



# Tracking US Coronavirus Testing Capacity

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## Updated Monthly Capacity Numbers: Current and Future EUA's

**417M**

September 2021

**479M**

October 2021

**537M**

November 2021

**601M**

December 2021

## What Happened Last Week

*The FDA two new EUAs, five amendments, and two safety communications in the last week:*

- New EUAs (2):
  - Flu/RSV Panels (1): PerkinElmer PKamp
  - Collection Kits (1): Quest
- New Amendments to Existing EUAs (5):
  - Molecular Tests (4): Quest | Quest HA (Hologic Aptima) | Quest RC (Coche Cobas) | Quest PF (Panther Fusion)
  - Serology Tests (1): DiaSorin LIAISON
- Safety Communications (2):
  - Recalls (1): Copan FLOQSwab ([Recall announcement](#); [FDA Post](#))
  - FDA Guidance Updates (1): [Alcohol-based sanitizers](#): Announcement of 12/31/21 withdrawal of temporary policies allowing non-drug manufacturers to produce

## New & Noteworthy

*Independent Review of the FDA's EUA Process: How Did the FDA Do?*

In March 2021, the FDA commissioned management consultants Booz Allen Hamilton to conduct an independent review of the FDA's own COVID-19 EUA response. The [report](#), which was made public this week, lays out what we already knew - the pandemic created demands of such a scale that existing FDA IT and staffing tools were inadequate, and test manufacturers often did not have enough guidance on what was required to receive an EUA. Nevertheless, the FDA successfully authorized 600 devices, including 360 tests, using an EUA approach tenfold more than in any prior emergency, plus a further 900 using traditional approval processes. COVID is as unique at FDA as it has been elsewhere – 2,133 submissions for COVID reviewed, of which 17% were issued, versus just 20 for Zika, 13 for Ebola, 2 for MERS and none at all for SARS-CoV 2003 (p13: Figure 3-3; p14 Table 3-6).

The FDA's response was published with the full report. FDA agreed with all 3 priority recommendations, intending to help build better capabilities for dealing with a public health emergency (PHE) in the future: #1, Optimize IT systems to include EUAs; #2, Develop a systematic strategy to allocate and track staff; and #3, Create a framework for validation of diagnostic tests for emerging pathogens.

The report is an excellent historical record of what happened at FDA from January 2020 through April 2021. Many important data are provided to clarify the toughest questions FDA faced:

How much control should FDA exert over new COVID tests? Early in the pandemic, the FDA asserted control over complex laboratory-developed COVID tests (LDTs) that might otherwise have been launched without formal review. This approach to LDT PCR tests was then discontinued in August 2020, when HHS announced that COVID LDTs need no longer go through the FDA.

This level of control stood in stark contrast to the “notification-only” process that was in place for serology/antibody tests, which generated a tidal wave (largely from Asia) few of which proved much value in controlling the epidemic. Thus far, 266 antibody tests have been placed on FDA’s “no longer use” list. For reference, in October 2021, there remain 89 EUAs for antibody tests.

How should tests be validated? Early in the pandemic, clinical samples were scarce. For that reason, required validation samples were few, and users had little reliable data to evaluate accuracy. Subsequently, FDA released standard reference panels for molecular tests that were mandatory for all past EUA’s to provide test to test comparability. Compliance was limited - 126 of 360 EUA holders had submitted publishable data by December 2020 (p19: Table 3-8), but non-responders faced no published consequences. Post-market reporting is also required by the EUA process, but again, compliance has been spotty and consequences few (p21: Table 3-9). Three EUAs have been outright revoked, and 331 “no longer use” letters sent - 80% of them being for notification-only serology tests.

One important detail that is now public (p15: Figure 3-6): In mid-2020, the FDA was taking much longer to review requests that were eventually denied (5-8 months) than it was to review those that were authorized (1-2 months).

Commentary: For all intents and purposes, COVID is the first modern-era pandemic requiring and receiving major public health intervention. This report demonstrates that the FDA was just as surprised as the rest of us by how fast the pandemic spread and how pervasive it became.

