Tracking US Coronavirus Testing Capacity

VOLUME 1, ISSUE 05      JANUARY 26TH, 2021

Current National Capacity Projections
(Tests / Month)

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

- Joe Biden was sworn in as the 46th president of the United States. On his first full day in office, he released a 200 page National Strategy for the COVID-19 Response and Pandemic Preparedness. The strategy aims to expand access to testing by:
  - Ensuring free or insurance covered COVID-19 testing for all
  - Calling for a national strategy for safely reopening schools, support for school screening testing programs, plans to develop "protocols to inform the use of testing...among asymptomatic individuals," and a $130 billion budget request for schools.
  - Creating a dedicated CDC Testing Support Team and a U.S. Public Health Job Corps with 100,000 COVID-19 contact tracers and other public health workers,
  - Directing agencies to use the Defense Production Act (DPA) to fill immediate supply shortfalls including swabs, reagents, pipette tips, PCR machines, and rapid test kits.

- The FDA issued:
  - 7 EUA amendments: 2 serology tests and 5 molecular tests, including:
    - Cleveland Clinic assay (updated to add home collection with physician oversight)
    - NeuMoDx assay (updated to add saliva sample collection)
  - 1 new EUA for molecular test: Ambry Genetics Laboratory assay, which was approved for home collection with saliva samples


**What to Watch for this Week**

*Increasing interest in and concern about new viral strains*

- Moderna is developing a “booster” vaccine dose to specifically protect against the South Africa strain.
- Early data from the UK suggests that the B.1.1.7 strain, which displays increased infectivity, may also be associated with increased mortality, raising awareness for challenges in the months ahead.
- The Minnesota Department of Health confirmed its first known case of more contagious Brazil variant of COVID-19 in a person that became ill in the first week of January

**New & Noteworthy**

*Data on Test Effectiveness Begins to Impact Testing Protocols*

- An FDA warning earlier this month on the risks of false negative test results from the Curative SARS-Cov-2 Test has led to significant disruption of COVID-19 testing programs in school districts and communities nationwide, including in New Orleans and Colorado.
- Two studies, one in Arizona and one in Massachusetts, compared the sensitivity and specificity of Abbott BinaxNOW to RT-PCR Tests, finding that the specificity of BinaxNOW was high (99%+) in all populations, but the sensitivity varied significantly based on symptoms or lack thereof and age from a low of 35.8% among asymptomatic individuals over the age of 10 in Arizona to a high of 96.5% in symptomatic adults within 7 days of symptom onset in Massachusetts.

*New Insights on Asymptomatic COVID-19*

- A recent literature review found that, of those who tested positive for COVID-19 but had no symptoms at the time of testing, approximately two-thirds remained asymptomatic.
- A study evaluating reported transmission rates among pre-symptomatic and asymptomatic individuals found that asymptomatic patients can transmit SARS-CoV-2 to others, but confirmed that such individuals are responsible for fewer secondary infections than people with symptoms.
- A new report found that in Shenzhen, China where RT-PCR tests were used rigorously when indicated by close contacts, a substantial proportion of those who tested negative were found to later have COVID-19 antibodies, indicating that those infections were missed by the testing program likely due in part to when the test was administered to asymptomatic patients. Despite this, the program was still able to contain community spread.

**Food for Thought**

- The legal decision at HHS late last year that challenged FDA authorities over lab-developed tests (LDTs) and led FDA to stop issuing EUA’s for these tests has hampered the large-scale expansion of pooled testing and other LDTs for screening programs as, without an EUA, the laboratories lack PREP Act liability protections. Reversing this legal decision and empowering FDA to issue EUA’s for LDTs on pooled samples intended for asymptomatic screening could have a dramatic impact on test capacity for schools and other essential organizations.
- The University of Illinois is planning to leverage federal CARES Act funds to provide 1 million tests across the state’s 12 public universities pending EUA, illustrating the potential of using federal funds to deploy stranded laboratory capacity at research universities around the country.
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.

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Sep 2020</th>
<th>Dec 2020</th>
<th>Jan 2021</th>
<th>Feb 2021</th>
<th>Mar 2021</th>
<th>Apr 2021</th>
<th>May 2021</th>
<th>Jun 2021</th>
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</thead>
<tbody>
<tr>
<td>Antigen Point of Care EUA Today</td>
<td>36</td>
<td>55</td>
<td>111</td>
<td>138</td>
<td>155</td>
<td>167</td>
<td>181</td>
<td>196</td>
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<tr>
<td>Home DIY EUA Today</td>
<td>0</td>
<td>2</td>
<td>7</td>
<td>11</td>
<td>14</td>
<td>35</td>
<td>36</td>
<td>40</td>
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<tr>
<td>Molecular Point of Care EUA Today</td>
<td>5</td>
<td>6</td>
<td>9</td>
<td>11</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>15</td>
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<tr>
<td><strong>Subtotal POC &amp; Home EUA Today</strong></td>
<td>41</td>
<td>104</td>
<td>127</td>
<td>161</td>
<td>181</td>
<td>215</td>
<td>230</td>
<td>250</td>
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<tr>
<td>Antigen Point of Care Future</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>78</td>
<td>115</td>
<td>160</td>
<td>207</td>
<td>225</td>
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<tr>
<td>Home DIY Future</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>28</td>
<td>83</td>
<td>114</td>
<td>139</td>
<td>154</td>
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<tr>
<td>Molecular Point of Care Future</td>
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<td>0</td>
<td>0</td>
<td>4</td>
<td>8</td>
<td>10</td>
<td>11</td>
<td>12</td>
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<tr>
<td><strong>Subtotal POC &amp; Home Future</strong></td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>116</td>
<td>206</td>
<td>284</td>
<td>357</td>
<td>391</td>
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<tr>
<td><strong>Total POC &amp; Home</strong></td>
<td>41</td>
<td>104</td>
<td>130</td>
<td>271</td>
<td>387</td>
<td>499</td>
<td>587</td>
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<tr>
<td><strong>Total Antigen Central Lab Today</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>3</td>
<td>7</td>
<td>7</td>
<td>10</td>
<td>10</td>
<td>11</td>
</tr>
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<td>Lab Based PCR Today</td>
<td>75</td>
<td>100</td>
<td>100</td>
<td>105</td>
<td>115</td>
<td>125</td>
<td>125</td>
<td>130</td>
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<tr>
<td><strong>Total Antigen Central Lab Future</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>22</td>
<td>39</td>
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<td>52</td>
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<tr>
<td>Add'l Lab Based PCR with Pooling</td>
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<td>25</td>
<td>38</td>
<td>138</td>
<td>168</td>
<td>225</td>
<td>234</td>
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<tr>
<td><strong>Total Central Lab</strong></td>
<td>75</td>
<td>100</td>
<td>128</td>
<td>172</td>
<td>299</td>
<td>375</td>
<td>412</td>
<td>434</td>
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<td><strong>Grand Total</strong></td>
<td>116</td>
<td>204</td>
<td>258</td>
<td>442</td>
<td>686</td>
<td>874</td>
<td>999</td>
<td>1075</td>
</tr>
</tbody>
</table>

A special congratulations to our own Brandon M. Henry, MD, who was recognized as the most cited COVID-19 researcher in the United States by a recent study.

Based on published reports, company interviews, and proprietary analysis

A collaboration between COVID-19 Response Advisors & Health Catalysts Group

[www.covidresponseadvisors.org](http://www.covidresponseadvisors.org) & [www.healthcatalysts.com](http://www.healthcatalysts.com)