Tracking US Coronavirus Testing Capacity

DECEMBER 29TH, 2020

- **Current National Capacity Projections (Tests / Month)**
  - **205M** This Month
  - **274M** January
  - **676M** End of Q1
  - **1,069M** End of Q2

- **Last Week’s Major Emergency Use Authorizations (EUA)**
  - *A big week for rapid antigen testing*
  - **Abbott BINAX At-Home Antigen Test**
    - Online ordering and prescription
    - Capacity projections: Q1: 10 million/month, Q2: 30 million/month
    - Data collected on NAVICA app
  - **Ellume Antigen Test**
    - Fully at home with no Rx needed for age 2 and above
    - Low capacity projections: 7.5 million/month by June
    - Results only visible on smartphone. Zip code data collected
  - **Quidel QuickVue Rapid Antigen Test**
    - No instrument point of care (POC) test
    - Capacity projections: will rise from 10 million/month to 40 million/month by June

- **What to Watch for this Week 12/28/2020**
  - *A final blast of 2020 EUAs including many updates to existing EUAs*
    - 28 EUAs issued on December 28th, all were amendments or updates to existing EUAs
    - Roche point of care (POC) white label of SD Biosensor EUA expected
    - Cellex at-home rapid antigen test EUA expected

- **New & Noteworthy**
  - Becton Dickinson and OrthoClinical both have pending EUAs for central lab antigen tests for NP Swabs, potentially limiting interest in these tests
  - SalivaDirect is expanding: more than 70 labs are now trained and using protocols (Contact: SalivaDirect@gmail.com)
Food for Thought

- Unconfirmed reports indicate there are 1,700 COVID-19 test EUAs in the FDA approval queue across all technologies. Analyzing and prioritizing the EUA backlog, as legally appropriate, would generate significant testing capacity gains.

- Clarifying regulatory pathways for Laboratory Developed Tests (LDT) to seek “voluntary EUAs” could ease burden and expand capacity.

- Consider ways to leverage staff and resources from other HHS agencies to expand FDA review and authorization capacity.

Latest Monthly Capacity Estimates

<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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<tbody>
<tr>
<td>Antigen Point of Care EUA Today</td>
<td>36</td>
<td>95</td>
<td>110</td>
<td>140</td>
<td>157</td>
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<tr>
<td>Subtotal POC &amp; Home EUA Today</td>
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<td>104</td>
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Estimated US Monthly Testing Capacity, by Type

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Based on published reports, company interviews, and proprietary analysis