



# Tracking US Coronavirus Testing Capacity

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## ■ Current National Capacity Projections (Tests / Month)



**205M**

December 2020

**258M**

January 2021

**686M**

March 2021

**1,075M**

June 2021

No significant changes from last week. Please note that 32% of the future capacity in March and 42% in 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

### ■ The FDA issued:

- 3 EUA amendments: 1 antigen and 2 molecular tests
- 1 new EUA for molecular test: SML Genetree's [Ezplex SARS-CoV-2 G Kit](#)
- 1 new EUA for antigen test: OrthoClinical's EUA for a Central Lab based antigen test
- 2 new EUAs for serology tests: ADVAITE & Phaedria

- In last week's [FDA Virtual Town Hall](#) on COVID-19 testing, Dr. Timothy Stenzel, Director, FDA Office of In Vitro Diagnostics and Radiological Health, reiterated that antigen and molecular tests may be used off label for testing asymptomatic subjects, while encouraging new EUA submissions based on asymptomatic screening: "The FDA is allowing... antigen and molecular tests that are authorized to be used off label in testing asymptomatic patients. So that is completely legitimate to do."

## What to Watch for this Week



01/18/2021

- Joseph Biden and Kamala Harris will be [inaugurated](#) as President and Vice President of the United States. President-elect Biden will immediately begin working to pass a [\\$1.9 trillion rescue package](#), which includes \$20 billion to support vaccination, \$50 billion for a "massive expansion" of testing and \$130 billion for schools. The testing dollars will be specifically directed at purchasing rapid-result tests, expanding lab capacity, and helping localities implement testing programs.

# New & Noteworthy

## *New data on variants spreading in the U.S.*

- The [California Department of Public Health](#) indicated that an L452R variant has been linked to large outbreaks in multiple California counties.
- A new [study](#) predicts that a variant called 20C-US may already be the most dominant variant in the midwest U.S. [Another study](#) reports that two novel 20C variants were widely circulating in the December 2020-January 2021 period in Columbus, Ohio carrying the same spike mutation (N501Y) observed in the UK B.1.1.7 variant.

## *Less invasive samples show effectiveness for both active virus and serology tests*

- A new [meta-analysis](#) found that the diagnostic accuracy of saliva nucleic acid amplification testing (NAAT) is comparable to nasopharyngeal NAAT in the ambulatory setting, paving the way for increased interest in expanding saliva diagnostic tests.
- In an [analysis](#) of saliva specimens collected via three different techniques (supervised collection (SVC), oropharyngeal washing (OPW) and self-collection (SC) for NAAT), SVC samples had adequate diagnostic agreement with nasopharyngeal swabs and displayed significantly superior sensitivity compared to SC.
- Serology test [results](#) with dried blood sports (DBS) obtained via a finger prick showed high agreement to those obtained with serum from a venous blood draw, thus demonstrating adequate usability of DBS as an easy to obtain sample material for detection of anti-SARS-CoV-2 antibodies.

## *Central lab antigen tests show promise*

- A [head-to-head comparison](#) of a central lab automated antigen detection test versus 4 point-of-care rapid antigen tests found that the lab test had significantly superior performance for diagnosing SARS-CoV-2 infection and showed 100% agreement with NAAT for detecting contagious (Ct values ≤33) COVID-19.
  - This month to date, the first two central lab antigen tests received EUA's - Ortho Clinical and Quanterix.
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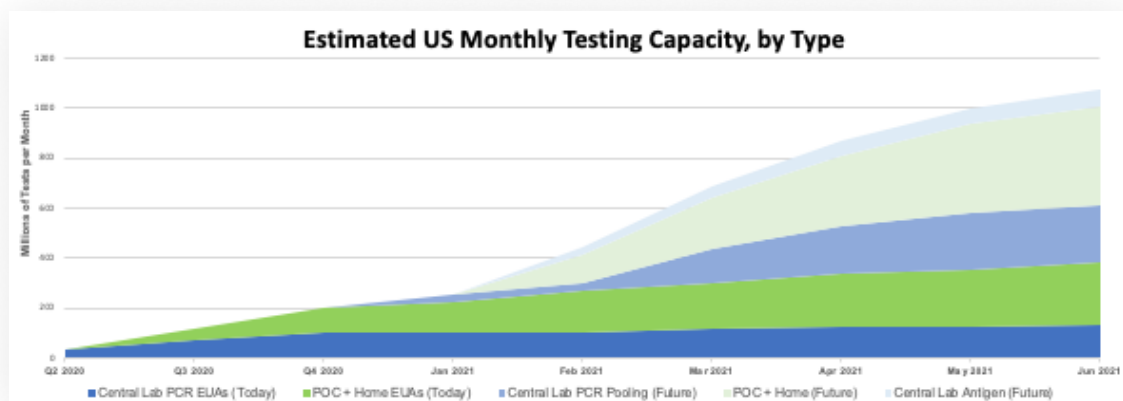
# Food for Thought

- It is increasingly important to find ways to break down regulatory and administrative barriers to implementing asymptomatic screening programs at K-12 schools and community sites, including making CLIA waivers more accessible, considering targeted liability waivers, and implementing standing Rx orders.

# Latest Monthly Capacity Estimates

No significant changes from last week. Please note that 32% of the future capacity in March and 42% in 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
Molecular Point of Care EUA Today	5	6	9	11	13	13	13	15
<b>Subtotal POC &amp; Home EUA Today</b>	<b>41</b>	<b>104</b>	<b>127</b>	<b>161</b>	<b>181</b>	<b>215</b>	<b>230</b>	<b>250</b>
Antigen Point of Care Future	0	0	0	78	115	160	207	225
Home DIY Future	0	0	3	28	83	114	139	154
Molecular Point of Care Future	0	0	0	4	8	10	11	12
<b>Subtotal POC &amp; Home Future</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>110</b>	<b>206</b>	<b>284</b>	<b>357</b>	<b>391</b>
<b>Total POC &amp; Home</b>	<b>41</b>	<b>104</b>	<b>130</b>	<b>271</b>	<b>387</b>	<b>499</b>	<b>587</b>	<b>641</b>
Total Antigen Central Lab Today	N/A	N/A	3	7	7	10	10	11
Lab Based PCR Today	75	100	100	105	115	125	125	130
Total Antigen Central Lab Future	0	0	0	22	39	52	52	59
Add'l Lab Based PCR with Pooling	0	0	25	38	138	188	225	234
<b>Total Central Lab</b>	<b>75</b>	<b>100</b>	<b>128</b>	<b>172</b>	<b>299</b>	<b>375</b>	<b>412</b>	<b>434</b>
<b>Grand Total</b>	<b>116</b>	<b>204</b>	<b>258</b>	<b>442</b>	<b>686</b>	<b>874</b>	<b>999</b>	<b>1075</b>



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