Tracking US Coronavirus Testing Capacity

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Current National Capacity Projections. (Tests / Month)

March 2021	June 2021	September 2021	December 2021
349M	379M	590M	707M

No changes this week to test capacity.

What Happened Last Week

The FDA issued one new EUA and 12 amendments over the last week:

- New EUAs (1)
  - Serology Tests (1): CareStart EZ COVID-19 IgM/IgG
- New Amendments to Existing EUAs (12)
  - Molecular Tests (9): Biomeme, Inc. | Viracor Eurofins | Fulgent Therapeutics | BillionToOne, Inc | Clinomics USA | Vela Operations | 3B Blackbio | OSANG Healthcare | Trax Management Services Inc.
  - Serology Tests (2): Acon Laboratories | Symbiotica
  - Flu/RSV Panels: (1) Roche cobas

Special Section: TestingComons.com Test Review

Today marks the halfway point of 2021 – 18 months since COVID-19 emerged on the global scene, and 15 months since regulatory agencies around the world began to issue Emergency Use Authorizations for tests to diagnose active and past SARS-CoV2 infections.

Regulatory agencies were challenged to accelerate traditional test approval processes – to loosen standards to help tests come to market but not delay too much in order to try to contain a rapidly escalating pandemic. Laboratories and manufacturers scrambled to apply their existing diagnostic technologies to these novel COVID tests or develop new ones that were suited to a scale never before imagined. The challenge then shifted to develop, validate and commercialize them at scale in a very short time period. There were inevitable ups and downs as knowledge about the virus and its human pathology was continuously defined.

In summary, there are now at least 2,418 tests authorized or in development around the world. More than half of these tests are available commercially in different parts of the world, and the remainder represent important developments that will help us emerge from this pandemic successfully and lay the groundwork for the next viral threat (which, if we have learned anything from the past 18 months is inevitable but unpredictable in its nature and timing). We may not need the same types of tests, but we now understand, hopefully, that diagnosis is critical to taking back control from the pathogen – whatever form it takes.

At TestingCommons.com, we are proud to have been compiling this data since the beginning and making it available in an organized and searchable web tool. We are particularly proud to have become a trusted source of information to those with urgent needs for testing and those working to analyze the technologies and the companies behind these tests – all to enable a return to our normal social, business and educational activities, hopefully, in 2021.

A special thank you to the ASU College of Health Solutions and ASU Decision Theater who are critical to the success of this system and to The Rockefeller Foundation for the enabling grant for TestingCommons.com and all the activities encompassing ASUCovidCommons.com.

New & Noteworthy

Laboratory Test Legislation introduced again:

There has been a long-standing debate within Congress and Federal healthcare agencies over the who, where, what, when, and how of diagnostic test regulation. In a very small, overly simplistic nutshell, two systems currently co-exist:

- The FDA oversees in-vitro diagnostics (IVDs): tests created by a single manufacturer and sent to labs across the country (and the world) to be run and analyzed.
- Through a system called CLIA (Clinical Laboratory Improvement Amendments) CMS oversees laboratory-developed tests (LDTs): tests developed, validated, run, and analyzed in one single lab.

While there are many important aspects of the regulation of diagnostics (and its impact on reimbursement), the biggest point of contention has been over where and how LDTs should be approved. This week a bipartisan and bicameral team introduced the Verifying Accurate and Leading-edge IVCT Development (VALID) Act. This act would bring LDTs securely into the FDA fold, allowing the FDA to regulate LDTs in much the same way they regulate in vitro diagnostics (IVDs).

In contrast, Senator Rand Paul re-introduced the Verified Innovative Testing in American Laboratories (VITAL) Act of 2021. This bill would place LDTs under the purview of HHS during public health emergencies, expressly excluding the FDA from regulating LDTs in those circumstances.

Food for Thought

Higher Ed Preparing for the Fall

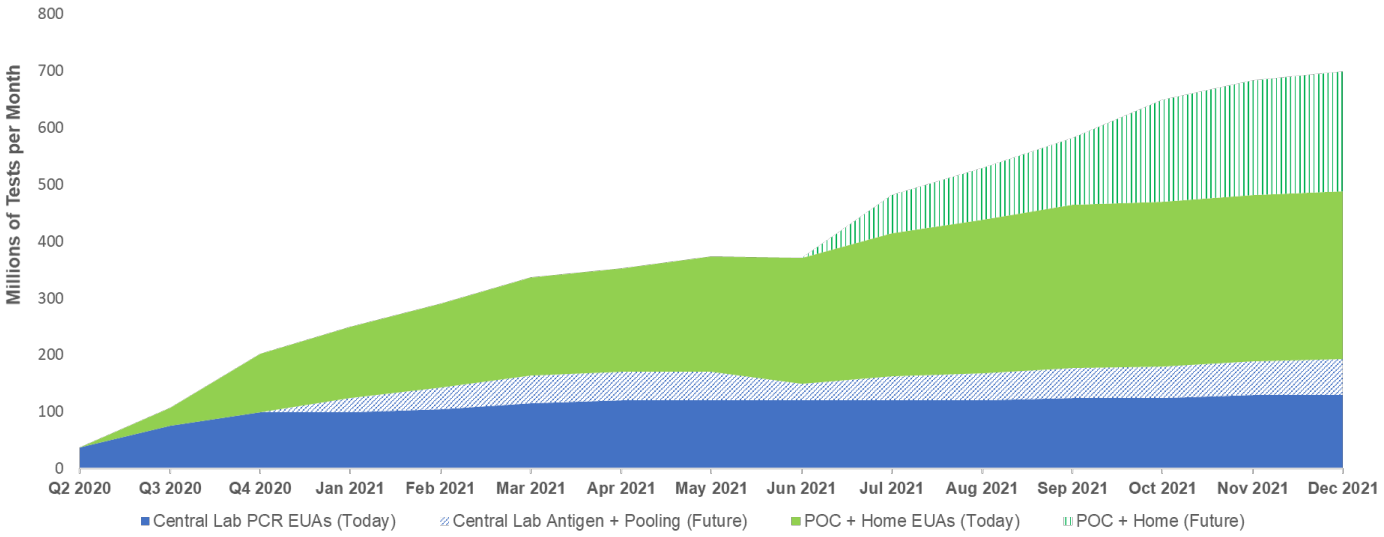
- *The Chronicle of Higher Education* now counts 544 universities that will require vaccines for the fall semester, up from 510 last week..

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	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**
Antigen Point of Care Future	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*43*	*61*	*74*	*89*	*102*	*102*
Home / Self Tests Future	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*12*	*18*	*30*	*75*	*85*	*95*
Molecular Point of Care Future	*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**
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*	*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
Addt'l Lab Based PCR with Pooling	*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



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