Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

516M	593M	631M	912M	1,017M
November 2021	December 2021	January 2022	February 2022	March 2022

No changes in the capacity estimates this week. We note one additional EUA for an OTC antigen self test (see below). We do not anticipate any material impact on capacity from this test in the next 2-4 weeks but will continue to monitor.

What Happened Last Week

The FDA issued two new EUAs, 13 amendments to existing EUAs, and four new safety/policy communications in the last week:

- New EUAs (2):
  - Molecular Tests (1): Mammoth Biosciences DETECTR BOOST SARS-CoV-2 Reagent Kit
  - Antigen Tests (1): MaximBio ClearDetect COVID-19 Antigen Home Test
- New Amendments to Existing EUAs (13):
  - Molecular Tests (6): Kaiser Permanente KPMAS | Viracor Eurofins DTC | Illumina COVIDSeq Test | Fast Track Diagnostics Luxembourg | DiaCarta Quantivirus | Nat'l Jewish Health MassArray
  - Antigen Tests (1): Access Bio CareStart Home Test
  - Serology Tests (5): Diazyme DZ-Lite IgM | Diazyme DZ-Lite IgG | Siemens Dimension Vista | Siemens Dimension EXL | Siemens Atellica IgG
  - Flu/RSV Panels (1): PerkinElmer PKamp
- Safety/Policy Communications (4):
  - Safety Communications (1): LuSys Laboratories
  - EUA Revocations (2): BioPlex 2200 SARS-CoV-2 IgG | MosaiQ COVID-19 Antibody Magazine
  - FAQ Additions (1): Can I use an authorized at-home COVID-19 diagnostic test if it was left outside in the freezing temperatures?
    - Short answer: Yes, after thawing, as long as test line(s) appear as they should.

New & Noteworthy

The First 500 - Delivery

At the end of last week, supply chain issues, particularly at international ports and airports, were frustrating companies trying to distribute the first round of free COVID tests from the federal government. Fortunately, things have been looking better this week. We are now hearing many accounts of Americans already receiving their four free tests in the mail.

The First 500 - Equity

At least some of the folks who've already received their tests should be folks who really need them, too - according to NPR, "The first 20% of each day's orders are directed to ZIP codes that measure high on the federal government's Social Vulnerability Index." We were also glad to see the rollout last Friday of a hotline that allows folks to order their free COVID tests by phone (open 8 am to midnight ET seven days a week and offers assistance in more than 150 languages). Commentary: Both of these efforts are critical. We need to make sure that these tests are getting to our most COVID-vulnerable populations. Not everyone has consistent internet access, and some people may need additional assistance that a simple web-based form can't provide.

The First 500 - Competition

We agree on the importance of these tests getting to Americans - but we continue to hear about schools who are finding it challenging to get point-of-care antigen tests for their Test to Stay and symptomatic testing programs. Not clear if this is a direct result of the 500 million program or an unintended consequence of the increased focus on self tests. The federal program to add 10 million tests a month helps, but demand is still exceeding supply in many states. Retail access to tests seemed to have eased a bit - we anticipate more improvement in February.

Food for Thought

Antigen Tests Work Just Fine - As Long As You're Asking the Right Question

Commentary: There has been a lot of press on how antigen and PCR tests work and whether they are effective in detecting Omicron. Official statements by the FDA are helpful, but the quest for Real World Evidence remains. Many of the stories have focused on the false negative and positive results for both PCR and antigen tests. Without oversimplifying or creating further divisions (there are many people who are and will continue to be "All PCR," while others are fully "Team Antigen"), we reiterate our position: There is a need and place for both. Antigen tests work very well to identify those who are *infectious*, not necessarily those who are *infected*. Antigen tests may "miss" people who are infected, as they are less sensitive than PCR tests. But while PCR tests may be the gold standard for individual diagnosis, they are ultimately more useful as a tool for doctors, not for public health purposes.

Here are the questions that antigen tests can and should answer:

- Is someone contagious? There has been so much hand-wringing over the fact that we don't know precisely what load of virus people must have in order to be infectious. And yes, antigen tests (and PCR at times), will miss a few infectious people. But we've been letting the perfect be the enemy of the good for far too long. Antigen tests work *well enough* to answer this question. Trust the result and see below.
- Does someone need to confirm a positive antigen test with a PCR test? Antigen tests have a very small, <2%, false positive rate. So, if someone gets a positive antigen test and has symptoms, the test should be believed, and no additional testing should be needed. If no symptoms - the test should be believed, but an additional antigen test can be taken one day later. Important to remember - at least 20% of people with infectious COVID have no symptoms at all.
- When is it all right for someone to leave isolation? Despite the CDC's guidance, we believe that those who are COVID-positive should have a negative antigen test before they exit isolation, especially if that isolation has only lasted five days. Data from the UK and Japan estimates that about 30% of people are still infectious at this point. Antigen tests should catch these people.

How is the NHL like a day-care center?

Um… it's not. At all. Even less Even less so now, as the NHL stopped testing vaccinated asymptomatic players (despite the fact that they could still carry and potentially transmit Omicron). It clearly wasn't a related event, but at the same time that was happening, Massachusetts initiated free screening testing for all of the state's child care programs. Commentary: We struggle to interpret and comment. But yes, there might still be one overlap - both places may require time outs for bad behavior.

K-12 Round Up:

Burbio reported that the number of schools that went virtual or closed was down last week by 38%: 4,473 vs. 7,164 the previous week, when many closings were tacked on to the national holiday.

Schools Can Say No to Contact Tracing

Contact tracing has been one of the most challenging aspects of asymptomatic screening programs in K-12 schools from the very beginning, and the Omicron surge may have made it impossible. Burbio and *The 74* both note a trend of schools giving up contact tracing altogether. On the state level, Massachusetts, Connecticut, Vermont, and Maine have all changed their K-12 guidelines to allow schools to stop contact tracing, and some districts in California, Florida, Michigan, and Pennsylvania have either cut back or eliminated the process. Dr. Nirav Shah, director of the Maine Center for Disease Control and Prevention, may have said it best, "Trying to catch Omicron by contact tracing is like trying to catch a bullet train on a bicycle."

Latest Monthly Capacity Estimates

Estimated Monthly Capacity of All Tests (M)

Test Type	Nov '21	Dec '21	Jan '22	Feb '22	Mar '22
ANTIGEN					
Antigen Professional + Point of Care EUA Today	174	185	187	187	191
Antigen OTC: Home/Self EUA Today	141	216	260	535	636
Antigen Central Lab Today	11	7	7	7	7
Antigen Total	**326M**	**408M**	**454M**	**729M**	**834M**
MOLECULAR					
Molecular Professional, Point of Care, OTC EUA Today	32	36	36	36	37
Lab Based PCR Today	130	130	125	130	130
Addt'l Lab Based PCR with Pooling	29	20	16	16	16
Molecular Total	**190M**	**185M**	**177M**	**182M**	**183M**
Total Test Capacity	**516M**	**593M**	**631M**	**912M**	**1,017M**

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