



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current and Future EUA's

417M

September 2021

479M

October 2021

540M

November 2021

653M

December 2021

Changes this week reflect recent new EUAs for OTC self tests: two antigen (Celltrion and iHealth, which should have large capacity) and one molecular (Detect Labs). However, we remain conservative about new entrants' ability to scale up and distribute in the first few months of market entry, so have discounted their launch numbers.

Several readers have been in touch to ask why, if we have seemingly large amounts of test capacity, is it still difficult to find tests on retail shelves? We are not entirely sure, but we strongly believe that much antigen capacity goes directly from manufacturers to businesses. Companies are using these tests for their unvaccinated workforce and for regular testing of everyone else. It is a tough choice - should tests go to retail stores where the public can access them? To schools so kids can stay in in-person learning? To businesses so we can keep the economy moving forward?

What Happened Last Week

The FDA issued one new 510(k), two new EUAs, and eight amendments in the last week:

- New 510(k) Premarket Notifications:
 - Molecular Tests (1): [BioFire COVID-19 Test 2*](#)
* First 510(k) for COVID-19 only test; second overall following March 2021 510(k) of [BioFire's Respiratory Panel 2.1-EZ](#)
- New EUAs (2):
 - Molecular Tests (1): [Talis Biomedical](#)
 - Antigen Tests (1): [iHealth Home \(OTC\)](#)
- New Amendments to Existing EUAs (8):
 - Molecular Tests (2): Abbott Alinity | LetsGetChecked
 - Antigen Tests (2): Abbott BinaxNOW OTC | Quidel QuickVue
 - Serology Tests (3): Nirmidas MidaSpot | Sugentech SGTi-flex IgG | Jiangsu Orawell IgM/IgG
 - Flu/RSV Panels (1): PerkinElmer PKamp

New & Noteworthy

PCR and Antigen Go Head-to-Head At Home

In the ongoing effort to accumulate evidence showing that serial self-administered antigen tests really, truly can work as asymptomatic screening tools, NIH's RADx program and FDA have rolled out the [Test Us At Home](#) initiative. Participants will receive one of three brands of self-administered OTC tests and will take the tests every other day for two weeks. They'll also send samples to Quest for PCR testing. According to a report from the UMASS Chan Medical School, whose researchers are involved with the study, "Data collected from the study should also be [available as a reference](#) to help other companies applying for authorization from the FDA." We look forward to the results.

Trust but Verify: OSHA Says Employee Self-Tests Must Be Proctored

The *Wall Street Journal* noticed an [interesting](#) aspect in the Biden Administration's get-vaccinated-or-get-tested requirements for employees of large businesses, which were officially published by OSHA on November 5. Included in the rules: Employees can use self-administered OTC tests, but [they cannot simply perform those tests unsupervised](#) and report the results to their employer. If self-administered OTC tests are used, they must be proctored by the employer or by telehealth.

Who Foots the Bill for Testing the Unvaccinated?

The same OSHA publication, while it requires employers with more than 100 employees to test unvaccinated employees, does not require those employers to pay for the tests. Which then begs the question - who does? We have heard both sides of this discussion - some employers will pay for tests to avoid losing employees, while others will place the burden on employees in order to give them yet another incentive for vaccination.

More At-Home Rapid Antigen Tests → More POC Molecular Tests

Meanwhile, the Biden administration believes that increased at-home testing will - at least for a while - result in increased need for molecular testing, as well. Why would that be the case? Well - remember those unsupervised at-home tests that OSHA won't allow employees to use? "If someone buys an over-the-counter rapid antigen test at their local pharmacy to take at home and tests positive, they may seek out a health care provider who would conduct another test to confirm that result." The Department of Health and Human Services is investing \$650 million to make sure that [point-of-care molecular tests](#) will be available for the purpose.

Food for Thought

Deer in the Headlights (or Headlines) Again

An Iowa study found that [82.5% of deer tested positive for COVID-19](#) during the winter of 2020 - a [significant and startling increase](#) since the fall of 2020. So many questions here. One that has an answer: According to researchers, eating properly cooked venison is not a risk to humans. But why did these researchers decide to test deer in the first place? How are deer getting exposed to COVID? Per genome sequencing, the exposure came directly from humans - so how did that happen? Could the deer harbor a new mutation, and how could that spread? Are they under a vaccine or test mandate?

Now to domestic animals. Arizona researchers have documented COVID spread from pet owner to pets - again through genomic sequencing, which gives more reliability to the diagnostic. The same mutation was seen in these humans and their two pets: B.1.575, an early mutation. (No data on the pet species here - dog? cat? Probably not a deer. We think.)

