



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

624M	904M	814M	734M	706M
January 2022	February 2022	March 2022	April 2022	May 2022

Small increase in capacity estimates - mostly from OTC At-home antigen tests. Driving change:

#1 Supply: Two new EUAs for OTC antigen tests.

#2 Demand pulling supply: Increase in cases has delayed manufacturers' decisions to cut back on capacity.

#3 Demand pulling supply: Extended expiration dates for existing EUAs (OTC and POC antigen tests) are giving states, businesses and soon, consumers, additional confidence to purchase tests to hold in inventory for spring and summer season...

What Happened Last Week

The FDA issued one new EUA, 16 amendments to existing EUAs, and no new safety/policy communications in the past week:

- New EUAs (1):
 - Volatile Organic Compound Tests: InspectR Breathalyzer
- New Amendments to Existing EUAs (16):
 - Molecular Tests (10): Avellino | BioMeme | Cleveland Clinic | LabCorp | DC Dept of Health | Detect | Euroimmun | EXCITE | MicroGEM | UCSD
 - Antigen Tests (5): Abbott BINAX | Ellume | iHealth | InBios | OraSure
 - Antibody Tests (1): Abbott AdviseDx IgG

New & Noteworthy

Masks off on public transportation

Unless you've been off the grid during the past few days, you already know that the federal government's mask mandate for public transportation was declared an overreach of the CDC's authority and therefore not valid by a federal judge in Florida. Reaction was instantaneous - masks flung off everywhere. We just heard that the Justice Department will appeal on behalf of the CDC.

Commentary: We are disappointed by the judgment but not surprised. The current mask mandate was likely to expire shortly in any case, and absent a new surge, the net effect of this ruling on 2022 public health will be hopefully minor. The bigger issue is that this case was not filed to rule that masks are no longer required, it was filed back in July 2021 to object to CDC imposed mask mandates ever. It's become increasingly clear that the nation has become divided in yet another fundamental way - between those who believe in public health (which, by its very nature, is prescriptive and involves mandates), and those who believe that public health has no place in a "free" country - each person should be responsible for their own health alone, and if that imperils others, so be it. We are pleased that the CDC / DOJ will appeal - it is all about the future. So, masks are off despite the fact that 1) COVID remains at least 4x as deadly as the flu overall and worse than that for the unvaxxed, 2) children under age five still

cannot be vaccinated, and 3) 10-30% of people get Long COVID (unlike flu) if we get infected. We knew it was coming, and actually understand the glee of not having to wear a mask - but that does not negate the benefit of using one.

Everyone's breathless with anticipation about this test

Another one you've probably already read about, because the media is super excited: After two years of innumerable announcements from universities and companies about the potential of breath as an analyte for COVID, the FDA has now granted its first EUA for a [COVID breath analyzer](#).

How does it work? Breathing stabilizes the gas balance in the blood, transporting O₂ in and CO₂ out. Along with the CO₂, exhalations include 4,000-plus other trace compounds. Sometimes the abundance of a single compound enables a simple test (e.g., alcohol for intoxication; urea for H. pylori; nitric oxide for asthma). COVID isn't so simple: The standard laboratory technique is to use gas chromatography first, followed by mass spectroscopy to separate and identify the compounds present in any one breath. Question 1: Is there a common, COVID-unique, fingerprint to be found among everyone with COVID? Question 2: If the answer to Question 1 is "yes," can the fingerprinting task be simplified enough to enable a cost-competitive portable instrument? This EUA indicates that the answers to these questions are "yes" and "maybe": The company claims that a (secret) five-compound fingerprint is indeed unique enough, and a simplified suitcase-sized highly automated instrument can do the job. But it cannot be cheap.

How well does it work? Claims are impressive, but no details yet. A clinical trial of 2400 asymptomatic patients showed 91% sensitivity and 99% specificity, a combination that's better than the OTC antigen tests. Availability? The company said that they will produce only 100 units a week. No word on price.

Commentary: Great to have this technology functional, and we now have no doubt that others will follow. Could breath analysis provide broad, fast, and accurate testing for events and maybe even airline flights? Stay tuned.

Home tests have left public health blind - NIH & APHL trying to get sight

The vast majority of COVID testing is now done at home. (Mara estimates at least 4x as many at-home tests (90-plus percent of which are antigen tests) vs lab PCR every day.) But there is no system in place by which to capture the number of tests used and the results from those tests. The [Association of Public Health Labs \(APHL\)](#) has now received [\\$8.8 million from NIH](#) to help create such a system using the association's secure data platform, APHL Informatics Messaging Service (AIMS). AIMS is already used to capture public health data from sources that range from local public health labs to the CDC.

Commentary: Great start, but is it a large enough scope backed by enough money to build a sustainable and comprehensive system? In the meantime, trends in hospitalizations and wastewater viral load remain our only reliable (though only incompletely tracked) pandemic surveillance tools.

Food for Thought

K-12 Roundup

Vax'd teachers in Illinois: paid time off for breakthrough COVID

A newly signed law in Illinois provides fully vaccinated school employees with [paid administrative leave](#) if they have to stay home because of COVID - and if they had to use sick days earlier in the school year for that reason, they get those days back, too. Hourly employees also receive wage protection if they lost hours because of school closures or a switch to virtual learning.

The Good News is...

A pandemic weather service is on the way

Predicting hurricanes and tornadoes saves lives. Over the last 20 years, NOAA created an early warning system to predict severe weather. It is about time that we had this in health care. The Good News is that we have the beginning of a system within the CDC: the new [Center for Forecasting and Outbreak Analytics](#), with a grant of \$200 million. The center has already awarded \$21 million to academic institutions to develop modeling and forecasting methods.

Commentary: Will this impact COVID or the next pandemic? We don't know - but we are very happy that there was funding in the federal COVID bill for this.

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	418	422
Antigen Total	315M	401M	447M	722M	643M	583M	578M
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
Add'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	734M	706M

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