



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

516M	593M	631M	912M	1,017M
November 2021	December 2021	January 2022	February 2022	March 2022

Last week, we saw the yin and yang of manufacturers increasing commitments but struggling to keep up with orders. This week, the first manufacturer contracts for the government's initial 500 million free tests were issued. How does that impact capacity? The stated guidance in the Federal Test RFP is that capacity for the program be "new" capacity and not take away tests from other programs. In reality, this does not seem to be the case. The good news is that the first step of this national program has launched. The bad news is that there is competition (or at least overlap) between this Federal program and other state and school initiatives that want and need tests. The Federal program has succeeded in expanding test capacity especially in antigen self tests - but in the short term there is still a shortage of tests for retail and other uses.

We have included this additional capacity in our numbers - but this program has created more challenges in estimating capacity - so we expect to be adjusting in the coming weeks.

What Happened Last Week

The FDA issued one new EUA, 7 amendments to existing EUAs, and no new safety/policy communications in the last week:

- New EUAs (1):
 - Antigen Tests (1): [iHealth COVID-19 Antigen Rapid Test Pro](#)
- New Amendments to Existing EUAs (7):
 - Molecular Tests (6): SEASUN BIOMATERIALS (2) | DiaCarta QuantiVirus | Viracor Eurofins | Detect Covid-19 Test (Home) | Univ. Illinois covidSHIELD
 - Antigen Tests (1): PHASE Scientific INDICAID

New & Noteworthy

500 Once, 500 Twice

The Biden administration has doubled down on free tests for the public. Last Friday, they announced a commitment to provide [a second 500 million tests, for a total of 1 billion tests](#) to be mailed straight to American households. Right now, the feds are only prepared to deliver on the first 500M (as of last Friday, they had 420M under contract). No word yet on when the second 500M will be coming our way.

What We Know About the 500 Million Tests

- Americans can order up to four free rapid antigen tests per residential address on the official website, [COVIDTests.gov](#). The site opened January 18, one day earlier than expected. Tests will be delivered by the US Postal Service. (Pro tip - skip COVIDTests.gov and go straight to [special.usps.com/testkits](#) to order your tests).

- Folks who have trouble ordering can call the Postal Service for help at 1-800-ASK-USPS. Some [glitches](#) we've heard: Confusion over whether tests can be delivered to post-office boxes, and the system's inability to accept more than one delivery to apartment buildings.
- Tying access to free tests to internet access raises red flags regarding equity. The administration says they're launching a free hotline so that people can call in test orders. They're also working with "national and local organizations with deep experience serving communities of color, people living with disabilities, and other high-risk communities" to get the word out and help people order. In addition, 20% of these first 500 million will be dedicated to the most vulnerable communities.
- So who's making these tests? As we mentioned last week, the [tests that are going out right now](#) are coming from what we think are a few distributors' stockpiles. In addition, contracts were awarded to three manufacturers for 380 million tests, with the expected delivery date to the federal government for all tests of March 14, 2022:
 - iHealth - \$1.275 billion
 - SDBiosensor/Roche - \$340 million
 - Abbott BINAX - \$304 million
- Questions still to be answered:
 - Does the second 500 million get distributed in the same process as the first 500?
 - Can someone order from the first and second 500?

Food for Thought

You Can't Treat a Population the Same Way You'd Treat a Patient

An opinion piece in *The New York Times* by Dr. Aaron E. Carroll, chief health officer of Indiana University, resonated with us. The key point: Medicine works at the level of individuals. Public health works at the level of populations. The requirements at these levels are (or should be) [different](#). But here in the US, we've been handling a major-league public health event with responses based on requirements from medicine.

Examples:

- Emphasizing more-accurate PCR tests over faster and potentially more accessible rapid antigen tests, used frequently.
- Telling the public not to wear masks, because the highest-quality masks were in short supply - even though wearing any kind of mask at all would have been better than wearing no mask.
- People choosing not to vaccinate themselves or their children, because their individual risk is low - even though the only way to protect the entire population is to get enough individuals vaccinated.

Commentary: We've been facing a pandemic for nearly two years. It's time to start thinking in terms of public health, not just medicine.

