Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current and Future EUA's

417M	433M	465M	516M
September 2021	October 2021	November 2021	December 2021

A resetting of capacity estimates beginning this week, with current focus through the end of 2021. A few changes in the way the data is presented. Capacity is now grouped by technology - antigen and molecular - and then divided by test location (central lab/point of care/home - OTC). In addition, we are not forecasting capacity from future EUAs, as there is too little visibility and too much potential variability. We will continue to offer our best estimates on what future capacity might look like.

Key Insights/Highlights

Antigen: Clearly the headline today is the scarcity of antigen OTC tests. Capacity is indeed rising for OTC tests, and the recent advance purchases ($647 million) will help, but the question is whether new capacity can be built quickly enough to satisfy short-term demand. $1.2 billion of the advance purchases are for professional tests, and a substantial number of those require an NPS swab (Celltrion). These tests will help with capacity in physician offices and hospitals, but they will not fill the need for the simple while-you-wait rapid antigen tests that the OTC home / employer market craves.

Molecular: PCR lab capacity appears to be stable and keeping up with demand, at least as measured by the time it takes for results to be returned to test takers (within 48 hours). We expect that this field will have more demand moving forward into flu season. We believe that, at least in doctors' offices, the vast majority of tests will be for flu and COVID (and RSV if possible).

New EUAS: The FDA is continuing to receive dozens of EUA applications each month. In the short term, however, there are only a few large-scale manufacturers that are capable of making a significant impact on capacity: Those who can churn out 10 million a month or more. In the rapid-antigen field, we believe the companies most likely to have a material impact, if they apply, and if they are granted EUAs are Roche (with SDBiosensor test), Siemens (with Healgen test) and LumiraDx (Amira).

What Happened Last Week

The FDA two new EUAs, three amendments, and no new safety communications in the last week:

- New EUAs (2):
  - Molecular Tests (1): Life Sciences Testing Center
  - Antigen Tests (1): ANP Technologies
- New Amendments to Existing EUAs (3):
  - Molecular Tests (1): Kaiser Permanente
  - Antigen Tests (1): GenBody
  - Serology Tests (1): NOWDiagnostics

New & Noteworthy

FDA Revises Test EUA Requirements to Account for Varients

Last Thursday, the FDA established additional conditions for the EUAs of nearly all SARS-CoV-2 tests, requiring them to "evaluate the impact of SARS-CoV-2 viral mutations" on their product's performance.

And it's not a one-time ask: These evaluations have to continue on an ongoing basis. If any mutation affects a test's performance, FDA has to be notified "immediately." Multi-analyte tests are included under the new rules. Not covered: IL-6 assays, standalone specimen collection devices, and standalone home collection kits.

School Mask Requirements Still Help, Even Against Delta

Two new studies (CDC MMWR) provide evidence that universal masking continues to make schools safer, even with Delta in the mix. One looked at schools in two Arizona counties and found that schools without mask requirements were 3.5x more likely to experience an outbreak than schools with mask requirements. The other investigated how pediatric COVID case rates changed after schools opened in counties across the country, with similar results: Counties in which schools didn't require masks experienced significantly higher increases in pediatric case rates as compared to those that required masks. While both studies show only association, not causation, it's still good to see two new data points telling the same story.

Food for Thought

Rapid Tests Still Running Short, but Labs Can Pick Up the Slack

You may not be able to find a rapid test at your local pharmacy, but don't despair - if you need a test, labs have your back. In an ironic turnaround from where we were in March 2020, the CDC has been urging folks who want to get tested to go to labs, where there remains plenty of capacity. We measure capacity here not just from anecdotal evidence but from data published by the larger labs on their test turnaround time (TAT), which is steady at 24 to 48 hours. (Remember, though, that labs measure TAT based on the time at which the sample arrives at their door - not the time the sample is taken.)

Commentary: Let's be careful not to go from guard rail to guard rail on testing. We can't rely exclusively on either PCR or antigen tests - we need both. While some use cases favor one vs. another, much of the time either can be effective.

Swabs versus Saliva? Coke versus Pepsi?

