



Diagnostics Year in Review - 2021

January 2022

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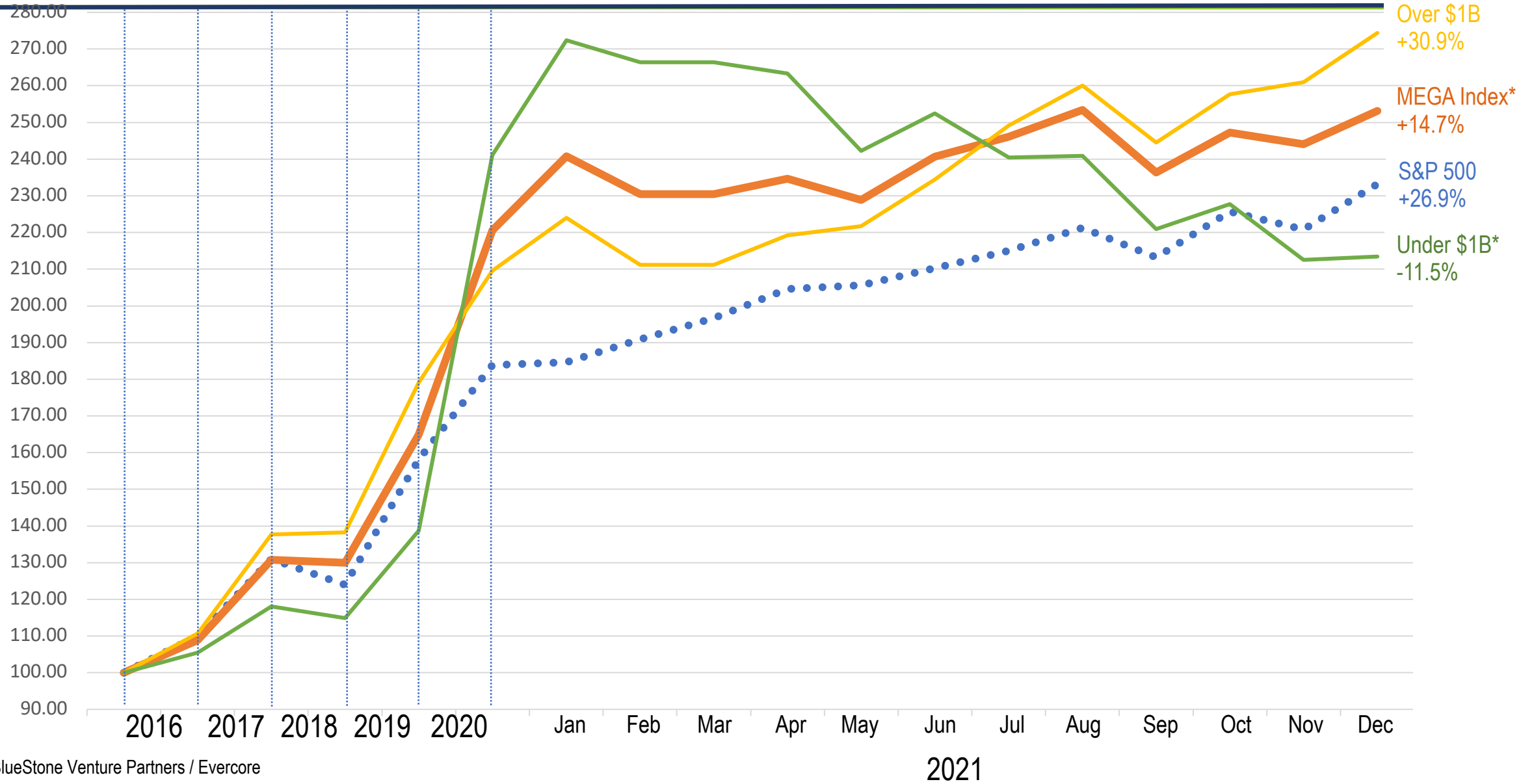
The Diagnostics World 2021

- Diagnostics in the Public Markets
 - The MEGA Index
 - Diagnostic IPO's
 - Diagnostic Mergers & Acquisitions

