



Tracking US Coronavirus Testing Capacity

VOLUME 5, ISSUE 6

June 1, 2022

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 one new EUA, no new amendments to existing EUAs, and two new safety/policy communications in the past week:

- New EUAs (1):
 - Serology (1): [LG Chem, Ltd. AdvanSure IgG](#)
- Safety Updates (2):
 - Warning Letters (2): [Santhigram Kerala Ayurvedic Co.](#) | [Haniel Concepts, Inc. DBA Free State Oils, LLC](#)

New & Noteworthy

The next pandemic: Monkeypox? Nah.

Monkeypox has been circulating in West Africa for at least the past 50 years - but as local observers have noted, Western Europe and the US paid no attention until it arrived on their shores. Historically, contact with host animals was assumed to be required for transmission, but compelling [evidence](#) indicates that it now can be transmitted from human to human. With that change plus modern travel patterns that enable ultra-fast viral distribution, are we now looking at our next pandemic?

We think not. Smallpox vaccination appears to be 85% effective against monkeypox (which, like smallpox, is in the orthopox family), and until 1972, all US infants over one year of age received a smallpox vaccine. Since neutralizing antibodies against smallpox have a 92-year half-life, the over-50 population is pretty likely to have retained some immunity. In addition, monkeypox is primarily spread by direct contact, so hand hygiene and avoidance of bodily fluids are effective deterrents. And finally, for younger people the current form of the virus appears to be relatively mild.

All that said, we do need to continue comprehensive viral surveillance on a worldwide basis. The next spillover from animals to humans may not be as easily contained.

A tale of two antivirals - complete with cliffhanger

Two antiviral drug treatments are now available to treat COVID: Pfizer's Paxlovid (nirmatrelvir + ritonavir) and Merck's molnupiravir. Spoiler alert: Paxlovid has been prescribed 15x more often than molnupiravir in the US, and for good reason.

Before it was even released, molnupiravir's mechanism - hypermutating a virus to extinction - came under scrutiny. It created the possibility of worrisome side effects, and researchers fretted that it might generate new variants. Meanwhile, Paxlovid's clinical trial (during Delta) reported a reassuring 89% decrease in hospitalization rates. While those numbers haven't quite held up for Paxlovid in the real world against Omicron, the data from two recent (Omicron BA.2) studies from Hong Kong continues to reassure. [Wong et al.](#) reported that Paxlovid reduced inpatient fatality rates (versus no treatment) by 68% versus molnupiravir's 45%; and [Yip et al.'s](#) review of community hospitalization rates found that molnupiravir was actually worse than no treatment at all (17% more admissions), while Paxlovid offered a 21% reduction. Paxlovid has clearly earned its place as the therapy of choice.

But what about patients who rebound after Paxlovid? Rebound (basically relapse) happens when a patient's symptoms disappear and they test negative, only to become symptomatic and test positive again up to 15 days later, without having been in contact with anyone who's contagious. How often does this happen? The reality is that we have [no idea](#). Some small percentages of patients have been relapsing from COVID since the pandemic began (Liz was one of them). In Pfizer's trial, roughly 2% of people relapsed whether given Paxlovid or placebo. Anecdotal and individual physician reports now describe numbers much higher than that post-Paxlovid, but real data has yet to appear. The CDC [stands behind](#) the use of the drug combination despite these reports, because, well, it still helps keep people out of the hospital.

If indeed the rebound numbers are higher in the real world than they were in the trials, why might this be happening? The Paxlovid trial was conducted with only unvaxxed, high-risk people - it might work differently in vaccinated folks or lower-risk patients. In addition, Paxlovid was tested during the Delta surge and then put into practice during Omicron, which might make all the difference. Stay tuned...

How big is the BA.2 - 2.1.12 surge? Depends on who's estimating.

Well, folks, we're in yet another surge. A big surge. How big? Depends on who you ask. Our analysis, based on the number of antigen tests used, implies that at least 5x more cases are occurring than are currently reported. So, with current confirmed cases of ~110,000 cases per day, the true number is a very considerable >500,000 cases per day. The [WSJ published](#) an even more extreme analysis (based on Johns Hopkins and IHME data), suggesting there are 10x more real cases than officially confirmed, up from about 1.7x during the year-end Delta surge. Doing the math, that estimate suggests that the Delta surge topped out at about 1.4 million new cases per day in mid-January, while the current Omicron surge is driving 1.1 million new cases per day. A [preprint](#) out of the City University of New York School of Public Health estimated that case counts in NYC this spring were - wait for it - 31x higher than reported. No matter whose numbers you agree with, the underlying message is the same: This surge is big, but we've lost the data that would allow us to measure it precisely. [Commentary](#): We expect this wave to get worse before it gets better - we predict 150k+ reported cases per day this coming week. It is still wise to mask up in all enclosed public spaces, and outdoors when in close proximity to others.

Food for Thought

Lessons Learned: Testing Edition #11

Were Japan's COVID policies in the Goldilocks zone all along?

In our article "Taiwan steers its own course" in last week's Newsletter, we emphasized the difficult balancing act required to reopen economies while successfully maintaining public health. Until about six weeks ago, both China and Taiwan had been almost equally successful in containing COVID, with 11

and 14 cases per million population respectively and almost no deaths per million. (In comparison, the US is at 84 cases and 2 deaths per million.) When Omicron hit, China locked down aggressively, and cases dropped to 3 per million (although China's higher burden of proof to record COVID as cause of death may be a distortion here). Taiwan opened up in spite of Omicron, and saw cases explode to 3,442 per million. However, with low mortality at 4 deaths per million, Taiwan believes that they have the better balance point.

However, recent press reports ([Nature](#); [Bloomberg](#)) have highlighted a third way that may have been "just right" all along. Japan's consistent approach to the pandemic has been to protect the vulnerable and advise all to avoid the "3Cs": closed environments, crowded conditions, and close contact settings (a combination the Japanese call *sanmitsu*, after the Buddhist "three mysteries"). Combined with extensive vaccination (98% of Japan's over-80 set are vaccinated, versus just 51% in China), Japan's "steady as she goes" policy has delivered continuing declines in both cases and deaths at levels 1/15th those of Taiwan.

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
Add'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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A collaboration between Health Catalysts Group & COVID-19 Response Advisors.

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