



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

516M	593M	631M	732M	907M
November 2021	December 2021	January 2021	February 2021	March 2021

Antigen test manufacturers continue to emphasize their focus on increasing test capacity and distribution. As positive as that sounds, we also continue to hear that most manufacturers are “on allocation,” meaning that everything that they are producing has been allocated to a specific customer even before it is fully manufactured.

In addition, manufacturers are in the same situation as other businesses that require on-premises work (from [education](#) to [laboratory diagnostics](#) to [garbage disposal](#) to [public transit](#) to [food supply](#) and more): They have too many of their staff out with COVID. Thus, even if they have the physical capacity for production, they don't have the staff. A further complication: the (hopefully) soon-to-be-announced final winners of the Federal 500-million-test program. In light of all that, we are not changing our capacity estimates this week. We stand by the sad reality that we will see only small improvements in rapid test availability until mid to late February.

What Happened Last Week

The FDA issued one new EUA, 13 amendments to existing EUAs, and no new safety/policy communications in the last week:

- New EUAs (1):
 - Molecular Tests (1): Premier Medical Labs' [PMLS SARS-CoV-2 Assay](#)
- New Amendments to Existing EUAs (13):
 - Molecular Tests (5): PreciGenome FastPlex Triplex | George Washington Univ. rtPCR Test | Season Biomaterials AQ-TOP | KogeneBiotech | PowerChek | Roche cobas (Liat System)
 - Antigen Tests (6): Abbott BinaxNOW x ([Ag Self | Ag Card | Ag Card Home | Ag 2 Card | Ag 2 Card Home] | Roche/SD BioSensor At-Home
 - Flu/RSV Panels (2): Roche cobas (Liat System) | PerkinElmer PKAmp

New & Noteworthy

Eight At-Home Tests Per Person, Per Month Now (Mostly) Covered

Starting Saturday, January 15th, insurers and group health plans (GHPs) will be required to cover the cost of a limited volume of at-home tests - fulfilling a promise the Biden administration made back in [December](#). The [basics](#) of how it's going to work:

- Insurers and GHPs must cover up to 8 at-home tests per person, per month that are purchased without a health-care provider's order.
- Tests that health-care providers order are still covered - and don't count against the eight tests you can buy on your own.
- Insurers and GHPs are [incentivized](#) to set up systems to cover the costs up front, so folks don't have to submit receipts and claims.

The tricky bit is in that last line. Let's say your insurer or GHP has set things up so that if you buy your tests at Pharmacy X, you don't have to pay out of pocket. If you then go to Pharmacy Y and buy a test, your insurer/GHP is allowed to limit your reimbursement to \$12 per individual test (\$24 for a box of two). If your insurer/GHP *hasn't* set up a place where you can buy tests without paying out of pocket, then they have to reimburse the full price of a test, no matter where you buy it.

What We Know About the 500 Million Tests

Information about the Biden administration's planned distribution of half a billion tests to the American public is seeping out slowly. Here's what we know:

- [Website and logistics to be managed by the US Post Office](#)
- [First contracts signed for OTC rapid tests](#). Two contracts were awarded – one to Goldbelt Security for \$51 million (unclear how many tests) and another to Revival Health for 13.3 million tests. Both of these appear to be distributors, not test manufacturers, so we presume that these contracts are intended to kick-start the program with existing inventory.
- No word yet on winning manufacturers.

Curious George Goes to the Hospital

"Hospitalizations of US [children under 5](#) with COVID-19 soared in recent weeks to their highest level since the pandemic began," Time magazine reported. While the individual risk of severe disease remains low for these kiddos - many are [hospitalized for other reasons](#) and then diagnosed as COVID-positive on admission - it's still a worrisome trend.