- Overview of COVID Testing

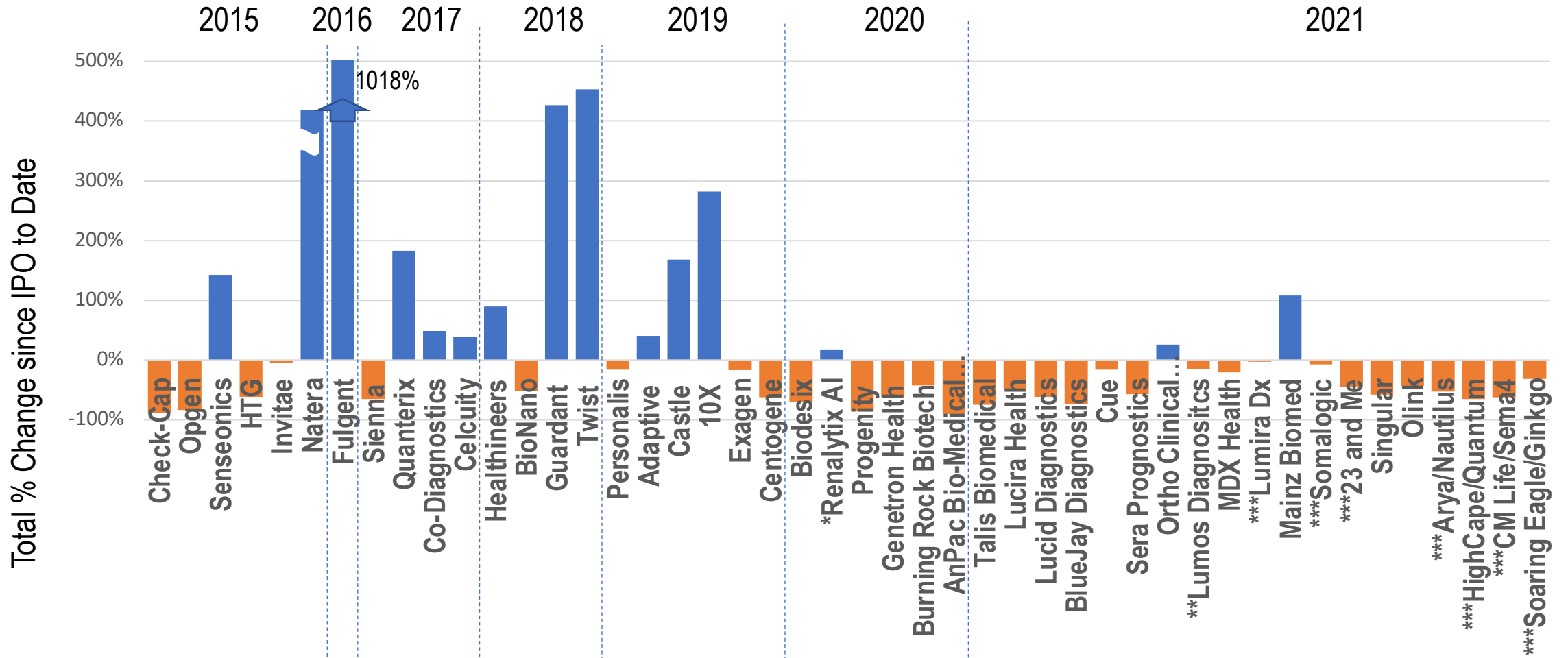


Clinical Diagnostics MEGA Index (2016-2021)