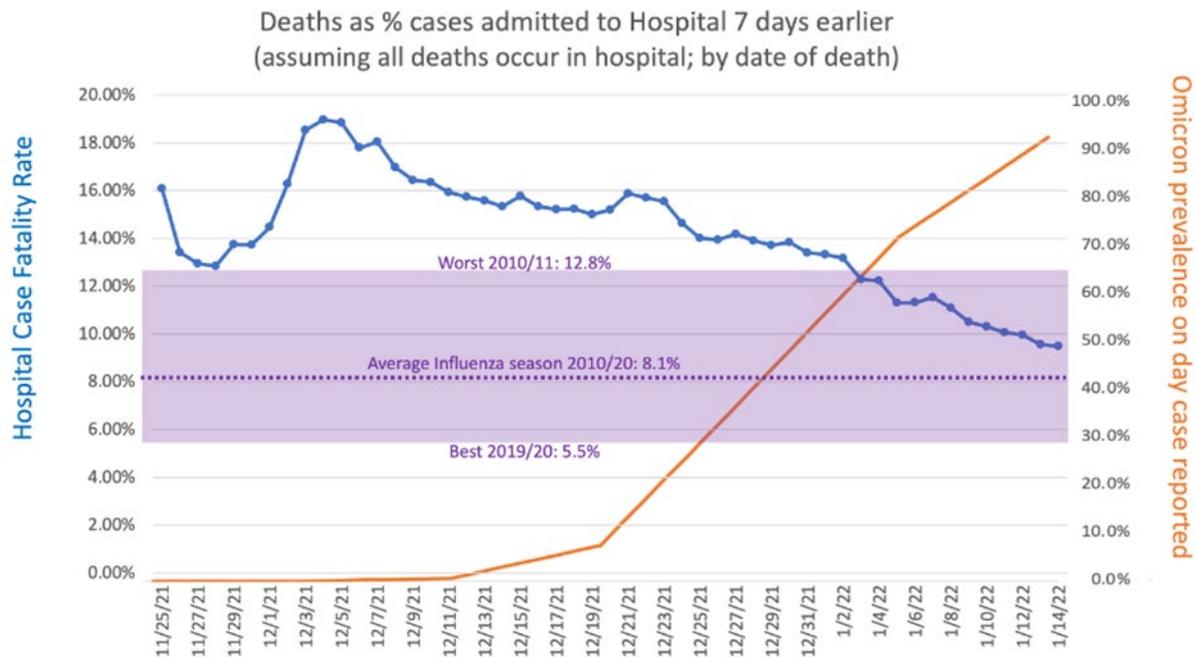
Is COVID-19 Approaching Influenza's Morbidity and Mortality?

Before we get started, we need to remember two important aspects of any comparison of COVID-19 to seasonal flu.

- #1 Seasonal flu is *not to be taken lightly*. On average, in the decade before COVID-19 (BCV), 10% of the US population caught influenza each year; 1.5% of those needed to be hospitalized; and 8% of those hospitalized died. In a "good" year, that meant 12,000 deaths; in a bad year - 61,000.
- #2 COVID-19 morbidity and mortality reflect the results of extraordinary precautions (lockdowns, masking, isolation). COVID has also been mitigated by a vaccine that's more effective - and has been taken by more people - than any we've had for the flu.

With those caveats, take a look at the chart below, based on analysis of CDC data for COVID/Omicron and flu.

- As of January 15, 19.1% of the US has *reported* a COVID case - close to 10% a year since the pandemic began - which is essentially equivalent to the BCoV flu. (However, current case counts are 750,000 a day and rising, far above flu.)
- *Hospitalization rates* declined from ~7% under Delta to ~3.5% with Omicron, but are still ~ 2.5x the flu average of 1.5%.
- *Overall case fatality rates* declined from ~1.5% under Delta to 0.45% with Omicron, but are still ~ 4x the flu average of 0.12%.
- *Hospital case fatality rate* for Omicron, at 9.5%, is still above the flu average of 8.1%. But this analysis includes both vaccinated and unvaccinated people. Multiple states and cities' analysis show that hospitalization case fatality rates are 10 to 15x higher for unvaccinated. That is consistent with the vaccinated having no greater risk of death from Omicron than they do from the flu.



