*0*	*0*	*3*	*28*	*83*	*114*	*139*	*154*
PCR Point of Care Future	*0*	*0*	*0*	*4*	*8*	*10*	*11*	*12*
Subtotal POC & Home Future	**0**	**0**	**3**	**110**	**206**	**284**	**357**	**391**
Total POC & Home	**41**	**104**	**130**	**271**	**387**	**499**	**587**	**641**
Total Antigen Central Lab Today	*N/A*	*N/A*	*1*	*2*	*2*	*3*	*3*	*4*
Total Antigen Central Lab Future	*0*	*1*	*2*	*27*	*44*	*59*	*59*	*66*
Lab Based PCR Today	75	100	100	105	115	125	125	130
Additional Lab Based PCR with Pooling	*0*	*0*	*25*	*37.8*	*138*	*187.5*	*225*	*234*
Total Central Lab	**75**	**101**	**128**	**172**	**299**	**375**	**412**	**434**
Grand Total	**116**	**205**	**258**	**442**	**686**	**874**	**999**	**1075**



Editor Mara Aspinall, Arizona State University

Contributors Melea Atkins, COVID-19 Policy Alliance

Simon Johnson, Massachusetts Institute of Technology

Brandon M. Henry, MD, Cincinnati Children's Hospital Medical Center

Designer Fer Sagastume, Design To Combat COVID-19

Based on published reports, company interviews, and proprietary analysis

Contact: mara.aspinall@healthcatysts.com