



Tracking US Coronavirus Testing Capacity

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Updated Monthly Capacity Numbers: Current and Future EUA's

417M

September 2021

484M

October 2021

516M

November 2021

645M

December 2021

Updates to the capacity numbers this week include a lowering of November and December estimates mostly in antigen OTC tests. We still believe that there will be a material increase in OTC antigen test availability in December - but several companies have indicated that they will not be available to get to their peak manufacturing until early 2022.

What Happened Last Week

The FDA issued one new EUA, one amendment and three safety/policy communications in the last week:

- New EUAs (1):
 - Molecular Tests (1): [Meridian Bioscience Revogene](#)
- New Amendments to Existing EUAs (2):
 - Molecular Tests (1): Verily Life Sciences
 - Serology Tests (1): GenScript USA cPass
- Safety/Policy Communications (3):
 - Recalls (1): [Recall](#) of 2.2 million [Ellume COVID-19 Home Tests](#) for “higher-than-acceptable” false-positive rates – expansion of [October 5 recall](#) of 200,000 tests for the same issue
 - Policy Withdrawals (1): [HHS policy on LDT's](#) that had previously directed the FDA not to enforce premarket review requirements
 - Policy Updates (1): [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency](#); updated to prioritize review and approval efforts for highest-accessibility tests (i.e. home or POC tests, as well as certain high-volume or high-capacity lab-based tests)

New & Noteworthy

FDA: Back to the Future for LDTs and More

FDA released its revised [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency](#) this week, marking a shift in the agency's agenda and approach to COVID-19 tests.

There are three major aspects of the new plan, all focused on increasing the reliability and thereby the confidence in COVID tests:

1. Reintroduce premarket review for Laboratory Developed Tests. The review process for these tests has ping-ponged back and forth. At first, they were reviewed by FDA like all other tests, then they went to HHS, where they could essentially be self-authorized, and now they're back to FDA.
2. New states will no longer be allowed to authorize high-complexity CLIA labs to develop and use their own tests without EUA.

3. FDA will no longer allow the commercial distribution of tests that have submitted for EUA but haven't yet received it.

These revised policies, reflecting current testing preferences, focus on increasing the availability of certain kinds of tests (OTC self tests; POC tests; lab-based tests that involve pooling, home collection, or detection of multiple respiratory viruses; and fully quantitative antibody tests) from manufacturers that can scale up quickly - to 500,000 tests per month within three months of EUA. The new policy also puts tests submitted by other federal agencies at the front of the line.

Commentary: Hard to know what prompted these changes right now. The bottom line, however, seems to be the FDA asserting the importance of accuracy for *all* tests - but with a clear message that more is more. We appreciate their transparency about scale-up manufacturing volume, most importantly for OTC rapid antigen tests.

Follow-Up: Quality Control Still Matters – UK Lab Gets the Hook

One month ago, we reported on the discovery that Immensa Lab, an unaccredited facility in the UK, reported 43,000 false negative results based on their RT-PCR test. Immensa is now on a lockdown of its own - its testing operations have finally been [suspended](#) while the UK Health Security Agency investigates.

Food for Thought

California Moves First in K12 Student Vaccine Mandates

California has announced that they'll require COVID-19 vaccines for all K-12 public-school [students](#) once those vax receive full FDA approval, but several Cali cities aren't willing to wait that long. [Los Angeles](#) and [Oakland](#) want students ages 12 and up to be vaccinated by January in order to continue in-person learning; LA kids are already required to be vax'd if they want to participate in after-school activities. [Sacramento](#) students who are 12 years old or older must have a first dose on board by the end of November; [San Diego's](#) requirement starts in January but is only for those ages 16 and up (for whom the Pfizer vaccine already has full FDA approval). Predictably, lawsuits against the mandates are already in the works in at least two of the cities: Los Angeles and San Diego.

Commentary: It is distressing that vaccination for kids is still so controversial. As a country, we eliminated polio through school vaccination mandates. We have essentially controlled measles, mumps, and rubella in the same way. We understand why mandates would hinge on full FDA approval of the vaccines, but once that happens, can we learn from the successful public health initiatives in the past? We all should be on the same side here - keep kids safe and in school.

Learning Network Series Takeaways

The Rockefeller Foundation's [Learning Network for School Leaders](#) is in full swing, helping schools start and strengthen their COVID testing programs. Participants, who include school and district leaders from 25 states, have identified a number of key takeaways:

1. School-based testing and vaccination in conjunction with models that incentivize regular testing (including 'test-to-play' and 'test-to-stay') have increased in-person school days and participation in extracurricular activities.
2. Barriers to starting or expanding in-school testing programs include understaffing and employee burnout.
3. Solutions to staffing issues include:
 - a. Leveraging non-traditional employment arrangements (e.g., practicum hours for nursing students, hiring retired nursing staff, and recruiting parent volunteers for non-clinical tasks)
 - b. Texting (instead of calling) families of close contacts and including quarantine start and end times (helps family record keeping), and
 - c. Prioritizing individuals to test based on vaccination status and risk level (e.g., prioritize athletes in close-contact sports (high risk) over students in well-ventilated rooms with social distancing (lower risk)).

School can still [register](#) for remaining sessions. Note: Mara and Liz are involved in this series.

K-12 Metrics:

School closures are up dramatically, per Burbio's 2021/2022 [School Disruptions](#) Tracker. Total closures to date: 769 districts (up from 675 last week), and - wait for it - 7,001 schools, up from 3,224. The reason for the jump: a continuation of the trend of mental health breaks, mostly bracketing holidays, as well as closures due to staffing issues.

Higher Ed vaccine mandates:

The Chronicle of Higher Education now counts [1,132 colleges and universities](#) that require vaccines, up from 1,127 last week.

Latest Monthly Capacity Estimates

Estimated Monthly Capacity of All Tests (M)

Test Type	Sep '21	Oct '21	Nov '21	Dec '21
ANTIGEN				
Antigen Professional + Point of Care EUA Today	149	163	174	197
Antigen OTC: Home/Self EUA Today	81	130	141	242
Antigen Central Lab Today	10	11	11	11
Antigen Total	239M	304M	326M	450M

MOLECULAR				
Molecular Professional, Point of Care, OTC EUA Today	28	31	32	37
Lab Based PCR Today	125	125	130	130
Add'l Lab Based PCR with Pooling	25	25	29	29
Molecular Total	178M	181M	190M	195M

Total Test Capacity	417M	484M	516M	645M
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