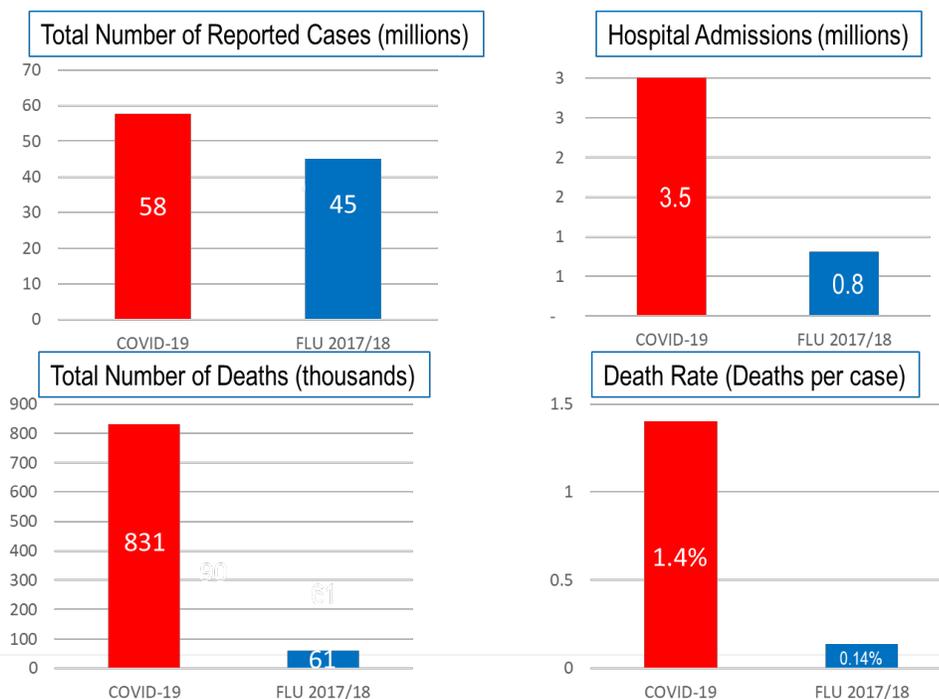
Separate but related - [Massachusetts and New York state have changed COVID related hospitalization reporting](#) to indicate whether COVID is primary or incidental: "for COVID" or "with COVID," respectively.

Real World Data Confirmation of Antigen Test Omicron Sensitivity (University of California)

A [medRxiv pre-print](#) compares BinaxNow to RTqPCR for 731 visitors to a San Francisco clinic on 3rd to 4th January 2022. 296 were positive (Ct <40) by PCR (40.5% test positivity), and a random sample of positives was sequenced and 97% were Omicron. Binax sensitivity was 95.2% for Ct < 30; 82.1% for Ct<35; and 65.2% for all PCR positives, i.e. Ct<40. This study appears to confirm antigen tests are less sensitive than PCR but will detect virtually all of those infectious with Omicron (Ct counts under 30).

Food for Thought

COVID-19 is not "just the Flu" (20 months, US only)



K-12 Round Up:

[Feds Counter Omicron Surge with Testing Surge for Schools](#)

The Biden Administration is doubling down on testing in K-12 schools. They're making five million free point-of-care rapid tests and five million free lab-based PCR tests available (states have to request the rapid tests; schools can access the PCR tests directly, through Operation Expanded Testing), and figuring out how surge testing units that are being deployed to high-risk and hard-hit communities can also support schools there. In addition, CDC and the US Department of Education "will work with states and outside organizations to help schools make connections to testing providers."

[Vermont Switches COVID-19 Testing, Tracing Tactics](#)

In the face of Omicron, [Vermont](#) has folded its surveillance-testing and contact-tracing cards and switched to another game. Officials explained that its previous tactics simply didn't move fast enough to make a difference in infection rates. So now, instead of undergoing weekly pooled PCR surveillance tests, students will receive rapid-antigen tests that they can use at home if they become symptomatic or (if they're unvaccinated) have contact with someone who tests positive. School nurses will use rapid tests to assess anyone in school with symptoms, but they will [no longer contact-trace](#); that burden now falls to families.

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	355	526
Antigen Central Lab Today	11	7	7	7	7
Antigen Total	326M	408M	454M	549M	724M
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	732M	907M

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