



Tracking US Coronavirus Testing Capacity

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July 21, 2021

■ Current National Capacity Projections. (Tests / Month)

349M

March 2021

379M

June 2021

590M

September 2021

707M

December 2021

No changes this week to test capacity.

What Happened Last Week

The FDA issued one new EUA, 13 amendments and one recall in the last week:

- New EUAs (1)
 - Antigen Tests (1): GenBody Inc.
- New Amendments to Existing EUAs (13)
 - Molecular Tests (8): Color Health | Color Health DTC | ISPM Labs | KimForest | PerkinElmer | Altona Diagnostics | Ambry Genetics | Enzo Life Sciences
 - Antigen Tests (2): DiaSorin LIAISON | Access Bio CareStart
 - Serology Tests (2): Salofa Oy | Roche Elecsys
 - Flu/RSV Panels (1): Exact Sciences Laboratories
- Recalls/Safety Communications (1)
 - Recalls (1): [Curative](#) (Recall issued at the company's request after January 4, 2021 warning of false results, especially false negatives.)

New & Noteworthy

δ continues to spread and spread and spread:

As of today, Delta is estimated to [account for 83%](#) of all new infections in the [US](#). To give some perspective on this, the Alpha / B.1.1.7 variant took three months to become the dominant variant across the country, while Delta took only one month to reach 51%. Two weeks after that - it moved to 83%. Not since the beginning of the pandemic has one variant been responsible for such a large percentage of US infections. There is considerable selection pressure for any virus to become more transmissible, but the same pressure tends to make the virus less fatal. That seems to be holding for SARS-CoV-2 for now.

Higher ed preparing for fall – first university vaccine mandate decision:

The Chronicle of Higher Education now counts [586 universities](#) that will require vaccines for the fall semester, up from 578 two weeks ago, including [the entire University of California system](#).

Federal judge upholds Indiana University Vaccine Requirement:

US District Judge Damon Leighty has upheld [Indiana University's requirement](#) that all in-person students and staff must be vaccinated against COVID-19. Judge Leighty noted that the school is not, in fact, requiring anyone to be vaccinated against their will: the university is offering both medical and religious exemptions, plus the option for students to attend classes virtually, and students and staff could also choose to go elsewhere for education or employment. The attorney for the eight students who brought the lawsuit has stated that he intends to appeal the matter to the Supreme Court.

Vaccination should not preclude testing:

A [JAMA Viewpoint](#) this week argued for continuing to COVID test all exposed and symptomatic individuals, even if they are vaccinated:

- Without enough testing, we will not know if decreasing case numbers mean fewer infections or just fewer tests. “Because the CDC surveillance system is passive... it may tend to underreport breakthrough infections.”
- If a vaccinated person is infected, but their immune response is not what it was expected to be, the person could still transmit disease to others.
- “CDC needs to be able to indicate that some very small number of symptomatic breakthrough infections is expected, and if the public becomes aware of a few breakthrough infections they should not be alarmed.” They can't do that with any authority if they aren't systematically tracking infections by testing.

Food for Thought

Commentary #1: You can't find what you don't look for:

The biggest challenge facing COVID testing is how little of it is now being done. US testing is down 13% over the last two weeks, to just one tenth the level of last winter's peak testing rate. The CDC has [stopped tracking](#) all but hospitalized and fatal COVID vaccine breakthrough cases. The diagnostic news media reflect the declining interest in COVID: on the excellent 360dx.com newsletter homepage today, only three of 30 items are COVID-related, a complete reversal from six months ago. Just yesterday Amazon announced the end to warehouse employee testing. To reduce surveillance is premature, overconfident, and foolhardy.

Commentary #2: We thought it was over, but we are now proven wrong

Back in May, we all breathed a sigh of relief that, at least for the US, the pandemic might be mostly over. The CDC relaxed masking rules on [May 13](#), and for several weeks, cases continued to drop. Yet now we are facing a new surge of cases, with [13 states](#) showing test positivity rates above 10%, thanks to the Delta / δ variant. In the [US, recorded cases have](#) doubled over the last two weeks to a level 5x our lowest level (just one month ago). [In the UK](#), new cases in July (mostly δ) are higher than at any time in 2020 and have reached 75% of their January 2021 peak. The UK January peak resulted from an ill-advised Christmas lockdown break, so now this week's “Freedom Day” will teach us many lessons.

