



# Tracking US Coronavirus Testing Capacity

VOLUME 5, ISSUE 7

June 8, 2022

## Updated Monthly Capacity Numbers: Current EUA's

<b>904M</b>	<b>814M</b>	<b>734M</b>	<b>706M</b>	<b>668M</b>
February 2022	March 2022	April 2022	May 2022	June 2022

*No changes in the capacity estimates this week, but the recent surge has created a quagmire for manufacturers. On one hand, there is broad acknowledgement that COVID will never go away. On the other hand, broad testing/screening programs have declined. A year ago, gatherings required vaccination. Omicron changed that, with breakthrough infections becoming common. Six months ago, gatherings required testing. Today, gatherings are "join us at your own risk." Modeling future test demand has become even more difficult.*

## What Happened Last Week

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

- New EUAs (2):
  - Molecular (1): [DxLab, Inc.](#)
  - Serology (1): [LG Chem Ltd AdvanSure SARS-CoV-2 IgG\(RBD\) ELISA](#)
- New Amendments to Existing EUAs (9):
  - Molecular Tests (4): BioFire Defense (2) | MiraDx | UCSD Excite | Broad Institute
  - Antigen Tests (4): InBios SCoV-2 Ag Detect Rapid (2) | QIAGEN QIAreach | Xiamen Boson Biotech OTC
  - Serology (1): Abbott IgG

## New & Noteworthy

### *Omicron variants BA.4 and BA.5: The next Big Bad?*

We don't yet know how these sub-variants will affect the US, where so many have been infected with other versions of Omicron. That said, the data that's starting to come out is [concerning](#) - according to Trevor Bedford at the Fred Hutchinson Cancer Research Center, current US trends indicate that they're going to out-compete even BA.2.12.1, the most transmissible sub-variant yet. Here's why that matters.

Omicron BA.1, which kicked Delta to the curb, introduced more novel mutations in the spike protein than any prior variant - 12 in the critical receptor binding domain alone. This dramatically reduced the neutralizing effect of both natural and therapeutic antibodies, driving up the reinfection risk and driving down the value of antibody treatment. That decline is continuing, albeit less drastically, with BA.4 and BA.5 - only [Lilly's bebtelovimab](#) remains effective.

Most worrisome, BA.4 and BA.5 have additional mutations that appear to increase both transmissibility and pathogenicity - particularly the [L452R](#) mutation. L452R, present in Delta, appears to be the mutation that leads to damaged alveoli in the deep lung and raises the risk of greater pathogenicity -

especially among immunocompromised and older individuals. The only good news here is that both PCR and antigen tests should still function effectively. (See next article.)

### *The tests and their tricks still work, even with Omicron*

The evolution of the SARS-CoV-2 virus hasn't done us a lot of favors along the way, but a couple of small ones have persisted through Omicron.

The first involves the spike protein H69/V70 deletion that causes S Gene Target Failure (SGTF). With each new dominant variant, this deletion has appeared, disappeared, and appeared again. When present, it allows quick and dirty variant detection through PCR without full sequencing. Alpha had SGTF, but Delta did not. Omicron BA.1 had it, but BA.2 and BA.2.12.1 do not. Now BA.4 and BA.5 have it again, allowing their presence to be monitored in an inexpensive way.

The second: None of the Omicron sub-variants have significant mutations in the N gene's key epitopes, so antigen tests remain viable. Commentary: While we know this in practice, it would be useful if manufacturers would publish data confirming it.

### *If masks work, then why didn't mandates?*

A recent NY Times [article](#) caught our eye - contrasting the data on whether masking helps decrease COVID transmission (it clearly does) with the data on whether mask mandates helped decrease COVID rates during the Omicron wave (it's not at all clear that they did).

Wait, what? Yup - counterintuitive, but in the US, at least, that appears to have been the case during the Omicron wave. Why? The author suggests a reason that makes COVID sense: With a variant as transmissible as Omicron, all you need is a few folks without masks to spread infection. Commentary: Our view continues to be that on the national level, the decision has been made to prioritize individual choice over public health. If you are concerned about COVID - wear a mask. It won't protect you perfectly, but it will help. Don't rely on others.

## **Food for Thought**

### *Lessons Learned: Testing Edition #12*

#### *Sometimes we need more testing fast.*

In the earliest days of the pandemic, the nation needed a vast increase in testing capacity, and we needed it yesterday. In hopes of being able to do a better job of ramping up capacity the next time around, the CDC recently signed a [memorandum of understanding](#) with an alphabet soup of lab-industry organizations. The upshot - when a public health emergency hits, the government can't go it alone. It takes a public-private partnership to provide the necessary testing capacity quickly enough to make a difference. (See next article.)