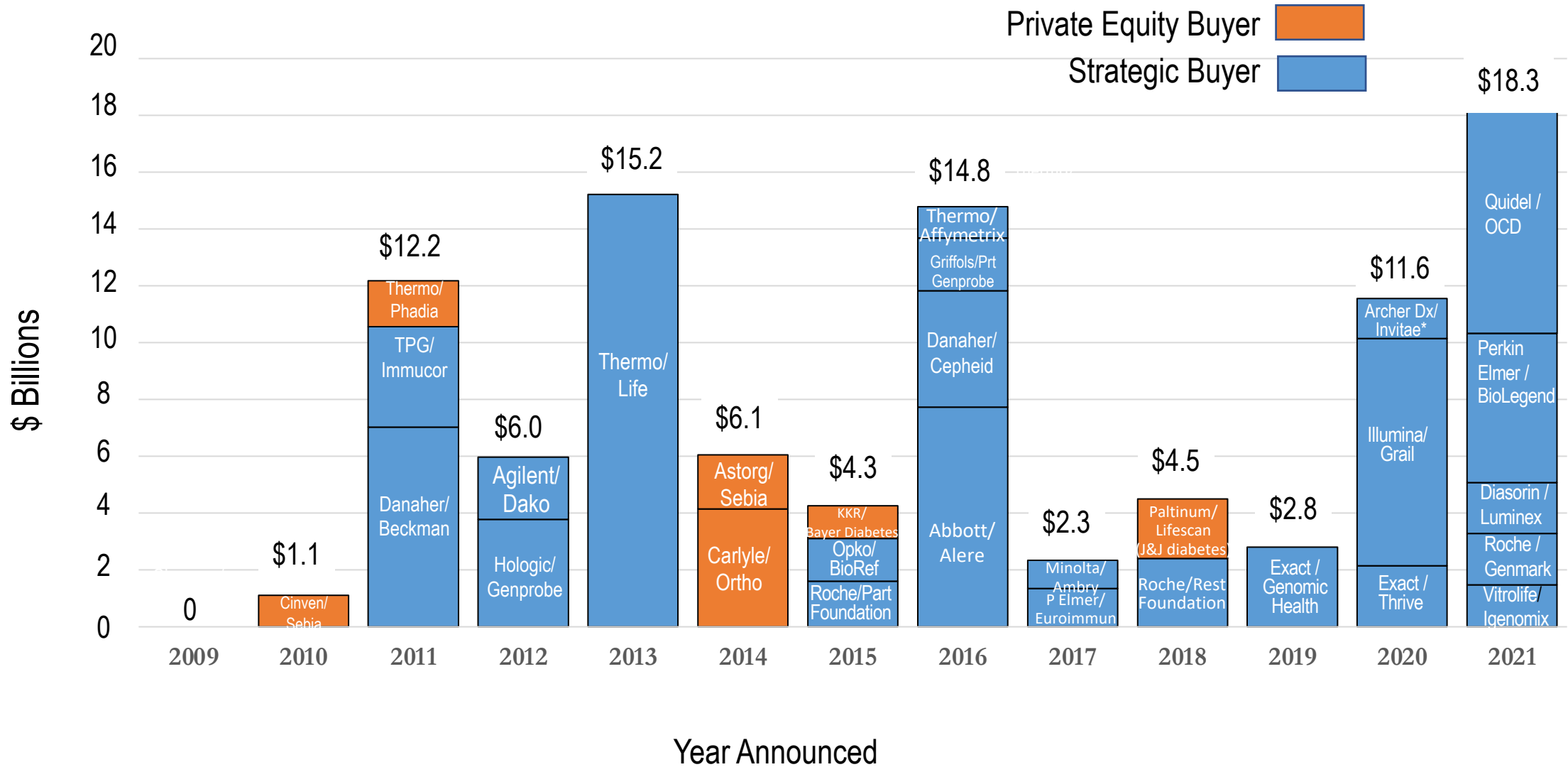


Diagnostic IPOs: Price Performance from IPO through 2021



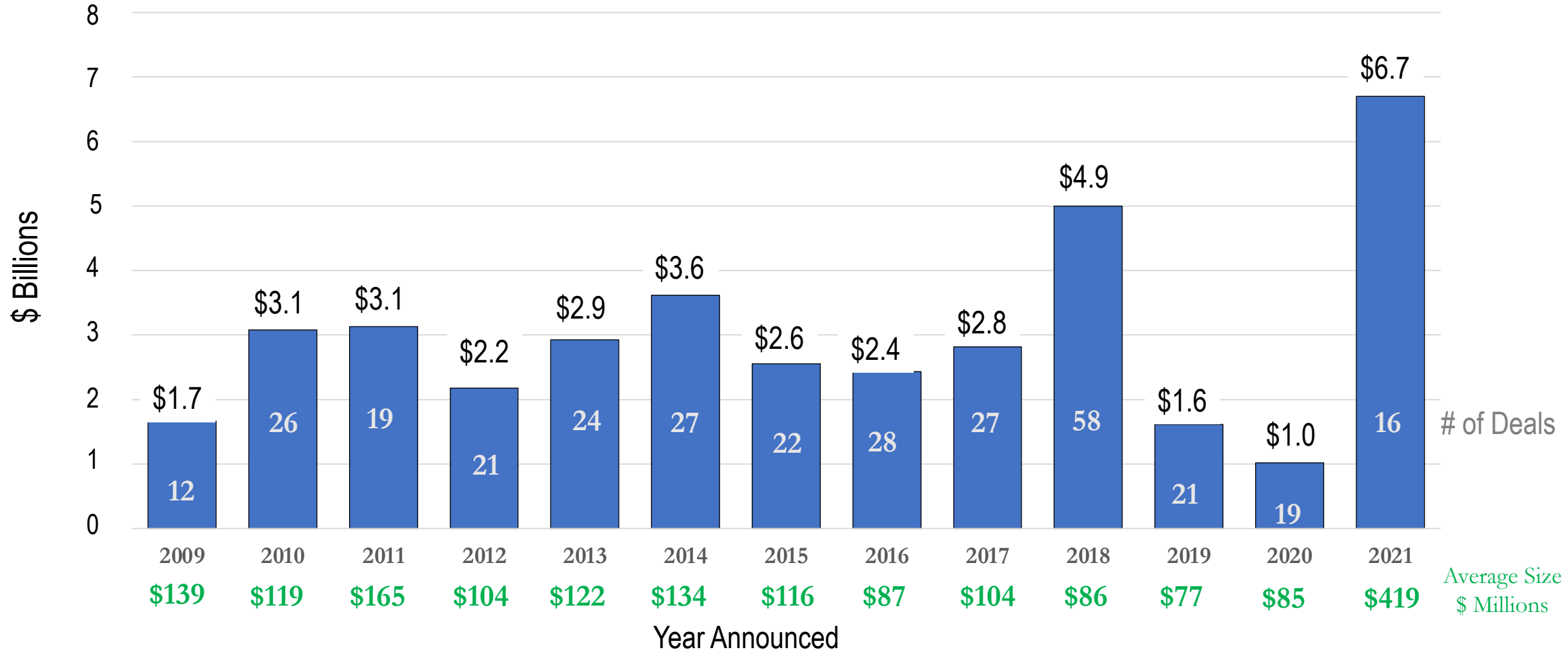


Diagnostic Industry Transforming Acquisitions (>\$1 Billion)





Smaller Diagnostic Acquisitions (<\$1 Billion)





