



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

516M	593M	631M	912M	1,035M
November 2021	December 2021	January 2022	February 2022	March 2022

Small bump-up of capacity for March. The Feds announced contracts for [150 million more tests](#) (104 million for iHealth and 50 million for Siemens). This brings the total allocations to 550 million tests out of the 1 billion tests promised. Depending on the timing and manufacturers chosen for the remainder of this initiative, we may see additional changes in capacity. What is clear already is that the number of antigen tests performed daily now far exceeds the number of PCR tests. Rough estimate now - but we believe that there are approximately 8-10 million antigen tests performed each daily.

What Happened Last Week

The FDA issued 14 amendments to existing EUAs, two new safety/policy communications, and one new vaccine approval in the last week:

- New Amendments to Existing EUAs (14):
 - Molecular Tests (7): Amazon/STS Lab Holdco (4) | Psomagen Psoma COVID-19 RT Test | Yale School of Public Health SalivaDirect | National Jewish Health SARS-CoV-2 MassArray Test
 - Antigen Tests (4): InBios International | OraSure Technologies IntelliSwab (3)
 - Serology Tests (1): Healgen Scientific IgG/IgM
 - Flu/RSV Panels (2): Color Health (2)
- Safety/Policy Communications (2):
 - Recalls (1): [Empowered Diagnostics CovClear COVID-19 Rapid Antigen Test and ImmunoPass COVID-19 Neutralizing Antibody Rapid Test \[FDA announcement\]](#)
- FDA Drug and Device Approvals (1): [ModernaTx, Inc Spikevax](#)
 - Officially approved under the Vaccine, Blood and Biologic category through the [Priority Review](#) process

New & Noteworthy

Rockefeller ACTs Alongside the Feds to Provide Free Tests

On Friday, The Rockefeller Foundation [announced](#) Project ACT ([Access Covid Tests](#)), which will send free at-home COVID tests to folks in vulnerable communities. The program will start by providing more than 1 million tests in six states (Arkansas, Illinois, Maine, Michigan, New Mexico, Ohio), and is intended to complement the feds' 500 Million Tests program. Note: Mara is involved in this effort.

Yes, Omicron's little sister IS more transmissible

The past week, reports from the [UK](#) and [Denmark](#) headlined that Omicron sister lineage BA.2 was about 30% more transmissible than Omicron lineage BA.1. However, there is still no strong hypothesis about how/why this is the case.

Digging further into the rich Danish data reveals a more nuanced picture:

- Omicron BA.2 is more transmissible than both BA.1 and Delta: 42% of BA.2 household members develop infections within 14 days, versus 35% for BA.1 and 25% for Delta.
- Even in households with BA.2, fewer than half of family members actually developed an infection. This is consistent with a new [UK challenge study](#), in which 47% of patients *directly inoculated* with 7x the required infectious dose still *did not develop* COVID infections.

Food for Thought

We Forgot to Light the LAMP in the Test Tech Debate

In our ongoing discussion of the best COVID tests for each use case, we realized that we have not profiled molecular tests using Loop-mediated Isothermal Amplification (LAMP or RT-LAMP) technology. Utilizing a single-tube technique for DNA amplification, LAMP provides a low-cost alternative to PCR. It takes 20 to 30 minutes to work - a few minutes longer than most antigen tests. Three EUAs exist for home/self tests that use LAMP: Cue, Detect, and Lucira. The good news: LAMP has accuracy approaching lab-based PCR. The bad news: The cost is between \$50 and \$75 per test, and availability is limited. Cue and Detect also require the purchase of an instrument to run their individual test kits.

So, can antigen tests detect Omicron, or not?

In late December, the FDA expressed [concern](#) about antigen test sensitivity due to the novel N protein mutations in Omicron, although they did not release any supporting evidence. In mid-December, [a Swiss evaluation](#) of eight antigen tests had found that all detected Omicron, but with decreased sensitivity. This week, researchers from Harvard and Boston's Beth Israel Deaconess Medical Center published a [preprint](#) comparing three antigen tests, none of which were in Swiss study: Abbott BinaxNow (OTC), AccessBio CareStart (OTC), LumiraDx (point-of-care with instrument) - using the gold standards for evaluation. Their results showed that BinaxNow (with the lowest limit of detection) was 3x more sensitive for Omicron than it was for the original Wuhan strain, and the others were at least as sensitive as they were for Wuhan.

Test Instructions Need to Be Clear

A recent JAMA [study](#) looked at a critical question: Do home test instructions do a good enough job of telling the user what to do when presented with a positive or negative result?

The study compared the instructions for Ellume's rapid test to 1) a set of instructions "designed along decision science principles," and 2) no instructions at all. The twist: Some users were asked to respond based on a scenario in which they had a high probability of being infected (e.g., they had COVID symptoms), while others were to base their answers on having a low probability of being infected.

The good news: 95% of people responded to a positive result appropriately. The bad news: People who were given the "you're likely to have COVID" scenarios were much more likely not to isolate after a negative result if they received the original instructions (33%) than if they received either the decision-science-based instructions (14%) or even no instructions at all (24%). (For the record: If you're likely to have COVID but you test negative on a home test, you should isolate until you can confirm with PCR or can take another antigen test a day or two later.)

Commentary: This is basically an object lesson in the importance of clarity. If you're trying to get a critical point across to a lot of stressed-out, possibly ill folks, don't use "legalese." And maybe consult a decision scientist when you're designing your instruction packet. While this study was done on only one antigen test, the importance of clear recommendations is relevant to all tests - antigen, LAMP, and PCR.

When is it all right for someone to leave isolation?

Speaking of clarity - with huge respect to the CDC and acknowledgment of the many challenges and constituencies they serve, we are going to be bold enough to suggest our own recommendations for exiting isolation after a positive COVID test:

After testing positive, you can exit isolation when two of the following three conditions apply:

- A. 10 days have passed since your positive test
- B. You test negative on a rapid antigen or PCR test
- C. You have no symptoms (no fever, no coughing, etc.)

Why do we recommend this system?

- Simplicity. If you can figure out the “you pick two” menu at McDonalds, you can understand these rules.
- Flexibility. Don’t want to get tested? No problem - hang tight for a few more days. (NB: We recognize that there’s an equity issue if people have difficulty accessing tests or don’t have the ability to work from home.)
- Science. About 30% of people are still contagious after a five-day isolation period. Testing will catch these people.

The Good News is...

In this new section, we’ll be highlighting news that reminds us that, despite all the setbacks, progress against COVID continues to be made. This week: a [preprint](#) from Israel that adds more evidence backing the idea that vaccination can help reduce the risk of Long COVID. We hope that takes your anxiety about the possibility of breakthrough Omicron infections down a notch.

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	260	535	654
Antigen Central Lab Today	11	7	7	7	7
Antigen Total	326M	408M	454M	729M	852M
MOLECULAR					
Molecular Professional, Point of Care, OTC EUA Today	32	36	36	36	37
Lab Based PCR Today	130	130	125	130	130
Add'l Lab Based PCR with Pooling	29	20	16	16	16
Molecular Total	190M	185M	177M	182M	183M
Total Test Capacity	516M	593M	631M	912M	1,035M

Editors	Mara G. Aspinall, Arizona State University Liz Ruark, DVM, COVID-19 Response Advisors
Contributors	Sarah Igoe, MD, Arizona State University Simon Johnson, PhD, Massachusetts Institute of Technology
Designer	Grace Gegenheimer, Health Catalysts Group
Technology	Casey Miller, Health Catalysts Group

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