Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

904M	814M	734M	706M	668M
February 2022	March 2022	April 2022	May 2022	June 2022

No changes in the capacity estimates this week.

What Happened Last Week

The FDA issued five new EUAs, eight amendments to existing EUAs, and five new safety/policy communications in the past two weeks:

- New EUAs (5):
  - Molecular (2): Abbott IDNOW 2.0 | Nexus Medical Labs
  - Flu/RSV Panels (3): Cepheid Xpert Xpress CoV-2 plus | Labcorp Seasonal Respiratory Virus RT-PCR Test | Labcorp Seasonal Respiratory Virus RT-PCR DTC Test
- New Amendments to Existing EUAs (8):
  - Molecular Tests (1): Thermo Fisher TaqPath
  - Antigen Tests (7): Abbott BinaxNOW Home Test | AccessBio CareStart Home Test | PHASE Scientific INDICAID (2) | Celltrion DiaTrust | Siemens Atellica IM Ag | Siemens ADVIA Ag
- Safety Updates (5):
  - Recalls (3): Skippack Medical Lab COVID-19 Direct Antigen Rapid Tests | Woodside Acquisitions Recalls Two COVID-19 Rapid Antigen Tests [1. Woodside Acquisitions Inc Oral Rapid SARS-CoV-2 Antigen Rapid Test Kit; 2. Joysbio SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)]
  - Vaccine Updates (1): FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children 5 through 11 Years
  - Treatment Updates (1): FDA Authorizes Shelf-Life Extension for Sotrovimab From 12 to 18 Months. "Due to the high frequency of the omicron BA.2 variant, sotrovimab is not currently authorized in any U.S. region. However, it is recommended that product be retained in the event that future SARS-CoV-2 variants, which may be susceptible to sotrovimab, emerge and become prevalent in the U.S."

New & Noteworthy

Round three of free tests from the feds

A third round of free home tests from the federal government became available while we were on break. This time, each household can order eight tests, up from four in previous offerings. If you neglected to order during either of the first two rounds, you didn't miss out - you can request additional tests to make up for the rounds you missed.

NIH to WHO: We can't share tools, but can share what you need to make them

In a patent-sharing deal with WHO, NIH is making 11 technologies available for use in low- and middle-income countries to help improve global COVID vaccine and therapeutic equity. The specific technologies include "the stabilized spike protein used in currently available COVID-19 vaccines, [plus] research tools for vaccine, therapeutic, and diagnostic development, as well as early-stage vaccine candidates and diagnostics." Commentary: The list does not include any short-term silver bullets. That's because the critical patents on current EUA products are held by commercial entities - and they're sharing technologies only on a very limited basis. Still, the tech being offered in this deal does provide a foundation for individual laboratories to develop their own treatments and vaccines. It's a small step in the right direction, but at least it's a step.

Flying blind through a surge: Testing volumes crater worldwide

For weeks we've been worrying that unreported home tests are causing a vast undercount of the number of COVID tests being taken in the US. (We believe that in this country there are four home tests done for every reported lab PCR test.) Now we have an additional problem on our hands - and it's not just an American issue. The AP reports that worldwide, reported testing volumes are down 70 - 90%, despite Omicron surges in both the US (BA.2 and BA2.1.12) and Africa (BA.4 and BA.5). Commentary: Even if all the tests worldwide *were* being reported, that number is lower than it needs to be for surveillance to work properly. At the same time, sequencing efforts are winding down, giving researchers less data to inform vaccine and treatment priorities. What's left? Wastewater testing. But while current efforts are effective and impressive, they're limited to just a few US jurisdictions. In order to fill the gap, we'll need to see significant acceleration in this area, and soon.

Swab at home for flu, RSV and COVID

It's not *quite* a complete home test, but it's a first step. FDA has authorized the first non-prescription broad respiratory panel: Labcorp's mail-in single-swab self-collection test, which distinguishes between the three most common respiratory viral diseases: Influenza (A&B), Respiratory Syncytial Virus (RSV), and COVID-19. Commentary: We like the trend and hope this is the first of many, with the next step being a while-you-wait at home test for respiratory illness. Good to see the FDA's openness here - but now we need providers and payers to get comfortable. We believe that Americans can handle the home technology and the results, but if these tests don't become an integrated part of the healthcare system, then only the wealthy will have access to them - and the tests won't be able to put a dent in the societal disease burden. And while we are hoping for the future - future generations of home tests need required reporting.

Food for Thought

Taiwan steers its own course

The current challenge for governments around the world is how to balance public health with reopening both society and the economy. Both mainland China and Taiwan have had strict but highly effective controls in place throughout the pandemic, sparing their populations from COVID mortality surges seen elsewhere. As they face Omicron, the two nations' paths are now diverging: China is committed to zero COVID, but Taiwan has decided to reopen, stating that 99.7% of reported cases there are mild or asymptomatic. Massive testing is the foundation for both these very different approaches.

The nose knows, Part 1

We can't believe we never heard about this before. Hat tip to Betsy Ladyzhets at COVID-19 Data Dispatch, whose newsletter clued us in to the Yankee Candle Index: "a well-known pattern, at least on COVID-19 Media and Data Twitter, that new national surges of the virus are generally preceded by one nontraditional indicator: an increase in one-star Yankee Candle reviews in which users complain that they can't smell their candles." Discovered in 2020 and then reported in the Washington Post (paywall), the index was right in December 2021 about the first Omicron surge, and it's spiking again now. So, if that new Peace + Tranquility candle doesn't smell as strongly of jasmine as you were expecting, you might want to break out a test.

The nose knows, Part 2

We here at the Newsletter are firmly of the belief that dogs are better than humans - and now we have another data point to back us up. Four sniffer dogs in Finland were able to detect SARS-CoV-2 in people with an accuracy that rivals PCR - in both randomized validation trials (92% sensitivity, 91% specificity compared to Rt-PCR) and a real-world study using skin swabs from airline passengers (they correctly identified 98.7% of the negative swabs). Woof!

The Good News is…

Wrong vax, right outcome

Fascinatingly, researchers found that health-care workers in Qatar who received a normal flu vaccine were 90% less likely to get infected with COVID. Other reports of this effect have surfaced in the past, but the mechanism is unclear. The influenza virus has nothing in common with SARS-CoV-2, except that the primary pathology it causes is in the respiratory system. The most likely hypothesis: The flu vaccine awakens the innate immune system in the lungs, helping fend off other respiratory pathogens. Commentary: Vaccines are our most useful tools in avoiding infectious disease - sometimes they work better than we even expect them to.

Latest Monthly Capacity Estimates

Test Type	Dec '21	Jan '22	Feb '22	Mar '22	April '22	May '22	June '22
ANTIGEN							
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
Antigen Total	**401M**	**447M**	**722M**	**643M**	**583M**	**578M**	**545M**
MOLECULAR							
Molecular Professional, Point of Care, OTC EUA	36	36	36	34	33	32	31
Lab Based PCR	130	125	130	124	108	90	85
Addt'l Lab Based PCR with Pooling	20	16	16	12	11	7	6
Molecular Total	**185M**	**177M**	**182M**	**171M**	**151M**	**128M**	**123M**
Total Test Capacity	**586M**	**624M**	**904M**	**814M**	**734M**	**706M**	**668M**

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