The FDA did not have the tools, systems, or staffing to deal with the volume or complexity of the onslaught of COVID-related test issues. There was no off-the-shelf handbook or past experience. Crises require flexibility and the willingness to try and implement new processes to meet the nation’s needs. The challenge is that the needs were evolving fast as knowledge of the virus grew and continue to do so. The pooling and OTC serial testing amendments were strong examples of flexibility and adaptation - could they have come sooner? Not clear what data was available at what time. Could they have reviewed more EUAs faster? 5-6 months for a rejection, 1-2 months for an EUA in a raging pandemic feels like a long time. Did they have enough staff and data to move faster? Not clear from the outside.

As for all of us, what matters most *now* is what we do *next* - how well the FDA learns the lessons of COVID, both before the next phase of COVID-19 and before the next inevitable pandemic. The three questions that we would like the FDA to tackle first: #1, How do they help increase supply of authorized high-quality rapid antigen tests, #2, How will they assess and authorize the coming surveillance tests and methods (from wastewater to breath tests), and #3, How will all these EUAs transition (or not) to fully approved status.

### *A Different Form of Surveillance Testing*

We had hoped that by this point we’d only need to be using surveillance testing to monitor the safety of our surroundings from an infectious-disease perspective. Turns out some folks are, though not in the way we had envisioned. They are parents - and some school administrators - who are using [portable CO2 monitors](#) to assess whether classrooms and cafeterias are adequately ventilated. Note - There are also professional systems available. Commentary: As it’s become clear that COVID-19 is an airborne disease, it makes sense to monitor the medium primarily responsible for that disease’s transmission. Testing must take many different forms especially in the next endemic phase of the pandemic.

## The Professional Version of Test to Play

In light of this unique time of year when all four major sports are playing games - we thought that you would like a review of the COVID testing-related policies for MLB, the NFL, the NBA, and the NHL.

Sports League	Player Vaccine Requirements	Spectator Vaccine Requirement
National Football League (NFL)	93% of players are vaccinated. Vaccinated players are tested weekly. Players with vulnerable cohabitants can elect daily testing. Unvaccinated and partially vaccinated test every day including off days, prior to entering the club facility.	Local/state laws guided vaccine/testing requirements.
National Basketball Association (NBA)	90% of players are vaccinated. Vaccinated players not required to test. Unvaccinated players must test daily for practice and on game days. Unvaccinated players who are unable to play due to local/state rules are not paid for missed games.	Over half of NBA teams are requiring fans in attendance to show proof of vaccine or recent negative test. NBA league policy requires fans within 15 feet of players be fully vaccinated or show a recent negative test.
National Hockey League (NHL)	Almost 100% vaccination amongst players. Vaccinated players must test every three days. For unvaccinated, must test daily (PCR) and are not able to enter arenas, gyms, etc. until a negative test is shown for that day.	Ten teams require proof of vaccination, eight teams allow the showing of a recent negative test to attend games
Major League Baseball (MLB)	23 of the 30 MLB teams have reached the 85% of their Tier 1 employees vaccinated which includes players. Required frequent PCR testing of players.	Local/state laws guided vaccine/testing requirements.

## Food for Thought

### *The Value of Ct Values:*

In April 2021, Mara published a [T3 blog](#) which advocated that viral load be made available to clinicians and epidemiologists as part of RTqPCR results. The reporting of Ct values however, has continued to face strong institutional resistance: First from the Infectious Diseases Society of America (IDSA) and the Association for Molecular Pathology (AMP) in [February](#) 2021, then from the American Association for Clinical Chemistry (AACC) in [July](#) 2021.

This week the AACC Journal of Clinical Chemistry [preprint](#) garnered widespread press ([Genomeweb](#); [MLQ](#)) under strong headlines, e.g., “Study validates AACC recommendation against using Ct values for SARS-CoV-2.” However, what that headline fails to say is that the preprint does advocate exactly what Mara proposed: Use viral load - but in copies per ml - just not raw Ct values.

