



# Tracking US Coronavirus Testing Capacity

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## ■ Current National Capacity Projections. (Tests / Month)

**349M**

March 2021

**470M**

June 2021

**595M**

September 2021

**713M**

December 2021

*No changes to the estimates this week; we will provide a comprehensive capacity update next week.*

## What Happened Last Week

*The FDA issued no new EUA's; there were nine amendments and one safety communication over the last week:*

- New Amendments to Existing EUAs (9)
  - Molecular Tests (5): Amazon (STS Labs HoldCo) DTC | Applied BioCode | Broad Institute | Fulgent Therapeutics | Harvard (HUCL) Quaeris
  - Flu / RSV Panels (2): Roche cobas | Abbott Alinity m Resp-4-Plex
  - Collection Kits (1): Clinical Enterprise EmpowerDx
  - Antigen Tests (1): Quidel Sofia

The [FDA released a Safety Communication](#), “Stop Using Innova SARS-CoV-2 Antigen Rapid Qualitative Test,” citing a potential health risk, unauthorized commercial distribution, and inadequately established test performance. This marks the fourth SARS-COV-2 test-related safety warning since the start of the pandemic, after [Lepu Medical and Leccurate](#) in May and [Curative](#) in January.

## New & Noteworthy

*The Antigen vs. PCR debate continues:*

- Concern about the accuracy of rapid antigen tests was [in the news](#) again this week after a [report](#) from the Irish Health Service Executive spotlighted Abbott's PanBio test, particularly its performance with asymptomatic people. (PanBio is the EU-focused “sister test” to the US- focused BINAX Now test. They use similar chemistry but different format. PanBio is a cassette and BINAXNow is a card.)
  - Commentary: The battle between antigen and PCR tests continues, with “combatants” forgetting that there is no perfect test (or drug or procedure) - the core issue is when and how to use each technology. While this latest study agrees that antigen tests have a place - especially when used serially - most of that “fine print” got lost once the story hit the press. As [The Lancet](#) summarized in April, PCR is too likely to pick up past disease to be the right gold standard for population infectivity monitoring, and it is too slow to enable while-you-wait intervention. As part of a frequent testing scheme, rapid antigen tests effectively curtail onward transmission in ways that PCR cannot.

- Analysis of antigen tests and more regulatory challenges. Mologic, a rapid antigen manufacturer, is suing the UK government for inaccurate assessments of their antigen test. The UK claimed that their lab tests with spiked virus revealed 30-60% failure rates while Mologic claims that in real clinical practice the error rate is running just 2%. The question is what comparator is being used. Do we need a new validation process specific to antigen / screening tests?

*Will ubiquitous rapid testing centers do the job in Germany, or is the US's increasing emphasis on at-home testing a better bet?*

- As part of Germany's re-opening plans, they have opened [15,000-plus rapid testing centers](#) offering free antigen tests for the unvaccinated. While proof that the strategy is working to date "is elusive," the testing program is particularly noteworthy given the nation's relatively slow vaccine rollout.
- In the US, Pitt County, North Carolina, and Chattanooga, Tennessee, just became [test sites](#) for an at-home testing model: the CDC will distribute two million QuickVue (Quidel) tests there, so that residents can test themselves at home three times a week. We look forward to seeing the results.

*RADx Tech II – The newest competition for impactful tests*

- The federal government [has announced](#) their continued interest in new test technology by announcing RADx Tech II. The fast-track program, which leverages the Point-of-Care Technology Research Network (POCTRN), part of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), is soliciting proposals to further advance SARS-CoV-2 testing technologies to fill what the feds see as "specific unmet national needs." Those needs include but are not limited to:
  - Point-of-care/over-the-counter tests with lab-test-level performance
  - Tests for multiple pathogens
  - Tests adaptable to emerging variants
- [All proposals](#) must be for tests ready to reach the market in 2021 – applications are due by June 28.

## Food for Thought

*When and where did COVID-19 first originate, and when did it first arrive in the US?*

- Commentary with data: The [lab leak theory](#) is a hot topic, but at a minimum, [complex questions](#) regarding the origins of SARS-CoV-2 still remain, since a viable pathway from bats to humans for the virus has not yet been found. (Pangolins from the Wuhan wet market were the big suspect in early 2020, but they are [not the intermediate host](#).) We need to remember that viral transfer from animals to humans has been known for 500 years. Origin analysis *may help* inform surveillance for future epidemics, but each virus's backstory is sufficiently unique to be largely useless for prediction. We have to prepare for the unexpected.
- Was COVID-19 in the U.S. earlier than we thought? A November 2020 analysis of [blood donations](#) found antibodies in 84 US samples collected between December 13, 2019 and January 17, 2020, before the earliest cases were reported in the US. Further, a [June 15 paper](#) found COVID-19 antibodies in two blood samples from the NIH's All of Us research program that were drawn during the first week of January 2021, indicating infections prior to mid-December 2019.