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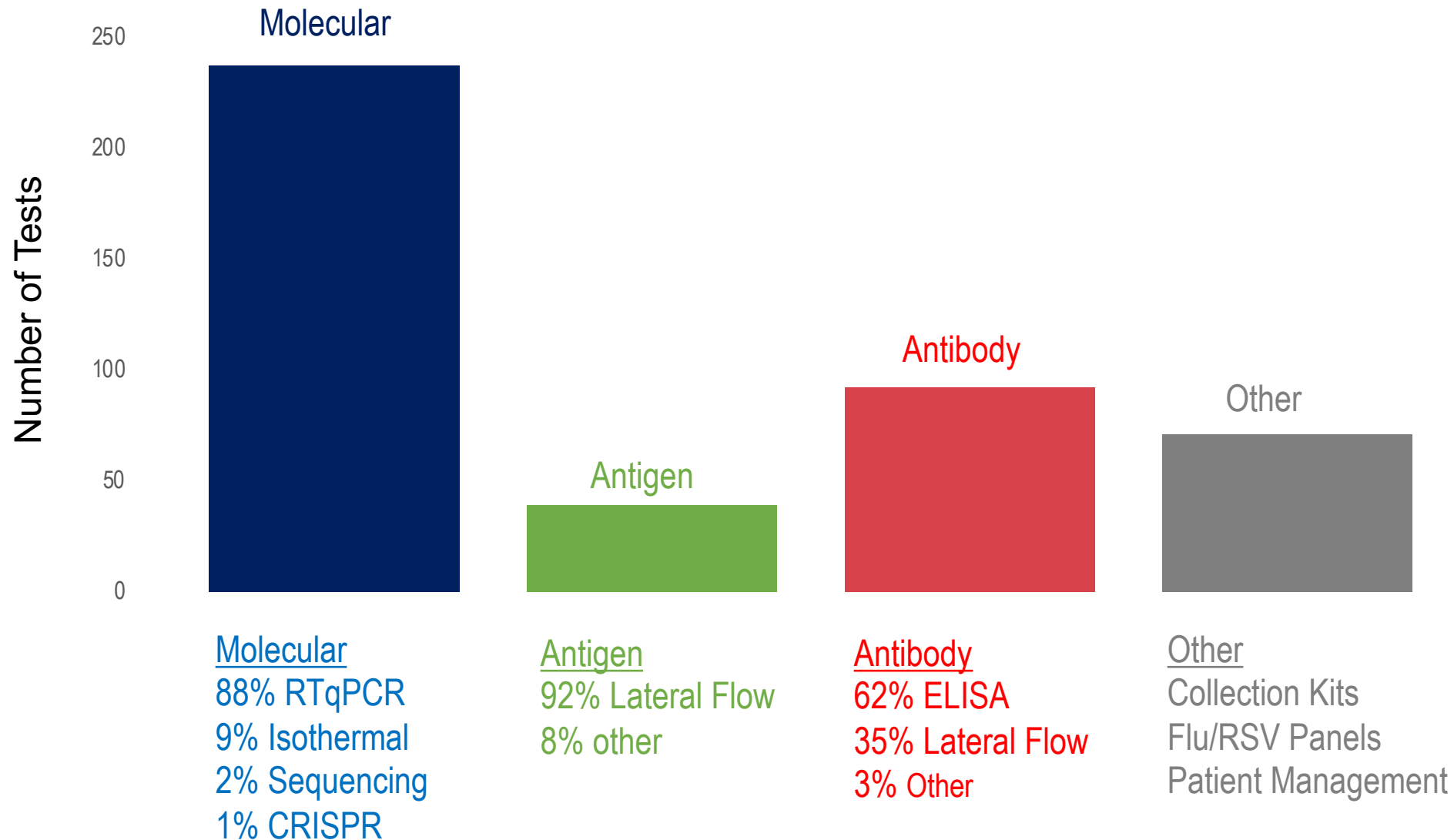
TestingCommons.com

A one-stop reliable source for comprehensive information about COVID-19 tests worldwide. Search all tests in the market and in the pipeline by multiple parameters including test type, technology, regulatory status, country of origin and more.

TestingCommons.com, part of COVID Diagnostics Commons initiative,
at Arizona State University's College of Health Solutions

Testing Commons is made possible with support from The Rockefeller Foundation

US FDA Emergency Use Authorizations COVID Tests



Pandemic Total
through 12/31/21

17 EUA's for OTC COVID Self Tests



MOLECULAR TESTS (3)

ANTIGEN TESTS (14)

