Updated Monthly Capacity Numbers: Current and Future EUA’s

417M  
September 2021

479M  
October 2021

537M  
November 2021

601M  
December 2021

No changes in total numbers this week – but there have been small shifts after the public companies released their earnings with hints at their manufacturing capacity. Rapid antigen self-test supply seems to be improving a bit – with reports of large buyers receiving some supply but OTC availability still remains limited. We don’t see significant improvements until the end of November into early December.

What Happened Last Week

The FDA issued one new EUA, seven amendments, and no safety communications and in the last week:

- New EUAs (1):
  - Molecular Tests (1): Detect, Inc. OTC

- New Amendments to Existing EUAs (7):
  - Molecular Tests (3): Hologic Aptima | Yale SalivaDirect | Yale SalivaDirect DTC
  - Antigen Tests (2): LumiraDx | OraSure IntelliSwab Home Test
  - Flu/RSV Panels (2): Hologic Aptima | Princeton BioMeditech Status

New & Noteworthy

Feds Add a Layer of Support for COVID-19 Testing in Schools

Regular testing of kids and teachers in schools has been a clear priority for the Biden administration. While much federal funding has been allocated to the effort, uptake has been slow and below expectations. This week the White House announced that the Department of Education (ED) and the CDC are partnering with The Rockefeller Foundation to help ensure that all schools can access and set up screening testing programs as quickly as possible. The endeavor is beginning with a series of twice-weekly forums for and by educators, which aim to provide tactical, real-time guidance on how to start and strengthen school testing programs. Open and Safe Schools.org, created by the Shah Foundation in partnership with the CDC, serves as the central resource for information and registration. Note: Mara has been involved with this effort through The Rockefeller Foundation.

CDC says Test to Stay might be okay. Maybe.

In their (appropriately) cautious way, CDC has given a first tentative thumbs-up to Test to Stay protocols in K-12 schools, calling it “a promising practice” on their page of FAQs about COVID-19 for School Administrators. They note that they’re “working with multiple jurisdictions implementing Test to Stay to evaluate the effectiveness of this strategy.” Anecdotal evidence suggests that Test to Stay is helping to keep thousands of kids in school in person - and out of ultimately unnecessary quarantine. Our fingers are crossed that further studies will bear out those reports, so that CDC can unqualifiedly endorse the practice and schools can find the staffing to implement appropriately.
One of the few areas of bi-partisan agreement – keep kids in school.

Continuing on our school theme this week. Experts disagree on what role school closures have on preventing community transmission. One underlying question is just how much risk is conferred by school attendance? On the one hand, younger children have milder cases with successful recovery (although important exceptions occur), on the other, contact between younger kids is more frequent than between teenagers and adults. A Nature Medicine paper compares actual community transmission (~770 of 1,741 Japanese municipalities) in places where schools stayed open vs. places where they closed, and controls for many confounding factors. It finds that closing schools led to no greater protection from community transmission. The biggest caveat: this research was carried out before variants became dominant in Japan. We will be looking for data on the impact of school re-opening in the UK.

Food for Thought

More Tests (If Done Right) → Fewer Masks and Lockdowns

A new model-based study out of Penn State indicates that COVID-19 testing, if it involves enough tests and has a short enough turnaround time, can reduce reliance on non-pharmaceutical interventions (NPIs) such as lockdowns, distancing, and masking. The takeaway: When NPIs decrease, rapid testing should increase: “otherwise, small additional lifting of these NPIs can lead to dramatic increases in infections, hospitalizations and deaths.” (We should note that increasing immunity (i.e., vaccination) decreases the level of testing or NPIs needed.) Commentary: There are two ways to identify dangerous new variants that require renewed intervention, both of which require sequencing: 1) Look for mutations in the genome known to be important for viral function; and 2) Examine cases in regional outbreak clusters. As we pointed out last week, the US is not doing nearly enough sequencing for us to have confidence that we will spot the next explosive variant early enough to react. The US must create a scaled, systematic sequencing process at least as good as the UK’s and preferably better – in other words, we have to up our genomic profiling game 10-fold.

What if testing sets us free?

This opinion from STAT News is one that we could get behind. The basic concept - rather than viewing COVID-19 testing as a punishment (for not getting vaccinated), could we as a nation start viewing it as the key to our post-pandemic freedom? Could testing (dare we say it) even be “cool”? Obviously, making this idea feasible requires that tests be cheap - or free - and easily available to everyone, everywhere. But the writers’ point is that testing accessibility is necessary but not sufficient. Our way of thinking about testing has to change, too. The question is - is it too late for that transformation to happen? Can we reach enough of the people who need to hear the message?

K-12 Metrics:

School closures remain low, per Burbio’s 2021/2022 School Disruptions Tracker. To date: 2,462 closures across 636 districts (up from 624 last week).

Higher Ed vaccine mandates:

The Chronicle of Higher Education now counts 1,127 colleges and universities that require vaccines, up from 1,069 last week.
## Latest Monthly Capacity Estimates

### Estimated Monthly Capacity of All Tests (M)

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Sep '21</th>
<th>Oct '21</th>
<th>Nov '21</th>
<th>Dec '21</th>
</tr>
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<tbody>
<tr>
<td><strong>ANTIGEN</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antigen Professional + Point of Care EUA Today</td>
<td>149</td>
<td>158</td>
<td>172</td>
<td>197</td>
</tr>
<tr>
<td>Antigen OTC: Home/Self EUA Today</td>
<td>81</td>
<td>130</td>
<td>162</td>
<td>194</td>
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<tr>
<td>Antigen Central Lab Today</td>
<td>10</td>
<td>11</td>
<td>13</td>
<td>14</td>
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<tr>
<td><strong>Antigen Total</strong></td>
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<td>299M</td>
<td>346M</td>
<td>404M</td>
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<tr>
<td><strong>MOLECULAR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Professional, Point of Care, OTC EUA</td>
<td>28</td>
<td>31</td>
<td>32</td>
<td>39</td>
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<tr>
<td>Today</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Lab Based PCR Today</td>
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<td>125</td>
<td>130</td>
<td>130</td>
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<tr>
<td>Add’l Lab Based PCR with Pooling</td>
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<td>29</td>
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<tr>
<td><strong>Molecular Total</strong></td>
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<td>181M</td>
<td>190M</td>
<td>198M</td>
</tr>
<tr>
<td><strong>Total Test Capacity</strong></td>
<td>417M</td>
<td>479M</td>
<td>537M</td>
<td>601M</td>
</tr>
</tbody>
</table>

### Manufacturing Capacity by Test Type Over Time

![Graph showing the increase in testing capacity over time](chart.png)

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*Based on published reports, company interviews, and proprietary analysis. A collaboration between COVID-19 Response Advisors & Health Catalysts Group.*

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