



# Tracking US Coronavirus Testing Capacity

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## Updated Monthly Capacity Numbers: Current EUA's

<b>814M</b>	<b>734M</b>	<b>706M</b>	<b>614M</b>	<b>518M</b>
March 2022	April 2022	May 2022	June 2022	July 2022

Over the last month, we and many others have been talking about the need to renew funding for COVID tests. Unfortunately, after months of no movement, businesses are now working under the assumption that no additional government funding will be forthcoming and are beginning to take action. This week, multiple companies announced [layoffs and closures](#) - in whole or in part due to weakened COVID test demand - including [Cue](#), [PerkinElmer](#), and [Siemens](#). We expect more test manufacturers and labs to take similar actions in the near future and have therefore decreased our estimates for test capacity in July.

## What Happened Last Week

The FDA issued no new EUAs, nine amendments to existing EUAs, and no new safety/policy communications in the past week:

- Amendments to Existing EUA's (9):
  - Molecular (1): LabCorp
  - Antigen (7): ACON Flowflex | MaximBio ClearDetect | Celltrion Diatrust | iHealth Labs | Quidel QuickVue | Phase INDICAID | Siemens CLINITEST
  - Flu/RSV Panels (1): Abbott Alinity

## New & Noteworthy

*Are we heading for an Omicron BA.4/BA.5 surge? Mixed signals...*

We have been living with Omicron for six months now - longer than any other variant except the original wild type. How do we assess the risk going forward as Omicron sub-variants emerge?

Commentary: We no longer have accurate case counts, but our best estimate is that current Omicron infections are running at least ~700,000 cases per day (reported: 109,000). CDC reports that together, BA.4 and BA.5 now dominate in the US, with a combined 52% of [sequenced cases](#) (16% and 36% respectively). These two sub-variants share identical spike proteins, but BA.5 is outcompeting BA.4 globally: Europe's [upswing in hospitalization](#) is driven primarily by BA.5, and the [UK Health Security Agency](#) observes that BA.5 is more transmissible than BA.4, with a ~23% transmissibility advantage over the BA.2 variants. Thus far there is no evidence that BA.5 is more pathogenic (current levels of immunity may be helping here), and vaccines remain effective against severe disease (although not against infection). For a more complete BA.5 review see Eric Topol's always excellent [Ground Truths blog](#) on this subject.

### *Serving the underserved: Filling critical need for testing*

The Rockefeller Foundation, through its public charity, RFCC, is [expanding](#) its Project ACT ([Access COVID Tests](#)) to enable all states to deliver tests to households in at-risk and underserved communities.

Five states are currently active in the program: Kansas, Maine, Michigan, North Carolina and New Mexico. It is now open for any state to consider participating. During Project ACT's [initial stage](#), Rockefeller invested \$7.5 million to purchase and deliver one million tests. Note: Mara is involved with Project ACT.

### *Even more data, this time in kids: Antigen tests detect the infectious*

Last week we covered a [paper](#) documenting one antigen test's 96% sensitivity when viral culture was used as the standard. The samples in that paper came from adults (ages 18 - 96, with a median of 38). This week we noticed a [preprint](#) out of the University of Florida with essentially the same outcome, but its samples came from kids ages 0 - 16 and were all Omicron BA.1.

The results: 100% concordance between viral culture and the antigen test used (BinaxNOW). Granted, this was a very small study (31 kids total, and the samples from only 21 were cultured), but still - it's yet another tidbit of data backing up the idea that antigen tests detect the infectious. Oh, and by the way, two thirds of the kiddos were still testing positive on Day 5 after symptom onset.

### *Monkeypox: Not official emergency worldwide; US testing expanding*

Global News: The [World Health Organization has decided](#) that monkeypox is not a global emergency at this time. (Interestingly, the announcement implied that the decision wasn't unanimous.) WHO did note the need to "closely monitor" the growing number of cases, and also acknowledged an uncomfortable truth - monkeypox has been endemic in Africa for years - with the implication that the disease has gained worldwide attention now because of its move into Europe and the US.

US News: The CDC will [expand monkeypox testing](#) by distributing tests to five large commercial laboratories. Commentary: We are pleased to hear this, especially if the decision came as a result of a lesson learned from the early days of COVID, when the CDC was more reluctant to involve commercial labs in testing. Separately, the US will distribute 1.6 million doses of monkeypox vaccine this year.

## **Food for Thought**

### *Are we neglecting T cells in the war against COVID-19?*

The human immune system is a complex and dynamic system, with both humoral (antibody) and cellular participants. T cells are the essential factor for fighting COVID over the longer term, but researchers watching our immune responses to new variants have mostly neglected them. Instead, they've focused intensely on the neutralizing antibody response, which can prevent initial infection by competitively blocking the virus from entering a cell: Antibodies are the gold standard "correlate of protection."

Logistically speaking, there's a good reason for that neglect. T cells are challenging to assess. Because they do their work in tissue (especially the lymphoid organs), they're essentially hidden from our view, which depends almost completely on serum testing.

Together, two recent papers cover both the easier-to-research humoral response and the complex interacting elements of the immune cell response. "The humoral response and antibodies against SARS-CoV-2 infection," a comprehensive review of the topic, appears in [Nature Immunology](#). As we now know, the Omicron family effectively [evades antibodies](#) derived from exposure (whether via vaccine or infection) to prior variants, and yet exposed individuals continue to be protected from serious disease. Are re-awakened T (and B) memory cells the reason?

A recent *Cell* [paper](#) looks at the cellular side of the story. Its conclusion: Antibody levels wane in folks who received mRNA vaccines, "but memory T and B cells are comparatively stable."

*The Good News Is...*

*In their first year, COVID vaccines prevented nearly 20 million deaths*

While we wish the COVID vaccines could have reached more people more quickly, they are still a stunning success story. A recent Lancet [article](#) quantified that success: During the first year that they were available, researchers estimate that they saved nearly 20 million lives worldwide.

## Latest Monthly Capacity Estimates

Test Type	Mar '22	April '22	May '22	June '22	July '22
<b>ANTIGEN</b>					
Antigen Professional + Point of Care EUA	181	165	156	131	105
Antigen OTC: Home/Self EUA	462	418	422	380	320
<b>Antigen Total</b>	<b>643M</b>	<b>583M</b>	<b>578M</b>	<b>511M</b>	<b>425M</b>
<b>MOLECULAR</b>					
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
<b>Molecular Total</b>	<b>171M</b>	<b>151M</b>	<b>128M</b>	<b>103M</b>	<b>93M</b>
<b>Total Test Capacity</b>	<b>814M</b>	<b>734M</b>	<b>706M</b>	<b>614M</b>	<b>518M</b>

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