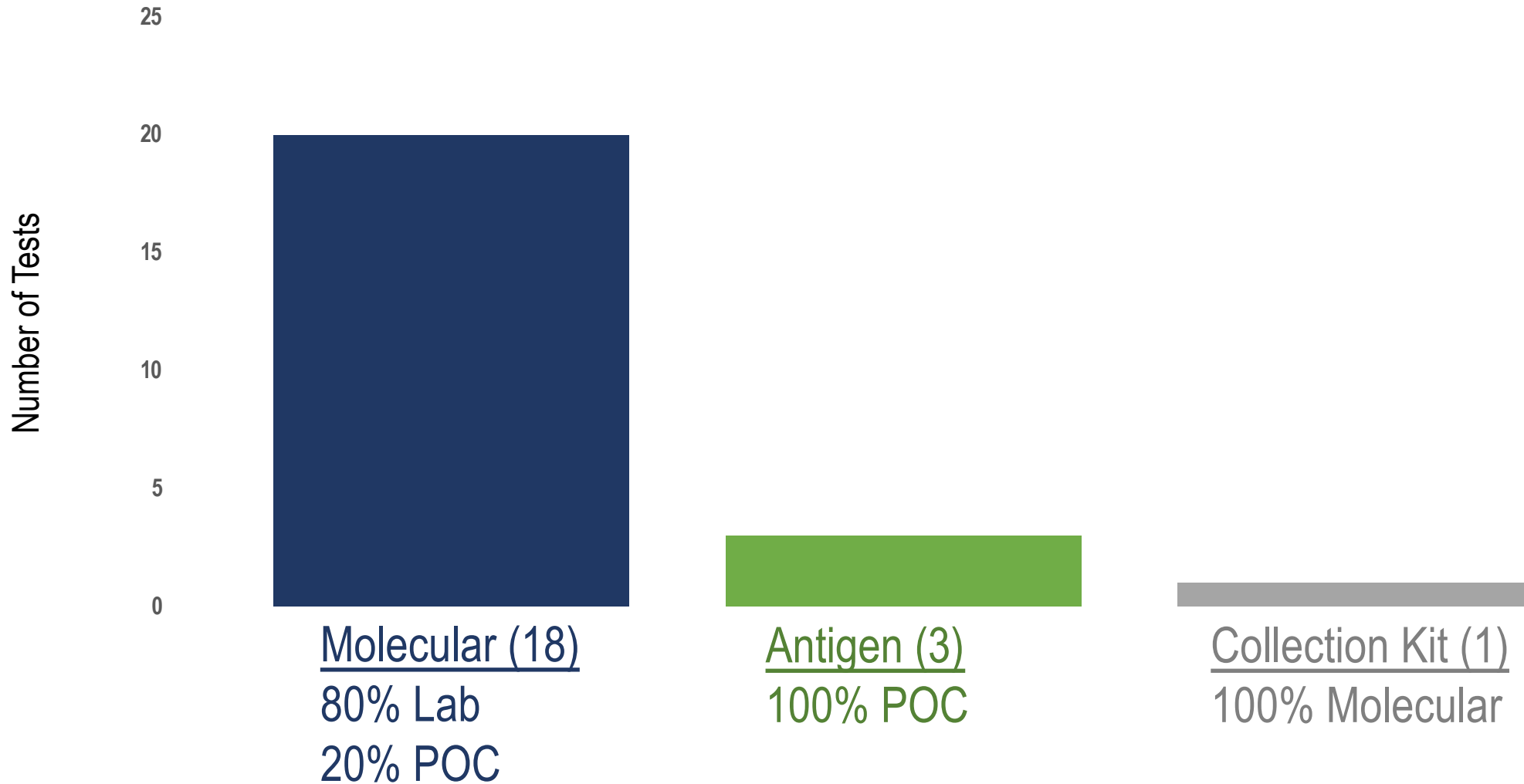
- Cue for Home & OTC:
SINGLE

- Detect At-Home:
SINGLE Sympt +
Serial Asymptomatic

- Lucira CHECK-IT Test:
SINGLE

- Abbott BinaxNOW Card 2 Home: Serial: Asympt. & Single: Sympto
- Abbott BinaxNOW Ag Self: Serial: Asympt. & Single: Sympto
- Access Bio CareStart Home: Serial: Asympt. & Single: Sympto
- ACON Flowflex: Single for both: Asymptomatic and Sympto
- BD Veritor At-Home: Serial: Asympt. & Single: Sympto
- Celltrion At Home: Serial: Asympt. & Single: Sympto
- Ellume COVID-19 Home: Single for both: Asymptomatic and Sympto
- iHealth COVID-19 Home: Serial: Asympt. & Single: Sympto
- InBios Int'l Detect Self: Serial: Asympt. & Single: Sympto
- MaximBio Clear Detect Self: Serial: Asympt. & Single: Sympto
- OraSure IntelliSwab Rapid: Serial: Asympt. & Single: Sympto
- Quidel QuickVue At-Home: Serial: Asympt. & Single: Sympto
- Roche / SDBiosensor At-Home: Serial: Asympt. & Single: Sympto
- Siemens CLINITEST: Serial: Asympt. & Single: Sympto

