



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

516M	593M	613M	641M	681M
November 2021	December 2021	January 2021	February 2021	March 2021

We added Q1 2022 capacity estimates this week. What changes have we seen, and what do we expect to see?

- *We hope that we are underestimating the total test capacity, especially with regard to OTC rapid antigen tests. Our estimates include only tests that have an EUA as of December 15 and we continue to be skeptical on companies scaling to their full capacity. We expect (and hope for) more EUAs for rapid antigen tests from large-volume manufacturers who can materially impact test supply. If these new EUAs are granted, we predict 50 million+ more tests on the market within 60 days.*
- *We expect a small contraction of PCR labs, as the many very small labs that popped up during 2021 will likely not continue. We hope and expect that the larger labs can handle the volume of COVID tests in addition to those for flu and other typical winter respiratory illnesses. With the high test positivity rate across the country, we expect a further reduction in pooled testing.*

What Happened Last Week

The FDA issued one new EUA, four amendments to existing EUAs, and one safety/policy communication in the last week:

- New EUAs (1):
 - Antigen Tests (1): [Nano-Ditech Nano-Check](#)
- New Amendments to Existing EUAs (4):
 - Molecular Tests (1): PerkinElmer
 - Antigen Tests (1): BD Veritor System (POC)
 - Serology Tests (2): ZEUS ELISA IgG | Immunodiagnostic Systems (IDS) IgG
- Safety/Policy Communications (1):
 - FDA Updates (1): Additional updates to [SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests](#) web page now states that the [Meridian Bioscience Revogene SARS-CoV-2 test](#), [Tide Laboratories DTPM COVID-19 RT-PCR test](#), and [Applied DNA Science Linea COVID-19 Assay kit](#) are all expected to fail to detect the Omicron variant and should not be used. Of note: The Revogene and Tide tests are the first to fail due to the novel N-gene mutations in Omicron, while Linea is an S-gene target failure.

New & Noteworthy

Home Test Results Stay at Home – For Better and Worse

We've hinted at this in previous issues, but now the problem is coming up front and center: As the proportion of OTC at-home tests increases, so does the proportion of unreported test results. Mara estimated in [STAT News](#) recently that of the roughly 40 million COVID tests performed each week in the US, about 28 million are antigen tests, "the vast majority [of which] are taken at home and never reported to public health agencies."

When reporters for the article “contacted public health agencies in 10 states now experiencing rising COVID cases... none was able to track home testing data.” And yet these same officials claimed that they were confident about their COVID data, based on “a patchwork of PCR test data, estimates, some self-reporting, and in some places, wastewater sampling.”

Commentary: This issue highlights the tension between individual health and public health. For the individual, reporting their result is their choice, and having that choice is one of the reasons that they are taking the test at home in the first place. But public health demands data – officials can’t make good decisions without it. What to do? We believe that federal action to mandate a reporting mechanism (requiring just zip code and result) on *all* at-home/OTC tests is needed in the short term. *Not today* – but now that people believe in testing, let’s use this opportunity to put the right processes in place for this and the next epidemic/pandemic, so that public health officials can get the information they need. And while we are at it – how about mandating standardized comparable data parameters for all 50 states?

The Debate Over Free Tests

It appears that HHS does not believe that at-home tests have outpaced in-lab PCR as the primary location for COVID testing in the US. According to a [piece](#) that ran last Thursday in *Politico*, that’s one of the reasons why the Biden Administration decided to focus on reimbursement from health insurers instead of providing free tests across the country. Other reasons cited were the sheer cost of the program, which would require additional appropriations from Congress; the possibility of stifling competition and thus innovation; and concern that distributing tests equally across the country would leave them languishing on the shelves in some places, while other areas would use them up quickly.

Commentary: We greatly appreciate the steps the administration has taken to elevate the importance of testing and increase access to testing. And there is logic in their reasoning that tests would be wasted if everyone got one or two tests. But the status quo is not acceptable – we must do better. We have to create the necessary partnerships to get more tests to more Americans ASAP. Recent [evidence in New Hampshire](#) shows that there is a HUGE appetite among the public for at-home testing. Are we at war with this virus or not? Yes, we are – and therefore we need to use every lever we have.