*Preparing for the Fall Semester*

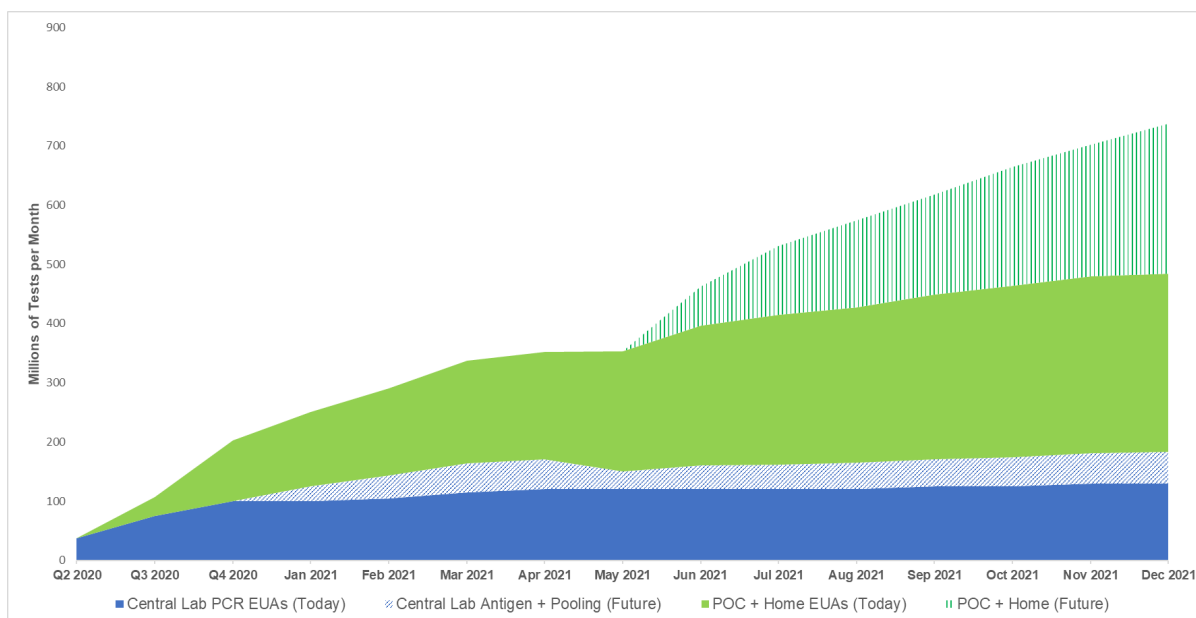
- Higher Ed: The Chronicle of Higher Education now counts 510 universities that will require vaccines for the fall semester, [up from 483 last week](#)

# 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        | 180        | 189        | 191        | 201        | 201        | 207        | 207        |
| Home / Self Tests EUA Today              | 0          | 2          | 6          | 7          | 17         | 12         | 24         | 43         | 50         | 58         | 63         | 75         | 77         | 80         |
| Molecular Point of Care EUA Today        | 4          | 5          | 8          | 10         | 12         | 12         | 13         | 13         | 14         | 14         | 14         | 14         | 14         | 14         |
| <b>Subtotal POC &amp; Home EUA Today</b> | <b>32</b>  | <b>103</b> | <b>125</b> | <b>147</b> | <b>174</b> | <b>181</b> | <b>203</b> | <b>236</b> | <b>253</b> | <b>263</b> | <b>278</b> | <b>290</b> | <b>298</b> | <b>301</b> |
| Antigen Point of Care Future             | 0          | 0          | 0          | 0          | 0          | 0          | 0          | 33         | 75         | 100        | 110        | 135        | 135        | 135        |
| Home / Self Tests Future                 | 0          | 0          | 0          | 0          | 0          | 0          | 0          | 23         | 29         | 35         | 45         | 51         | 73         | 104        |
| Molecular Point of Care Future           | 0          | 0          | 0          | 0          | 0          | 0          | 0          | 10         | 12         | 12         | 14         | 14         | 14         | 14         |
| <b>Subtotal POC &amp; Home Future</b>    | <b>0</b>   | <b>0</b>   | <b>0</b>   | <b>0</b>   | <b>0</b>   | <b>0</b>   | <b>0</b>   | <b>66</b>  | <b>116</b> | <b>147</b> | <b>169</b> | <b>200</b> | <b>222</b> | <b>253</b> |
| <b>Total POC &amp; Home</b>              | <b>32</b>  | <b>103</b> | <b>125</b> | <b>147</b> | <b>174</b> | <b>181</b> | <b>203</b> | <b>302</b> | <b>369</b> | <b>410</b> | <b>447</b> | <b>490</b> | <b>520</b> | <b>554</b> |
| Antigen Central Lab Today                | 0          | 0          | 3          | 7          | 7          | 8          | 8          | 8          | 8          | 8          | 8          | 8          | 8          | 8          |
| Antigen Central Lab Future               | 0          | 0          | 0          | 0          | 0          | 0          | 0          | 10         | 12         | 15         | 15         | 18         | 19         | 21         |
| Lab Based PCR Today                      | 75         | 100        | 100        | 105        | 115        | 120        | 120        | 120        | 120        | 120        | 125        | 125        | 130        | 130        |
| Add'l Lab Based PCR with Pooling         | 0          | 0          | 25         | 38         | 48         | 50         | 30         | 30         | 30         | 30         | 31         | 31         | 33         | 33         |
| <b>Total Central Lab</b>                 | <b>75</b>  | <b>100</b> | <b>128</b> | <b>150</b> | <b>170</b> | <b>178</b> | <b>158</b> | <b>168</b> | <b>170</b> | <b>173</b> | <b>179</b> | <b>182</b> | <b>190</b> | <b>192</b> |
| <b>Grand Total</b>                       | <b>107</b> | <b>203</b> | <b>253</b> | <b>297</b> | <b>344</b> | <b>360</b> | <b>361</b> | <b>470</b> | <b>539</b> | <b>583</b> | <b>626</b> | <b>672</b> | <b>710</b> | <b>746</b> |

## Estimated Future Capacity by Test Type



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