24 EUA's for Respiratory Panels (Flu, RSV, etc.)



Pandemic Total
through 12/31/21

Tests in Development Worldwide



Workplace Commons

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Evidence Commons

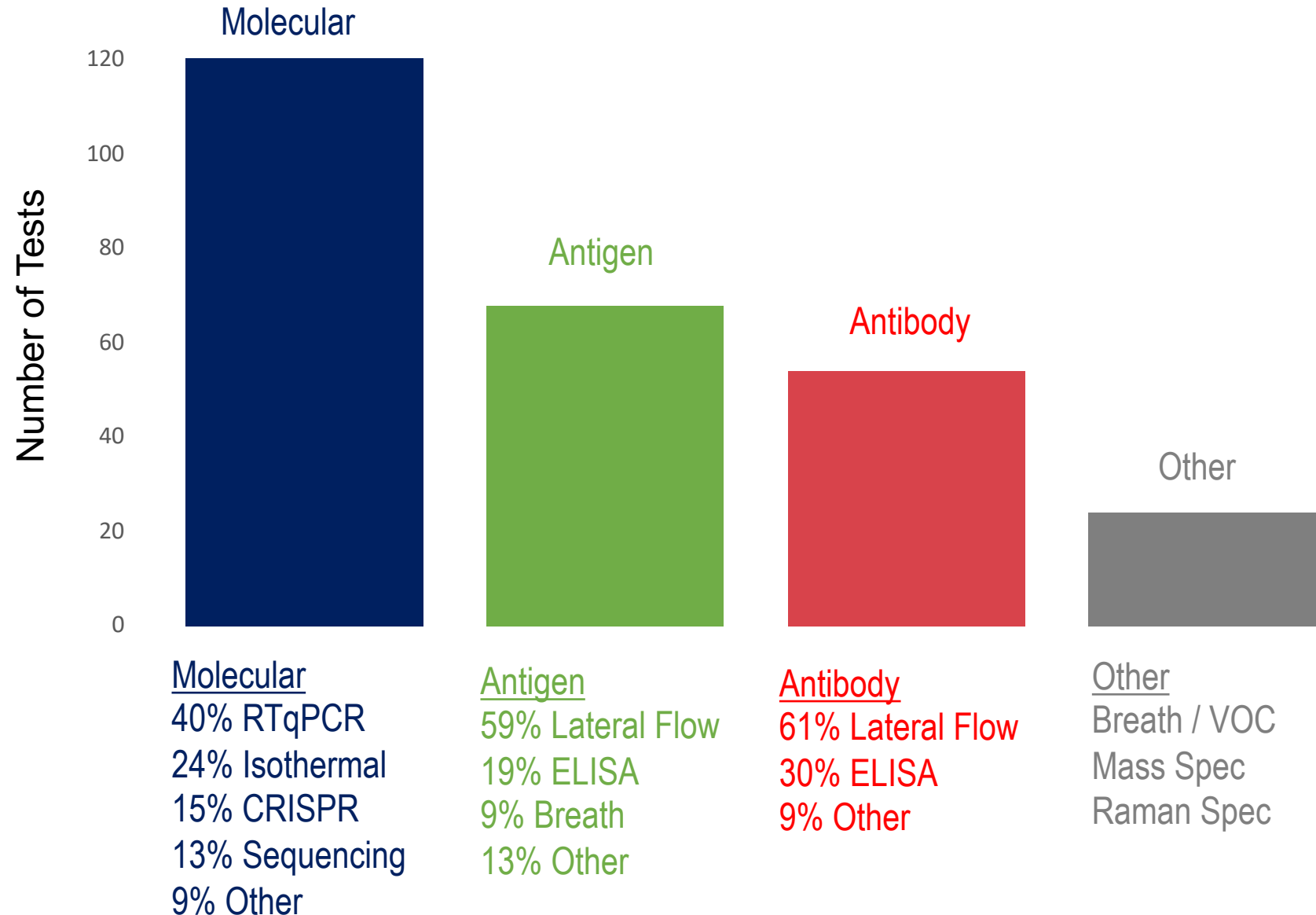
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Pandemic Total
through 12/31/21