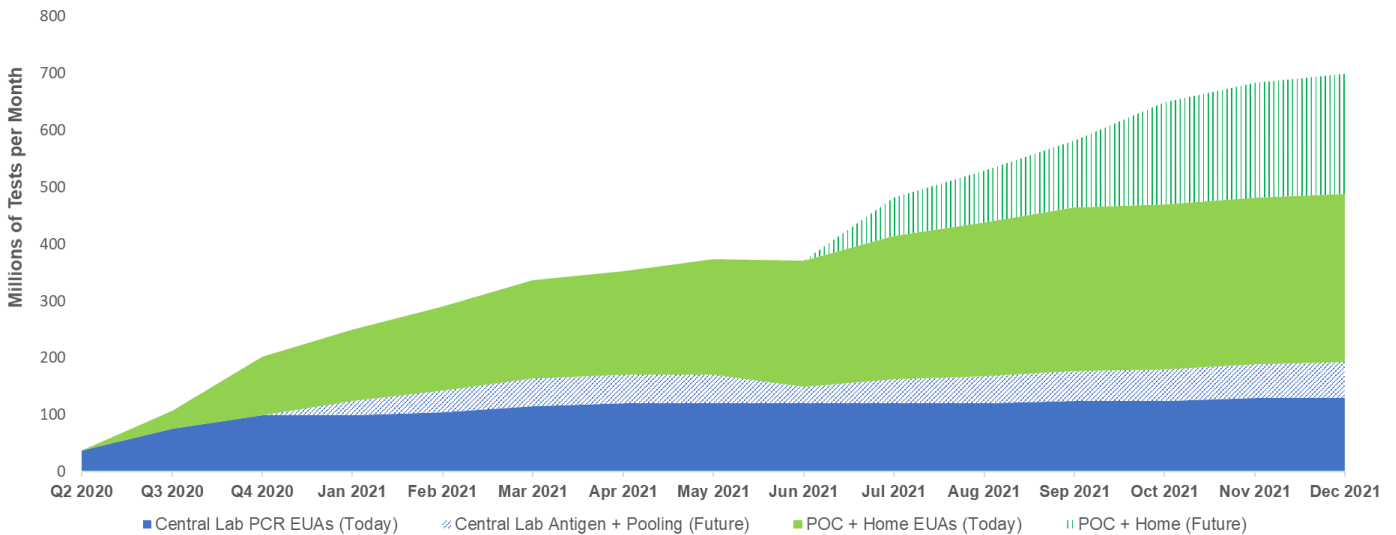
While on average, this δ surge's cases appear to be equally (or less) severe than before, we are still suffering over 300 avoidable deaths a day and rising. Averages obscure a massive divergence between vaccinated individuals well protected from the δ variant, versus the unvaccinated who comprise 95 - 99% of serious, hospitalized, and fatal cases. Vaccine “hesitancy” has declined, leaving a [more committed vaccine-resistant](#) group unlikely to ever be persuaded to vaccinate. As worrying - vaccination rates are plateauing at low levels in all age groups, including teens who have only just obtained vaccine access. If that remains so, COVID and annual COVID vaccine boosters will be with us for many years, and COVID testing will be our only path to a “normal” life.

Latest Monthly Capacity Estimates

Estimated Monthly Capacity of All Tests (M)

| Test Type | Sep '20 | Dec '20 | Jan '21 | Feb '21 | Mar '21 | Apr '21 | May '21 | Jun '21 | Jul '21 | Aug '21 | Sep '21 | Oct '21 | Nov '21 | Dec '21 |
|--|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Antigen Point of Care EUA Today | 28 | 95 | 111 | 131 | 145 | 157 | 166 | 163 | 178 | 190 | 204 | 206 | 206 | 206 |
| Home / Self Tests EUA Today | 0 | 2 | 6 | 7 | 17 | 12 | 24 | 44 | 56 | 61 | 63 | 64 | 66 | 69 |
| Molecular Point of Care EUA Today | 4 | 5 | 8 | 10 | 12 | 12 | 13 | 14 | 19 | 19 | 20 | 20 | 20 | 20 |
| Subtotal POC & Home EUA Today | 32 | 103 | 125 | 147 | 174 | 181 | 203 | 221 | 253 | 270 | 287 | 290 | 292 | 295 |
| <i>Antigen Point of Care Future</i> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 43 | 61 | 74 | 89 | 102 | 102 |
| <i>Home / Self Tests Future</i> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 18 | 30 | 75 | 85 | 95 |
| <i>Molecular Point of Care Future</i> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 12 | 14 | 14 | 14 | 14 |
| Subtotal POC & Home Future | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 67 | 91 | 118 | 178 | 201 | 211 |
| Total POC & Home | 32 | 103 | 125 | 147 | 174 | 181 | 203 | 221 | 320 | 361 | 405 | 468 | 493 | 506 |
| <i>Antigen Central Lab Today</i> | 0 | 0 | 3 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| <i>Antigen Central Lab Future</i> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 18 | 21 | 24 | 27 | 30 |
| Lab Based PCR Today | 75 | 100 | 100 | 105 | 115 | 120 | 120 | 120 | 120 | 120 | 125 | 125 | 130 | 130 |
| <i>Add'l Lab Based PCR with Pooling</i> | 0 | 0 | 25 | 38 | 48 | 50 | 50 | 30 | 30 | 30 | 31 | 31 | 33 | 33 |
| Total Central Lab | 75 | 100 | 128 | 150 | 170 | 178 | 178 | 158 | 170 | 176 | 185 | 188 | 198 | 201 |

Estimated Future Capacity by Test Type



Editors

Mara G. Aspinall, Arizona State University
Liz Ruark, COVID-19 Response Advisors

Contributors

Simon Johnson, Massachusetts Institute of Technology
Sarah Igoe, MD, Arizona State University

Designer

Fer Sagastume, COVID-19 Response Advisors

Based on published reports, company interviews, and proprietary analysis
A collaboration between COVID-19 Response Advisors & Health Catalysts Group

www.covidresponseadvisors.org & www.healthcatalysts.com