#### *Do we need more testing fast for monkeypox?*

While monkeypox ain't no COVID-19, it's still a big outbreak. And [not enough testing](#) is happening in order for the US to track and contain it, according to clinicians and researchers interviewed by STAT News. Commentary: While monkeypox doesn't necessarily require the same kind of full court press that COVID did, now would still seem to be the time for the CDC to take at least a bit of its own advice. (See previous article if you haven't already.)

#### *Wait a minute... "Cases understated by 31 fold"... can this be true?*

We all know that case counts for Omicron are understatements, due to lack of reporting of home tests - the only question is how much of an understatement they are. Readers of last week's Newsletter read our discussion of the array of estimates for this number, which highlighted a [WSJ](#) article (their guess is ~10x). In that article, we also name-checked a City University of New York (CUNY) study claiming that cases are actually undercounted by 31x, at least for New York City.

Commentary: We have now analyzed the CUNY [preprint](#) and are not convinced. Their conclusion was based on an automated voice-response and/or text survey of a representative sample of 1,030 people, carried out by a commercial survey [company](#) over the course of two days in early May 2022. According to the paper, 22% of respondents reported a positive result in the prior two weeks.

Extrapolating to the NYC population, this would be 1.5 million cases versus the 49,523 cases reported, hence the 31x headline. However, an alternative interpretation of the survey's own data would be to compare the survey respondents who had physician/clinic-confirmed (and likely reported) cases to all other cases – which would imply only a 1.5x undercount. Statistically valid extrapolations can be drawn from a 1,030-sample *if and only if* there is no bias in those who choose to respond vs. those who refuse to respond. Unfortunately, it is highly likely that those with recent experience of COVID are more likely to respond, invalidating extrapolating to the overall NYC population.

So, what do we believe? As we've said before, based on likely positive rates against the number of home tests distributed we believe the true undercount to be 5 to 7x - so with published cases running at 108,000/day, we believe the true current number is 540,000 to 750,000 cases per day.

*The Good News is...*

*For sniffer dogs, anything is paw-sible*

The data on [COVID-sniffing dogs](#) gets better and better. In a [prospective blinded study](#) in Paris, trained canines were doggone impressive, with a sensitivity of 97% (100% in asymptomatic people) and specificity of 91% (94% in asymptomatics) in comparison to PCR. Training the dogs (all of whom had prior odor-detection training) took between three and eight weeks.

## Latest Monthly Capacity Estimates

Test Type	Dec '21	Jan '22	Feb '22	Mar '22	April '22	May '22	June '22
<b>ANTIGEN</b>							
Antigen Professional + Point of Care EUA	185	187	187	181	165	156	143
Antigen OTC: Home/Self EUA	216	260	535	462	418	422	402
<b>Antigen Total</b>	<b>401M</b>	<b>447M</b>	<b>722M</b>	<b>643M</b>	<b>583M</b>	<b>578M</b>	<b>545M</b>
<b>MOLECULAR</b>							
Molecular Professional, Point of Care, OTC EUA	36	36	36	34	33	32	31
Lab Based PCR	130	125	130	124	108	90	85
Add'l Lab Based PCR with Pooling	20	16	16	12	11	7	6
<b>Molecular Total</b>	<b>185M</b>	<b>177M</b>	<b>182M</b>	<b>171M</b>	<b>151M</b>	<b>128M</b>	<b>123M</b>
<b>Total Test Capacity</b>	<b>586M</b>	<b>624M</b>	<b>904M</b>	<b>814M</b>	<b>734M</b>	<b>706M</b>	<b>668M</b>

<b>Editors</b>	Mara G. Aspinall, Arizona State University Liz Ruark, DVM, COVID-19 Response Advisors
<b>Contributors</b>	Sarah Igoe, MD, Arizona State University Simon Johnson, PhD, Massachusetts Institute of Technology
<b>Designer</b>	Grace Gegenheimer, Health Catalysts Group
<b>Technology</b>	Casey Miller, Health Catalysts Group

*Based on published reports, company interviews, and proprietary analysis.  
Content and commentary represents the views of the editors alone and not their organizations.  
A collaboration between Health Catalysts Group & COVID-19 Response Advisors.  
[www.healthcatalysts.com](http://www.healthcatalysts.com) & [www.covidresponseadvisors.org](http://www.covidresponseadvisors.org)*