Together, this paper and the institutional viewpoints released earlier provide a thorough review of the issues surrounding raw Ct values; they serve as a useful primer (pun intended) on benefits and risks. Agreed, raw Ct value alone is not valuable – it varies by probe/primer design, lab protocols, and instrumentation used. But when translated into viral load using a protocol-specific standard curve, it provides essential epidemiological and clinical data – high viral load indicates a patient at their most infectious, who may be approaching a crisis point.

### *K-12 Metrics:*

The number of school closures stayed low this week. Burbio's 2021/2022 [School Disruptions](#) count to date: 2,265 closures across 580 districts (up from 561 last week) across 45 states (no change from last week).

Of the nation's 500 largest school districts, 369 (74%) require masks; 180 (36%) require all staff to be vaccinated.

### *Higher Ed vaccine mandates:*

*The Chronicle of Higher Education* now counts [1,061 colleges and universities](#) that require vaccines, up from 1,058 a week ago.

# Latest Monthly Capacity Estimates

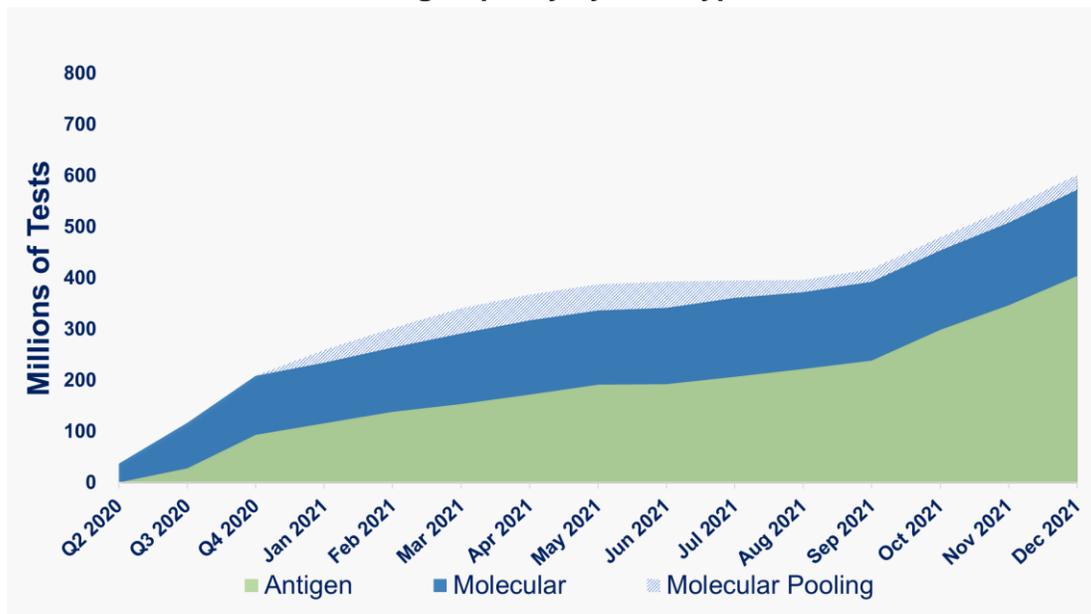
## Estimated Monthly Capacity of All Tests (M)

Test Type	Sep '21	Oct '21	Nov '21	Dec '21
<b>ANTIGEN</b>				
Antigen Professional + Point of Care EUA Today	149	158	172	197
Antigen OTC: Home/Self EUA Today	81	130	162	194
Antigen Central Lab Today	10	11	13	14
<b>Antigen Total</b>	<b>239M</b>	<b>299M</b>	<b>346M</b>	<b>404M</b>

<b>MOLECULAR</b>				
Molecular Professional, Point of Care, OTC EUA Today	28	31	32	39
Lab Based PCR Today	125	125	130	130
Add'l Lab Based PCR with Pooling	25	25	29	29
<b>Molecular Total</b>	<b>178M</b>	<b>181M</b>	<b>190M</b>	<b>198M</b>

<b>Total Test Capacity</b>	<b>417M</b>	<b>479M</b>	<b>537M</b>	<b>601M</b>
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## Manufacturing Capacity by Test Type Over Time



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