



# Tracking US Coronavirus Testing Capacity

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## 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

*Challenging forecasting the future at this moment. The public companies that announced their Q1 COVID numbers - saw substantial increases and strong growth since last year. But all commented that the second half is either likely to be significantly lower or so hard to predict that they don't want to guess. We therefore took a conservative view with continued reductions in future capacity. With this volatile environment, the primary determinant will be whether there will be large Federal and State bulk purchases in the next six months.*

## What Happened Last Week

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

- New Amendments to Existing EUAs (6):
  - Molecular Tests (2): Quidel Solana | Detect, Inc.
  - Antigen Tests (4): Oceanit ASSURE-100 | Xiamen | Abbott BinaxNOW Self Test | PHASE Scientific INDICAID
- Safety Updates (3):
  - [Skippack Medical](#) Antigen Rapid Test (Colloidal Gold) – not authorized in US | [Mesa Biotech](#) PCR Accula Test Recall | [FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals](#)

## New & Noteworthy

*A respiratory disease self-test - the start of the wave of the future?*

As we move toward this fall's likely surge of respiratory diseases, the ability to empower individuals to perform their own differential diagnosis could be very valuable. This week Lucira received a [CE-IVD](#) for their combined COVID/Influenza A&B single-use molecular self-test. Commentary: We hope and believe that there will be more of these to come - the question will be whether the FDA will be willing to authorize these types of tests for home use either with or without a doctor's prescription.

*Find the variant, skip the sequencing*

If sequencing can do it, so can PCR - according to this [paper](#) from the Journal of Molecular Diagnostics, which describes how to develop multiplexed tailored primers and probes to identify known variants. The technique is much cheaper and quicker than sequencing and is similar to an approach used by some other PCR vendors, but broader. Of course, with PCR you have to know what you are looking for before you can find it, and sequencing will always be the technique to discover novel mutations in old and new variants.

## *FDA wastewater testing program*

### *The birth of a true nationwide wastewater program?*

The FDA has received funding to establish a [nationwide wastewater sequencing program](#) through public health laboratories for the balance of 2022. The program will provide common sampling protocols, an analysis pipeline to collate inputs, and a central depository of results. With the rise of self-testing (which has caused severe under-reporting of test results, making clinical testing data unreliable for surveillance purposes), wastewater testing has become even more important. In addition, as we have previously reported, wastewater data tends to anticipate clinical testing data by two weeks. As of now, only eight states and 879 samples are currently being reported, so this program is urgently needed.

## **Food for Thought**

### *Is T cell immunity the key...*

Our immune system's protection against COVID-19 relies on a layered approach - a quick but rather indiscriminate counterattack by NK (natural killer) cells, followed by helper CD4+T cells stimulating B cells to produce neutralizing antibodies, and then a seek-and-destroy mission by CD8+T cytotoxic cells.

We know a lot about neutralizing antibodies and how they can prevent detectable infection altogether, but SARS-CoV-2 has been very successful at evolving to evade them (e.g., strong Omicron BA.4 / BA.5 immune [escape](#) and MAb [evasion](#)); and in any case, they wane after three or four months. We can see that protection against severe disease lasts longer than that, but how exactly the entire immune orchestra functions are an enigma. Some believe that the residual levels of these antibodies are enough to protect against severe disease. Others believe it is the CD8+T cell system (which takes longer to [develop](#) but [persists](#)) that provides severe disease protection. Commentary: We clearly do not know enough about how the orchestra functions after the initial overture of antibodies is over. After the antibodies' work is done, all immune elements are so intricately intertwined that teasing out what matters most has been an insurmountable challenge thus far. For example, why do vaccines designed against the ancestral strain continue to protect against severe disease caused by Omicron, even though they only generate about 1/10 of the neutralizing antibodies against Omicron that they did against the wild type? Is even that smaller amount enough? Is a vaccine-induced T-cell response doing the trick?

### *... to pan-variant vaccines?*

A recent perspective in [Nature Immunology](#) emphasizes that we need to identify which part each instrument in the orchestra is playing if we are to design better vaccines against emerging variants, including ones that provoke the T-cell system into taking a stronger role. Commentary: Diagnostics should play a key role here, and there is much to be done. We have many tests that detect antibodies, but very few tests that quantify virus-specific T-cell presence and effectiveness (ELISpot is the dominant technique, and it is expensive, slow, and indirect). As a result, Mara co-signed a [letter](#) to Robert Califf and Peter Marks at the FDA to emphasize just how important and urgent it is to undertake this work.

### *The Bad News is...*

#### *Collateral COVID damage: Childhood vaccinations*

While we hope not to make this a regular feature, we felt compelled to talk about some real Bad News. Childhood vaccination rates are decreasing globally, in large part due to COVID-related disruptions in routine medical care. In a frightening example of the repercussions these disruptions are now having, Unicef is now reporting an 80% increase in measles cases around the world.

In the US, the [CDC reported a 7% decrease](#) in non-COVID vaccines orders in 2021. (2020 was down 15%, much of which was due to the temporary closure of medical offices.) Commentary: The idea that COVID vaccine fears could create a vaccine backlash that risks the re-emergence of deadly preventable childhood diseases is terrifying. It could be one of the worst consequences of the politicization of the pandemic.

The Good News is...

### Operatic breathing improves Long COVID symptoms

In a study recently published in [The Lancet Respiratory Medicine](#), Long COVID patients suffering from breathlessness +/- anxiety were randomly assigned either to "usual care" or to a free online course on breathing techniques taught by singers from the English National Opera. Participants in the breathing course saw significant improvement both in feelings of breathlessness and in mental health. Metropolitan Opera singers, take note.

## 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>

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