A New and Deadly Threat: Hamsters

Okay, not really. But it's true that hamsters can get COVID-19. In Hong Kong, when the same strain of COVID-19 showed up in both a pet-shop worker and the shop's hamsters, health officials assumed that the hamsters were the spreaders and responded accordingly. All the hamsters at the shop were culled, and anyone who bought a hamster there from December 22 on were asked to turn their pet over for testing and then euthanasia. All this, despite the fact that no one is sure if people can catch COVID from hamsters - it seems just as likely that the hamsters got the virus from the pet-shop worker.

K-12 Round Up:

Burbio reported a new high for school disruptions this week: 6,273 vs. 5,513 the previous week.

Children's Hospital of Philadelphia [changed its COVID-19 guidelines](#) for schools and now recommends discontinuing required weekly surveillance testing of asymptomatic students and staff. Instead, they recommend offering "voluntary participation in weekly testing during periods of high community transmission for those with personal health concerns . . . or family health risk concerns." This follows last week's announcement that [Vermont](#) is also discontinuing weekly asymptomatic screening. Other states are showing increased surveillance, screening, and diagnostic testing. Will be interesting to see which way school testing goes.

We are hearing that schools need more guidance on how testing can and should work most efficiently. To help answer those questions, the US Department of Education is hosting educational sessions on the next three Fridays for schools to hear from districts that are testing, and to get their answers in real time. To register go [here](#).

Latest Monthly Capacity Estimates

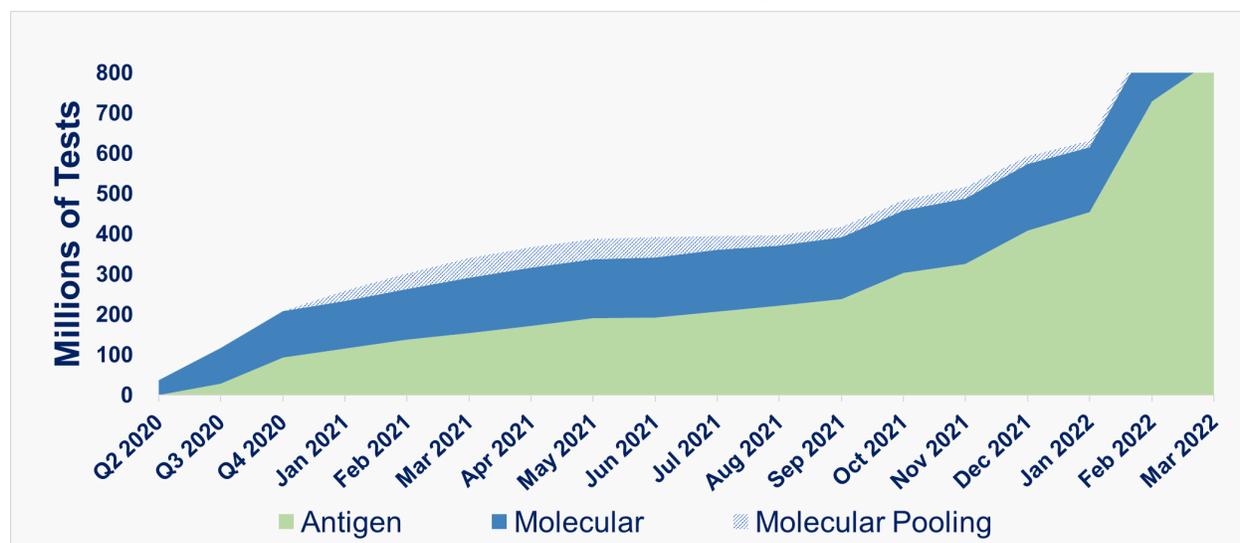
Estimated Monthly Capacity of All Tests (M)

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	636
Antigen Central Lab Today	11	7	7	7	7
Antigen Total	326M	408M	454M	729M	834M

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	1,017M
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Manufacturing Capacity by Test Type Over Time



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