



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

624M	904M	814M	734M	706M
January 2022	February 2022	March 2022	April 2022	May 2022

No update this week.

What Happened Last Week

The FDA issued one new EUA, 12 amendments to existing EUAs, and two new safety/policy communications in the past week:

- New EUAs (1):
 - Molecular: MicroGem POC (EUA granted on April 14th). Notable as it is the first saliva based POC system with results in less than 30 minutes.
- New Amendments to Existing EUAs (12):
 - Molecular Tests (9): Audere | BGI Genomics | BioFire Dx | Cepheid | Cue Health | Detect | Exact Sciences | LGC Biosearch Technologies | PlexBio
 - Antigen Tests (3): ACON | OSANG | SD Biosensor
- Safety Updates (2):
 - [Celltrion recalled](#) 300,000+ DiaTrust COVID-19 Antigen Rapid Point of Care Tests, as according to the FDA, the test was potentially distributed to unauthorized users. This DiaTrust POC test was granted an EUA in April 2021 for use in CLIA-certified laboratories.
 - The FDA issued a statement on [counterfeit COVID tests](#) - the dangers therein and hot to spot them - including photographs of the real vs fake tests. The two tests noted where counterfeits have been found are the ACON FlowFlex and iHealth Home Tests.

New & Noteworthy

Yes, antigen tests identify most contagious folks - here's more data

If you've been on the "antigen tests may not identify all COVID cases, but they find the ones that matter" bandwagon, you've probably seen some recent reports that have made you happy. A [comparison](#) of RT-PCR, antigen, and viral culture tests from CDC scientists (JAMA; 225 cases; same-day samples; pre-Omicron) found that antigen tests were 84% sensitive compared with culture - the gold standard for contagiousness. A Nature Microbiology paper got even more concordant results - in that study, antigen tests were 93% as sensitive as cell culture.

South Africa: Superstar of variant surveillance

Since 2021, South African scientists have been the first to identify emerging variants that have had a global impact, dramatically aiding other countries to prepare for emerging waves of infection. As a recently posted overview shows, the [surveillance efforts across Africa](#) are significantly more diverse and

systematic than those in the US, despite the fact that sequencing resources are so much greater here. Commentary: Kudos to African scientists in general, and South Africa's in particular. They have done the world a tremendous service. We hope that our nation can take some pages from their book to improve variant surveillance and reporting in and from our country.

Omicron's predecessors (Alpha & Delta) had double the viral load

A cautionary note sounded by a study of 3 million positive cases in the UK showing that sampled viral load varies between variants – Omicron BA.1 and BA.2 positive cases had ½ the average viral load of the Alpha and Delta variants. Commentary: This probably reflects more the amount of virus available to sample from the nose, rather than any absolute difference in the amount of virus present in the patient. Test manufacturers have to remain vigilant to ensure sampling methodologies remain effective, in addition to ensuring that mutations do not evade their tests.

Omicron's successor sub-variants are speedier, but not nastier (so far)

Just a few short weeks ago we were all shocked by the speed with which Omicron (BA.1) usurped Delta's lead role worldwide. Since then, we've seen Omicron's ever-more-transmissible offspring take over the universe:

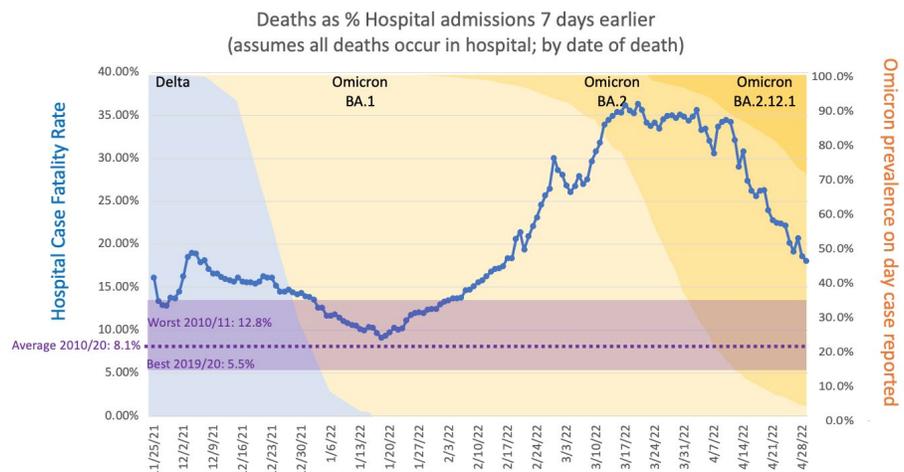
- BA.2 has come to account for 95% of the world's sequenced cases.
- BA.2's sub-variant BA.2.12.1 is now responsible for 38% for all US sequenced cases (62% of sequenced cases in New York).
- Variants BA.4 and BA.5 were identified first in [South Africa](#) (South African surveillance FTW again), and now BA.4 is being found in the US and Europe. Both variants substantially escape antibodies generated by either Omicron BA.1 infection or vaccination (although vaccination + infection combined win out here, with 5x less immune escape).

In spite of all of Omicron's efforts, the good news is that the case fatality rate of patients admitted to US hospitals is declining. See chart to the right.

China reports data on deaths

Mainland China's lockdown in 2020 was very successful at containing COVID mortality, however it is seemingly struggling in the face of a BA.2 surge - particularly among a relatively unvaccinated and

immune-naïve older population. Case fatality rate statistics [released by China](#) appear to show continued low mortality, leading [observers](#) to question their completeness: mainland China has reported [5,112 COVID deaths](#) since the beginning of the pandemic, of which ~600 occurred in the past three months. Commentary: By comparison: Hong Kong reported 213 COVID deaths in the first two years of the pandemic but has recorded 7,900 deaths in the past three months of Omicron. Given the mainland has 186x the population of Hong Kong, if Hong Kong's experience was typical of all China, total deaths from Omicron in 2022 would be ~1.5 million.



Food for Thought

Lancet commission aims to increase access to diagnostics

Last October, [The Lancet Commission on Diagnostics: Transforming Access to Diagnostics](#) provided 10 recommendations to improve access to and adoption of diagnostic tests in low- and middle-income countries (LMICs). Now [360Dx reports](#) that next year the Commission plans to launch “an international diagnostics alliance” to put those recommendations into practice. Commentary: This is good news and great to see diagnostics (COVID and beyond) become a priority. We understand the global consortiums

take a long time to come together and get funded - but the pace in which this is happening seems to be frustratingly slow.

K-12 Roundup

Schools are acknowledging that ventilation matters

One thing that COVID has taught us is that air quality matters a great deal for both individual and public health. At least half of the schools in the country have learned that lesson too - Burbio [reports](#) that 50% of US schools are using at least some of their ESSER III money on “HVAC and other initiatives to improve ventilation.”

The Good News is...

Regular boosters are effective at preventing severe disease

A [recent report](#) on the ongoing Israeli booster program using Pfizer/BNT mRNA vaccine showed that those who received boosters every four to six months saw a 50% reduction in mechanical ventilation and death from Omicron.

Latest Monthly Capacity Estimates

Test Type	Nov '21	Dec '21	Jan '22	Feb '22	Mar '22	April '22	May '22
ANTIGEN							
Antigen Professional + Point of Care EUA	174	185	187	187	181	165	156
Antigen OTC: Home/Self EUA	141	216	260	535	462	418	422
Antigen Total	315M	401M	447M	722M	643M	583M	578M
MOLECULAR							
Molecular Professional, Point of Care, OTC EUA	32	36	36	36	34	33	32
Lab Based PCR	130	130	125	130	124	108	90
Add'l Lab Based PCR with Pooling	29	20	16	16	12	11	7
Molecular Total	190M	185M	177M	182M	171M	151M	128M
Total Test Capacity	505M	586M	624M	904M	814M	734M	706M

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