



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current EUA's

516M	593M	631M	912M	1,035M
November 2021	December 2021	January 2022	February 2022	March 2022

No changes to capacity this week. We will add Q2 estimates in the next two weeks.

What Happened Last Week

The FDA issued 3 new EUAs, 12 amendments to existing EUAs, and 1 new safety/policy communications:

- New EUAs (3):
 - Molecular Tests (3): [Advanta Dx COVID-19 EASE Assay](#) | [Uh-Oh Labs OUL COVID-19 Test](#) | [ChromaCode, Inc. HDPCR SARS-CoV-2 Assay](#)
- New Amendments to Existing EUAs (12):
 - Molecular Tests (5): Cue Health OTC | 1drop Inc. 1copy Multi Kit | BD SARS-CoV-2 Reagents for BD MAX System | Roche cobas | Zymo Research Quick PCR kit
 - Antigen Tests (1): Siemens CLINITEST Self-Test
 - Serology Tests (3): Roche Elecsys (ECLIA) | Euroimmun (ELISA IgG) | Hangzhou Laihe LYHER IgM/IgG
 - Flu/RSV Panels (3): Abbott Alinity m Resp-4-Plex | Exact Sciences Labs COVID-Flu Multiplex Assay | Roche cobas SARS-CoV-2 & Influenza A/B
- Safety/Policy Communications (1):
 - EUA Revocations (1): [LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel](#)

New & Noteworthy

New Testing Technologies

New diagnostic technologies are still being developed to make COVID testing faster, easier and cheaper. This is important because even if the pandemic moves quickly into a new phase where there is little disruption, (crossing our fingers and toes) COVID testing at some scale will continue. On [TestingCommons.com](#) we show 268 tests in active development. A few technologies that caught our eye:

#1 A molecular test as accurate as PCR in four minutes (or less)

The future of diagnostics lies in electronic detection: Noting tiny voltage changes that happen when diagnostic molecules pass through or are bound to a substrate. Many applications already use some type of electronic detection, but [Fudan University researchers](#) were able to add a new level of innovation. The nano-chip geometry they designed can be tuned to detect a wide range of DNA, RNA, proteins, and simpler molecules quickly and accurately, without fouling in complex mixtures (e.g., saliva), and [without any time-consuming amplification](#) process. A disposable chip in a small portable device. Question: Timeline to reality?

#2 A \$51 molecular “lab in a backpack” from simple components

This highly [creative approach](#) repurposes a commercial disk drive to become a centrifuge, shows exactly how anyone can build their own RT-LAMP system, and provides a straightforward step-by-step protocol to test for SARS-CoV-2. It uses a lab-like workflow run by a technician but can be simply assembled wherever traditional lab resources are scarce. Question: Is it really scalable?

#3 The first breath test to achieve a CE-IVD/CE Mark

Breath tests are in many ways, the “Holy Grail” of rapid COVID screening: potentially close to antigen test sensitivity; the least invasive sample acquisition; fast answers. DSA BreathPass received a CE Mark with a multi-use portable device that provides a cloud-based result delivered to a mobile phone in 45 seconds. Several companies are working in this area: using electronic detection of volatile organic compounds in breath as input, with complex AI algorithms that match the profile present in COVID-infected individuals but not to those in healthy controls. Question: Real-World false positives and false negatives?

Short-term results may not predict long-term activity

Labcorp and Quest both [predict](#) between 60 - 70% decrease in COVID-testing revenue in 2022 (NB: We’re talking PCR here). Before the end of February, we’ll update the overall testing capacity, but we sincerely hope this announcement doesn’t presage a repeat of last summer’s mistakes. On the antigen side, Abbott is forecasted the same testing revenue for all of 2022 as it had in just the fourth quarter of 2021. [Commentary](#): Testing demand may come down in the short term in the post-Omicron-surge days. But we need to maintain the flexibility to ramp capacity up again quickly should we encounter a new, post-Omicron variant.

Food for Thought

Applying the Lessons of the Pandemic: Testing Edition, Episodes 1 & 2

As the peak of the Omicron wave subsides worldwide, we turn our attention to how not to waste what we have learned at great cost over the past two years. Two articles caught our attention.

Does self-testing become part of the standard of care?

The *Financial Times* [explored](#) two aspects of the COVID legacy. First, expanded and ongoing access to self-testing (primarily antigen tests) could enable individuals to know whether mild illness is worth staying home for. Is it just a cold, or is it COVID? Influenza? Something else? This knowledge will help protect both individuals and public health. Second, maintaining the flexibility and capacity to ramp up both PCR and sequencing when needed is critical - and needs to be in place regardless of wildly varying demand. [Commentary](#): We believe that home testing/DIY testing may finally take hold after years of failed expectations. COVID may be the catalyst - but we predict that home testing will expand into other infectious diseases, sexually transmitted diseases, metabolism, and then into blood testing. Now that the technology exists, the tipping point will be financial. Will physicians accept home tests - and payers pay for them - without repeating every test, thereby increasing cost instead of lowering it?

We’ve just begun to tap the power of poop.

Wired [explored](#) broadening and systematically applying wastewater surveillance. Where wastewater is monitored today, it has provided early warning of novel COVID variants and surges far earlier than case reporting allows. Unfortunately, COVID wastewater surveillance in the US is spotty – just 10 states do enough to effectively monitor their populations, and 18 do none at all. We have multiple opportunities in this space: to broaden the system nationwide; to include a wider and fuller array of potentially epidemic viral threats; and to monitor dangerous antibiotic-resistant bacterial candidates.

You know that testing itself has become endemic when...

... there’s a [Super Bowl ad](#) for a COVID test! We’ve become used to drug companies advertising at this event, but before this year we hadn’t seen diagnostics companies joining the party (except for the toilet-paper man from Exact). During Super Bowl LVI, Cue Health ran a 30-second ad emphasizing their device’s ability “to protect the family” and teasing, “*Just wait till you see what else I can do.*” Clearly, Cue and others are preparing the American public for ubiquitous home testing in the future.

K-12 Round Up:

The masks are starting to come off in schools

Burbio has reinstated its [state-by-state mask tracker](#), as mask mandates across the country continue to shift. By the end of March, at least 31 states will leave the decision of whether or not to mask in the hands of individual districts. [Commentary](#): States' inability or unwillingness to come up with data-driven metrics for the institution/removal of mask mandates is a huge source of frustration. There is no reason for these decisions to be arbitrary - by looking at test positivity rate, hospitalization for COVID, and percentage of available ICU beds, we can know (within reason) how bad the pandemic is in a given area and whether masking should be required. Local school boards and school superintendents have enough to do without having to be epidemiologists, too.

The Good News is...

COVID vaccination during pregnancy protects babies, too

A CDC [MMWR report](#) published yesterday showed that babies whose moms got vaccinated during pregnancy had a 61% lower chance of contracting COVID during their first six months of life. Odds were even better (80%) if mom got vaccinated during the second or third trimester, but that's not a reason to delay vaccination, docs say. The primary point of vaccination during pregnancy is to protect the mother - the fact that vaccination also protects the baby is a bonus.

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	654
Antigen Central Lab Today	11	7	7	7	7
Antigen Total	326M	408M	454M	729M	852M
MOLECULAR					
Molecular Professional, Point of Care, OTC EUA Today	32	36	36	36	37
Lab Based PCR Today	130	130	125	130	130
Add'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	1,035M

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