Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

624M	904M	814M	731M	683M
January 2022	February 2022	March 2022	April 2022	May 2022

No update on capacity estimates this week.

What Happened Last Week

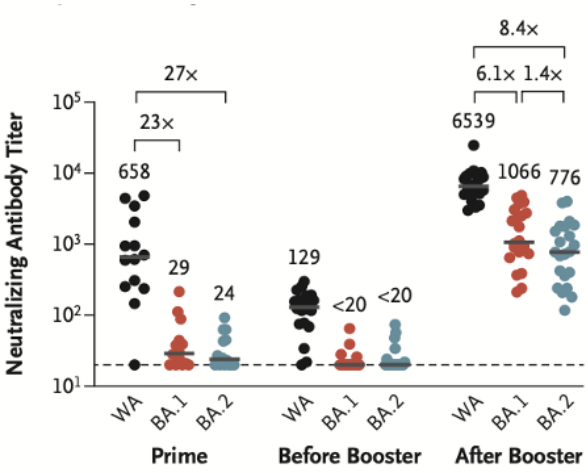
The FDA issued no new EUAs, 18 amendments to existing EUAs, and no new safety/policy communications in the past week:

- New Amendments to Existing EUAs (18):
  - Molecular Tests (13): Clear Labs | Helix | Hologic (3) | LabCorp | Quest (4) | Roche | Sansure Biotech | Uh-Oh Labs
  - Antigen Tests (5): AccessBio | BD | Celltrion | Maxim | Siemens

New & Noteworthy

Omicron updates

It is increasingly clear in Europe and Asia (especially China) that the now globally dominant BA.2 is fueling case growth among more immune-naïve populations. Two items of good news, per The Lancet and an NEJM letter: Omicron is 59% less likely to lead to hospital admission than Delta and 69% less likely to result in death, and a booster - even one designed against the initial form of the virus - creates resilient additional protection from both Omicron subvariants for at least four to six months. It is still an open question how the BA.2 will play out in the US – it is currently 55% of cases, up from 13% just three weeks ago.



Get your homework done: FDA urges test makers to go for full approval

The use of Emergency Use Authorizations (EUAs) is supposed to stop when the official COVID public health emergency ends. In late 2021, the FDA announced the roadmap from EUA to full FDA approval. Last week, FDA testing chief Tim Stenzel did the governmental equivalent of your mom reminding you to start that big science project now, not two days before it's due, by "encouraging all EUA manufacturers to "go ahead and perform their conversion studies" and apply for full approval, either De Novo or 501k. The FDA is planning to give EUA holders 180 days' notice before terminating their authorizations.

At-home testing rose - higher among some groups than others

A CDC MMWR report with data from August 2021 through mid-March 2022 (i.e., Delta to Omicron), provides data backing up what we already knew anecdotally: Americans' use of at-home rapid tests rose significantly during the Omicron surge. However, that use wasn't spread evenly across demographics. "Persons who identified as White were approximately twice as likely to report at-home test use (5.9%) compared with those who identified as Black (2.8%)," the report states. "At-home test use also increased with higher levels of household income and education."
Commentary: We agree with the authors' assessment that the factors behind these differences are likely to be "price point, marketing, education, or disparities in availability and accessibility of at-home tests," except we would replace that "or" with an "and": it's likely a combination of all the above. Equitable access to tests is not just critical to curbing disease spread - it's a moral imperative.

Note: Mara's estimates of at-home test use during January and February were that 7 to 8 million tests used per day (6 to 7 times the volume of lab-based PCR tests.)

The Feds are still buying rapid tests. For now.

The federal government continues to purchase rapid antigen tests to fulfill its free at-home test programs. The most recent contract, which adds to previous ones announced with iHealth, Roche and Siemens, comes from the US Army: $1 billion to Abbott for BinaxNOW and ID NOW.