Since the SARS-CoV-2 virus is a tissue-resident upper respiratory virus, it's been challenging to figure out which sample type will give the most reliable results. Common practice has evolved, as we've learned that samples from an invasive bronchoalveolar lavage, "brain-tickling" nasopharyngeal (NP) swab, and minimally invasive anterior nasal (AN) swab are all broadly comparable. Saliva has been more controversial. Some studies have reported that its diagnostic reliability is comparable to NP/AN, while others say that saliva works even better. However, a recent report in JAMA suggests that viral availability in saliva is lower for asymptomatic patients and declines faster than it does in the nose. According to this report, symptomatic saliva is ~90% as sensitive as NP in the first seven days but declines to ~25% sensitivity after 20 days; asymptomatic saliva is only 55% as sensitive as NP even in the first seven days.

Commentary: This report is not the last word on the topic. However, these results serve as a good reminder - both that RTqPCR accuracy depends on collection and handling, and that frequent antigen testing has practical utility.

K-12 Metrics:

Burbio's 2021/2022 School Disruptions tracker has logged just over 2,200 in-person school closures (up from 2,000 last week) across 539 districts (from 469) in 43 states (from 39). However, their data shows that closures peaked the week of 8/29.

Higher Ed vaccine mandates:

The Chronicle of Higher Education now counts 1,053 colleges and universities that will require vaccines for the fall semester, up from 1,033 a week ago.

Latest Monthly Capacity Estimates

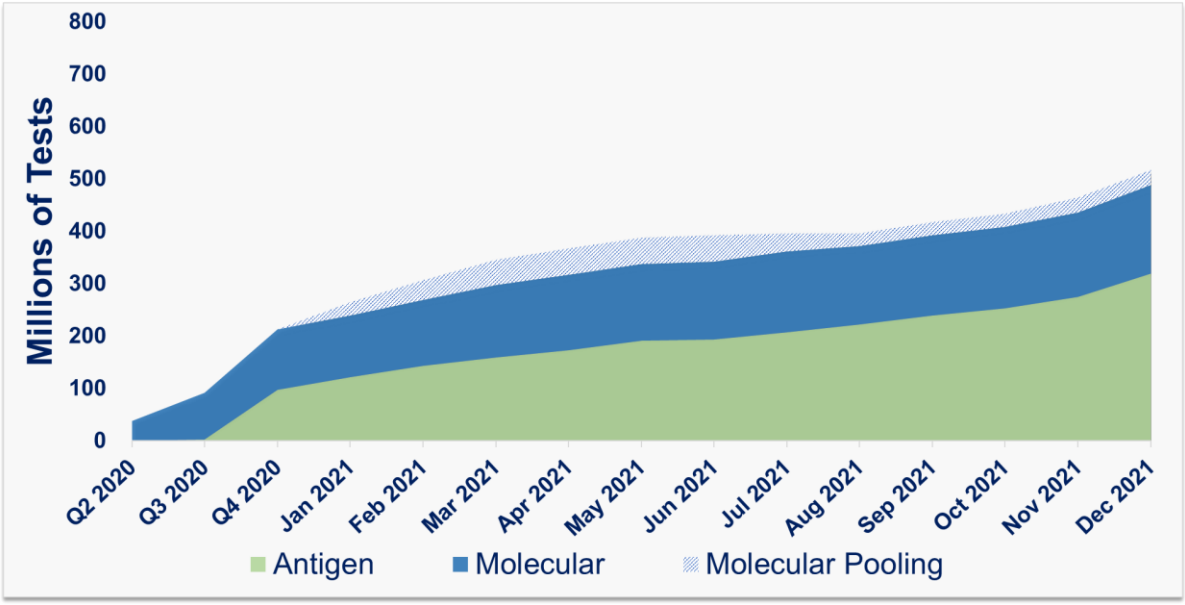
Estimated Monthly Capacity of All Tests (M)

Test Type	Sep '21	Oct '21	Nov '21	Dec '21
ANTIGEN				
Antigen Professional + Point of Care EUA Today	149	158	172	197
Antigen OTC: Home/Self EUA Today	81	84	90	109
Antigen Central Lab Today	10	11	13	14
Antigen Total	**239M**	**253M**	**274M**	**319M**

MOLECULAR				
Molecular Professional, Point of Care, OTC EUA Today	28	31	32	39
Lab Based PCR Today	125	125	130	130
Addt'l Lab Based PCR with Pooling	25	25	29	29
Molecular Total	**178M**	**181M**	**190M**	**198M**

Total Test Capacity	**417M**	**433M**	**465M**	**516M**

Estimated Monthly Capacity of All Tests (M)



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