



Tracking US Coronavirus Testing Capacity

DECEMBER 29TH, 2020

■ Current National Capacity Projections (Tests / Month)



205M

This Month

274M

January

676M

End of Q1

1,069M

End of Q2

Last Week's Major Emergency Use Authorizations (EUA)

A big week for rapid antigen testing

Abbott BINAX At-Home Antigen Test

- Online ordering and prescription
- Capacity projections:
Q1: 10 million/month
Q2: 30 million/month
- Data collected on NAVICA app

Ellume Antigen Test

- Fully at home with no Rx needed for age 2 and above
- Low capacity projections:
7.5 million/month by June
- Results only visible on smartphone. Zip code data collected

Quidel QuickVue Rapid Antigen Test

- No instrument point of care (POC) test
- Capacity projections: will rise from 10 million/month to 40 million/month by June

What to Watch for this Week



12/28/2020

A final blast of 2020 EUAs including many updates to existing EUAs

- 28 EUAs issued on December 28th, all were amendments or updates to existing EUAs
- Roche point of care (POC) white label of SD Biosensor EUA expected
- Cellex at-home rapid antigen test EUA expected

New & Noteworthy

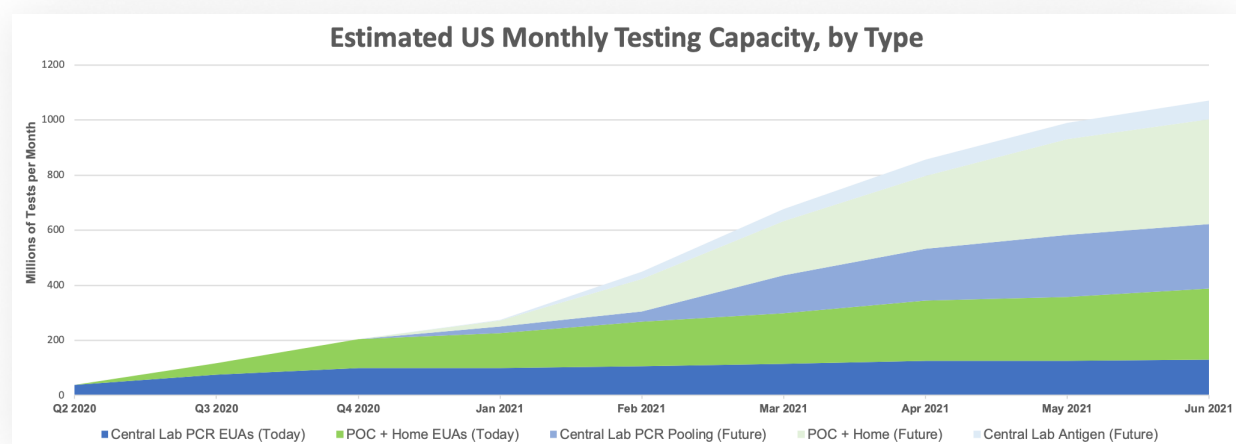
- Becton Dickinson and OrthoClinical both have pending EUAs for central lab antigen tests for NP Swabs, potentially limiting interest in these tests
- SalivaDirect is expanding: more than 70 labs are now trained and using protocols (Contact: SalivaDirect@gmail.com)

Food for Thought

- Unconfirmed reports indicate there are 1,700 COVID-19 test EUAs in the FDA approval queue across all technologies. Analyzing and prioritizing the EUA backlog, as legally appropriate, would generate significant testing capacity gains.
- Clarifying regulatory pathways for Laboratory Developed Tests (LDT) to seek “voluntary EUAs” could ease burden and expand capacity.
- Consider ways to leverage staff and resources from other HHS agencies to expand FDA review and authorization capacity.

Latest Monthly Capacity Estimates

Test Type	Sep 2020	Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	Jun 2021
Antigen Point of Care EUA Today	36	95	110	140	157	172	184	204
Home DIY EUA Today	0	2	7	11	14	35	36	40
PCR Point of Care EUA Today	5	6	9	11	13	13	13	15
Subtotal POC & Home EUA Today	41	104	126	163	183	220	233	258
Antigen Point of Care Future	0	0	18	80	105	140	197	215
Home DIY Future	0	0	3	33	83	114	139	154
PCR Point of Care Future	0	0	0	4	8	10	11	12
Subtotal POC & Home Future	0	0	21	117	196	264	347	381
Total POC & Home	41	104	147	280	379	484	580	639
Lab Based PCR Today	75	100	100	105	115	125	125	130
Total Antigen Central Lab Future	0	1	2	27	44	59	59	66
Additional Lab Based PCR with Pooling	0	0	25	37.8	138	187.5	225	234
Total Central Lab	75	101	127	170	297	372	409	430
Grand Total	116	205	274	449	676	856	989	1069



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Based on published reports, company interviews, and proprietary analysis