Food for Thought

Holding Labs and Testing Companies Accountable for Quality

As testing has become more ubiquitous, it is not surprising that watch dogs are finding more issues with test quality. It's important to recognize that these challenges can have widely differing root causes.

- #1 Unintentional errors from quality companies
    - Likely caused by pressure to increase capacity and throughput. Especially for inexperienced labs and manufacturers - shortcuts may lead to avoidable errors.
- #2 Shoddy quality from pop-up and questionable companies
    - One step above fraud. These are labs that do not have appropriate respect for regulations and quality-control systems or distributors that are cavalier with our precious samples.
- #3 Fraudulent businesses
    - Businesses that are designed to intentionally scam the customer. Some have played the long game, starting off as legitimate businesses and then moving into fraud.

Commentary: This is why watch dogs exist, especially in crises, when mistakes - whether honestly made or intentional - can more easily occur. While we wish it wasn't true, it doesn't negate the fact that speed and volume has been the priority over most of the past two years.

Do public health measures really need to be mandatory in a pandemic? Um, yes. Yes, they do.

During 2020 some loud voices called for letting the pandemic "play out" while protecting only the most vulnerable (remember the Great Barrington Declaration?). Sweden was the only country that did adopt an explicit strategy aiming for herd immunity by implementing few mandatory community restrictions. The results are in: Sweden did not adequately protect their people. Death rate was 10-15 times higher than neighboring Norway. This very comprehensive review of Sweden's strategy describes this tragic failure in detail.

Applying the Lessons of the Pandemic: Testing Edition, Episode 8

The KISS rule applies - and other sci comm lessons.*

The past two years have clearly been a trial by fire for those of us who try to communicate scientific concepts and data to a broad audience. A great review in Nature covered the lessons learned by folks who created some of the data dashboards we've all come to rely on for up-to-date COVID information. The pearls:

- Data needs to be "freely available, machine-readable, and standardized . . . including the use of consistent categories and naming conventions for age, gender, race and ethnicity."

- Keep both text and graphics as simple and clear as possible.
- Pay close attention to headlines, captions, and titles for charts and graphics - people will read those when they read nothing else.
- “The best data visualization might also not be the one that is most pleasing to the eye.” Translation: Don’t ask people which graphic they like better - ask them to tell you what they think the graphic is saying. If their answer isn’t correct, use a different image.
- “Let people see behind the scenes, share the data sources, and teach people what data methodologies were used and why. And always be transparent about any gaps or errors that could lead viewers astray.”

*Keep it Simple, Stupid

The Good News is…

The youngest children generate strong immunity

A new Johns Hopkins preprint finds that the youngest children generated 10 times the adult number of receptor binding domain antibodies against the Delta variant. It is a relatively small study: 682 individuals were tested, 56 had evidence of previous COVID infection, and 15 of these cases were in the 0-4 age band. This is consistent with other data that show that slightly older children (5-11 years) had vaccine-generated antibodies equivalent to adults even though they received 1/3 the dose. Commentary and our personal hope: The sooner we have vaccines available for all children, the better.

Latest Monthly Capacity Estimates

Test Type	Nov '21	Dec '21	Jan '22	Feb '22	Mar '22	April '22	May '22
ANTIGEN							
Antigen Professional + Point of Care EUA	174	185	187	187	181	165	156
Antigen OTC: Home/Self EUA	141	216	260	535	462	415	399
Antigen Total	**315M**	**401M**	**447M**	**722M**	**643M**	**580M**	**555M**
MOLECULAR							
Molecular Professional, Point of Care, OTC EUA	32	36	36	36	34	33	32
Lab Based PCR	130	130	125	130	124	108	90
Addt'l Lab Based PCR with Pooling	29	20	16	16	12	11	7
Molecular Total	**190M**	**185M**	**177M**	**182M**	**171M**	**151M**	**128M**
Total Test Capacity	**505M**	**586M**	**624M**	**904M**	**814M**	**731M**	**683M**

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