Plus: Testing is the cheapest, most cost-effective option we have (other than masks). In simple math: We could pay for *1,300 tests* for the same money that *one* hospitalization costs – while preventing that hospitalization and others.

States Getting on the Rapid Test Bandwagon

We’re glad to see that [some states](#) are now clearly on board with the concept that easy access to at-home and/or rapid tests is a Good Thing: Colorado, Iowa, Maryland, Massachusetts, Minnesota, and Ohio have all rolled out different programs with that underlying goal.

Interesting to see how the focus varies from state to state: In [Colorado](#), while the tests are technically available to anyone, they’re intended specifically for use on school-aged children, to help keep schools open. *The Boston Globe* reports that [Massachusetts](#) is sending their tests to “communities with the highest percentage of families living below the poverty level.” [Iowa’s](#) tests are at-home but not rapid – they’re home collection kits for a saliva-based PCR test – while [Minnesota’s](#) are the opposite – they’re rapid tests, but you have to go to a testing center to take them. [Ohio](#) is distributing rapid tests through their public libraries – and is ensuring that the tests get reported by handing out a test type that requires telehealth proctoring.

Confidence in Tests

More data and [commentary](#) from official regulatory authorities continue to reaffirm the ability of virtually all tests (PCR and antigen) to detect people with Omicron. The FDA reiterated their position, and FINDx (international organization for diagnostics) also stated “current testing tools are uncompromised.”

Food for Thought

Lions and Tigers... and Otters. And Hippos.

While the rest of us anxiously track SARS-CoV-2’s march through the human population, [National Geographic](#) has been keeping an eye on where it’s making inroads among other species – a critical task, given animals’ role as potential reservoirs and sources for human disease.

According to USDA's Animal and Plant Health Inspection Service, members of [15 different species](#) have tested positive for the virus here in the US. (Here's what a [coati](#) is, in case you were wondering.)

Across the Pond, [hippos](#) were the latest to join the list, when Imani and Hermien at Belgium's Antwerp Zoo tested positive. As of December 5, they had runny noses, but nothing worse. (Though we imagine that a hippo-sized runny nose is probably more than enough.)

K-12 Round Up:

In school news this week, we saw [California](#) announce that they will be sequencing all positive tests from K-12 schools, in an effort to track the Omicron variant.

This week Burbio's [School Disruptions](#) Tracker discontinued reporting total closures, to focus instead on closures per week (225 vs. 163 a week ago). Closures have plateaued, but we'll see what happens once winter begins in earnest.

Burbio has also been analyzing how schools spend money they received from federal ESSER III funding. Their research, covering about 40% of the K-12 population, shows that the number-one use of these funds has been air-filtration and HVAC system improvements – great news, since better ventilation is a key part of mitigating this airborne disease.

Latest Monthly Capacity Estimates

Estimated Monthly Capacity of All Tests (M)

Test Type	Nov '21	Dec '21	Jan '22	Feb '22	Mar '22
ANTIGEN					
Antigen Professional + Point of Care EUA Today	174	185	187	187	191
Antigen OTC: Home/Self EUA Today	141	216	243	270	305
Antigen Central Lab Today	11	7	7	7	7
Antigen Total	326M	408M	437M	464M	503M
MOLECULAR					
Molecular Professional, Point of Care, OTC EUA Today	32	36	36	36	37
Lab Based PCR Today	130	130	125	125	125
Add'l Lab Based PCR with Pooling	29	20	16	16	16
Molecular Total	190M	185M	177M	177M	177M
Total Test Capacity	516M	593M	613M	641M	681M

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

Based on published reports, company interviews, and proprietary analysis
A collaboration between COVID-19 Response Advisors & Health Catalysts Group
www.covidresponseadvisors.org & www.healthcatalysts.com