A Step in the Right Direction for US Sequencing

Speaking of SARS-CoV-2 sequencing, PacBio has announced an improved prep kit for that purpose. There are others - but we are highlighting this one because of its potential to lower sequencing costs. As we have discussed in prior newsletters, the US is far behind where it should be in sequencing cases so that novel, threatening variants can be identified. We're not systematic, our geographic sampling is too arbitrary, and far too small a proportion of our cases ever gets sequenced. We hope that this product - and any others that come after it - lead to expanded sequencing of positives in the US.

K-12 Metrics:

School closures remain low, per Burbio's 2021/2022 [School Disruptions](#) Tracker. To date: 3,224 closures across 675 districts (up from 636 last week). Interestingly, COVID-19 may only have been an indirect cause of many of these events - Burbio is noting a trend of closures being called both pro- and reactively in order to improve staff and students' mental health.

Higher Ed vaccine mandates:

The *Chronicle of Higher Education* now counts [1,130 colleges and universities](#) that require vaccines, up from 1,127 last week.

Latest Monthly Capacity Estimates

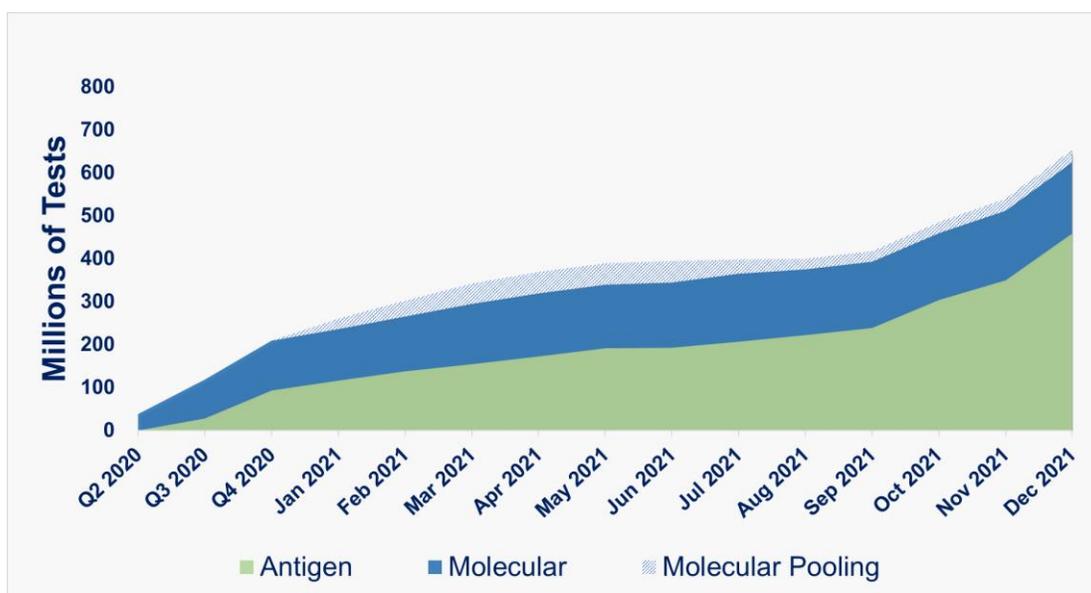
Estimated Monthly Capacity of All Tests (M)

Test Type	Sep '21	Oct '21	Nov '21	Dec '21
ANTIGEN				
Antigen Professional + Point of Care EUA Today	149	163	174	197
Antigen OTC: Home/Self EUA Today	81	130	165	251
Antigen Central Lab Today	10	11	11	11
Antigen Total	239M	304M	350M	458M

MOLECULAR				
Molecular Professional, Point of Care, OTC EUA Today	28	31	32	37
Lab Based PCR Today	125	125	130	130
Add'l Lab Based PCR with Pooling	25	25	29	29
Molecular Total	178M	181M	190M	195M

Total Test Capacity	417M	484M	540M	653M
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Manufacturing Capacity by Test Type Over Time



Editors

Mara G. Aspinall, Arizona State University
Liz Ruark, COVID-19 Response Advisors

Contributors

Sarah Igoe, MD, Arizona State University
Simon Johnson, Massachusetts Institute of Technology

Designers

Grace Gegenheimer, Health Catalysts Group
Fer Sagastume, COVID-19 Response Advisors

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A collaboration between COVID-19 Response Advisors & Health Catalysts Group
www.covidresponseadvisors.org & www.healthcatalysts.com