



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

814M	734M	706M	614M	518M
March 2022	April 2022	May 2022	June 2022	July 2022

No changes to capacity this week.

What Happened Last Week

The FDA issued no new EUAs and seven amendments to existing EUAs in the last week:

- New Amendments to Existing EUAs (7):
 - Molecular (3): Helix Opco | BD Max | Bioeksen R&D
 - Antigen Tests (4): Osang OHC | Ellume | ACON Flowflex | SD Biosensor

New & Noteworthy

Whether workplaces can require testing depends on pandemic situation

Last week the US Equal Employment Opportunity Commission (EEOC) updated its [guidance on mandatory screening testing for COVID](#), saying that such a requirement is only allowed if “it is job-related and consistent with business necessity.” While that may sound like a bit of a death knell for mandatory testing in the workplace, it isn’t. That’s because, according to EEOC, whether such screening is a “business necessity” depends on what’s going on with the pandemic at the time - and, critically, what the CDC, FDA, and/or state or local public health authorities are recommending. The new guidance also includes a warning that those recommendations will change over time.

Commentary: Kudos to EEOC for acknowledging that the COVID landscape is still in flux, and for setting up a guideline that explicitly follows public health guidance.

Pandemic to Date Test Review: What’s New

Testing Commons has tracked everything COVID testing since the early days when there were just a handful of tests available. Today there are more than 450 tests with EUAs in the US, 1,100 with a CE Mark in Europe, and about 1,000 on the market or in development elsewhere in the world. Our [Testing Commons Pandemic Test Review Report](#) tracks test evolution from PCR to antibody tests, and now to antigen self-testing.

EUA activity slowed in 2022, with 32 new EUAs in the first half of the year vs. 86 last year. The vast majority of this year's authorizations have been over-the-counter self-testing: primarily antigen tests, plus three molecular (isothermal) tests (see page 9). The FDA added two new categories in 2022 (see page 22) with the first official approvals for breath analysis and for genotypic lineage identification. On the other side of the ledger, the FDA issued 32 warning letters to companies for false COVID-related claims and revoked a further 16 EUAs.

Food for Thought

How long do virus-carrying aerosols hang out? Long enough to be a problem.

Folks, #COVIDisAirborne. You know it, we know it. A [recent study](#) in PNAS significantly advances what we know about how well virus-carrying aerosols persist under real-world conditions, and the news isn't great.

The shock of leaving the warm, humid environment inside the human respiratory tract kills 50-60% of the virus immediately, with a further 30% dying in the next 20 minutes. So far, so fantastic. Unfortunately, the starting number of particles is so enormous ([76,200 per minute per person in the gym](#), and 580 particles per minute at rest) that the 10% remaining are more than adequate for transmission, and in humidity- and temperature-stabilized indoor spaces they are remarkably long-lived and infectious. A [commentary](#) in the same issue of PNAS summarizes the complex issues that determine whether person-to-person transmission actually occurs.

Omicron's superpower: immune escape from nearly all mAbs except one

Omicron BA.5 is outcompeting all other variants wherever it is present - in the US, CDC reports that it now accounts for [77.9% sequenced cases](#). Why? Because BA.5 includes mutations that all but eliminate the ability of neutralizing antibodies to block infection - including almost all monoclonal antibodies (mAbs).

A [recent letter](#) in The Lancet Infectious Disease reports the comparative effectiveness of 11 mAb therapies against BA.5 and eight other variants, and only Lilly's bebtelovimab has a fighting chance against Bad Boy 5. No other mAb comes close - it's ~100x more effective than the Evusheld cocktail, and ~200x more effective than sotrovimab. Currently bebtelovimab is only just becoming available in the US (it's not yet approved elsewhere), emphasizing the enormous acceleration we require in therapy development and approvals if we are to keep up with SARS-CoV-2 ([see supporting commentary](#)).

The Good News Is...

Better masks are on the way

Where are my glasses-wearing compatriots in the crowd? You know how it is - you put on your mask and enter an air-conditioned building, and you get The Fog. Well, things may be about to improve for us glasses-wearers - and for everyone else who would love for masks to be a little more comfortable, reusable, better fitting, and effective.

WebMD News reported last week on the 10 [finalists](#) in the Mask Innovation Challenge, being run by the Biomedical Advanced Research and Development Authority (BARDA) at the Department of Health and Human Services (HHS). As a group, the finalists bring options like origami-based designs for better fit, ranges of mask sizes, clear and semi-transparent materials, nose bridge variations, different levels of filters, and other innovations to the table. BARDA will choose the winners in September, but some, like Airigami's Air99 and Air Flo Labs' Flo Mask Pro, are already on the market. Can't wait.

Latest Monthly Capacity Estimates

Estimated Monthly Capacity of All Tests (M)

Test Type	Mar '22	April '22	May '22	June '22	July '22
ANTIGEN					
Antigen Professional + Point of Care EUA	181	165	156	131	105
Antigen OTC: Home/Self EUA	462	418	422	380	320
Antigen Total	643M	583M	578M	511M	425M

MOLECULAR					
Molecular Professional, Point of Care, OTC EUA	34	33	32	30	28
Lab Based PCR	124	108	90	68	62
Add'l Lab Based PCR with Pooling	12	11	7	5	4
Molecular Total	171M	151M	128M	103M	93M

Total Test Capacity	814M	734M	706M	614M	518M
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