CE-IVD Certified Tests (Mostly Europe)



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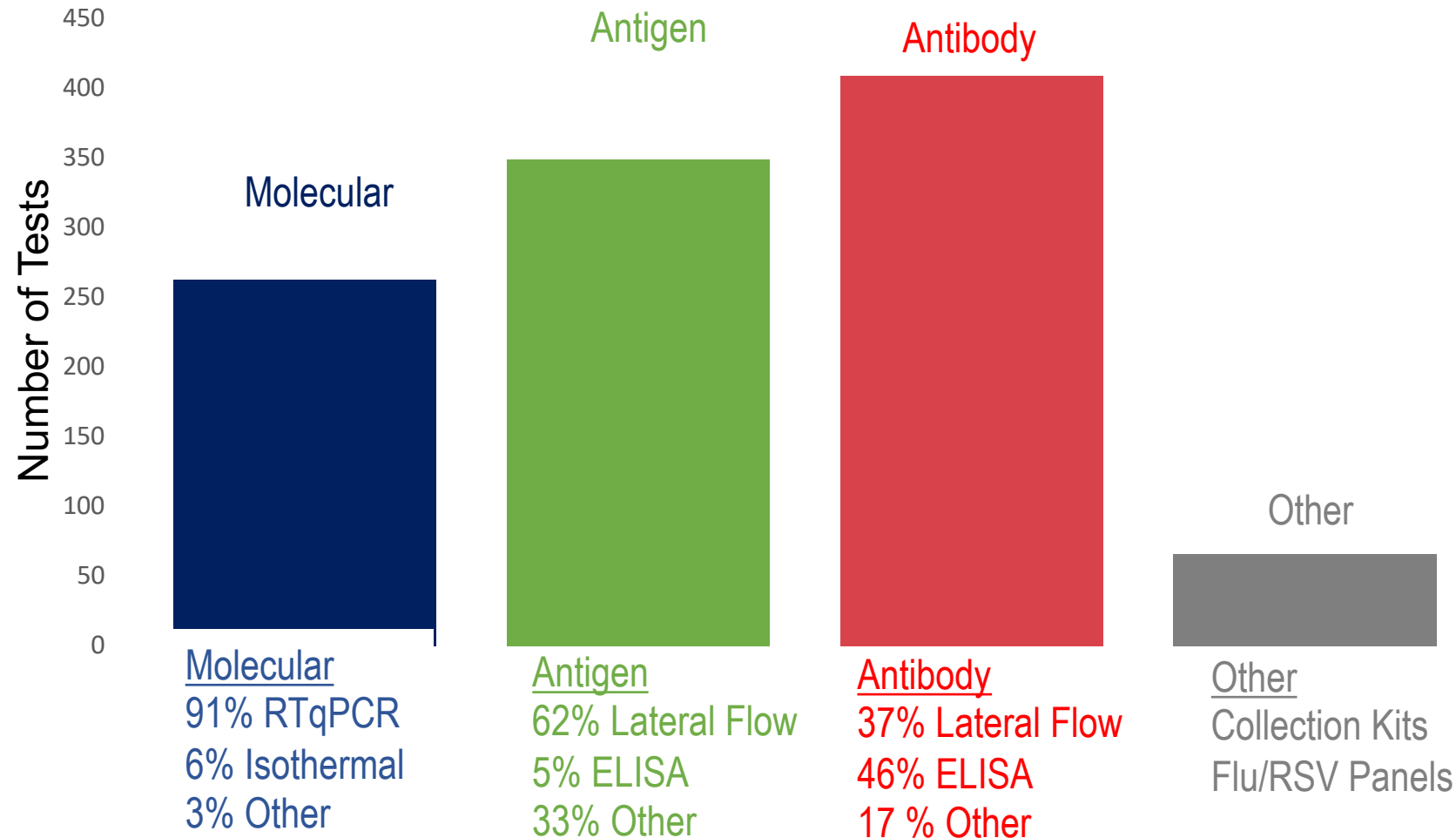
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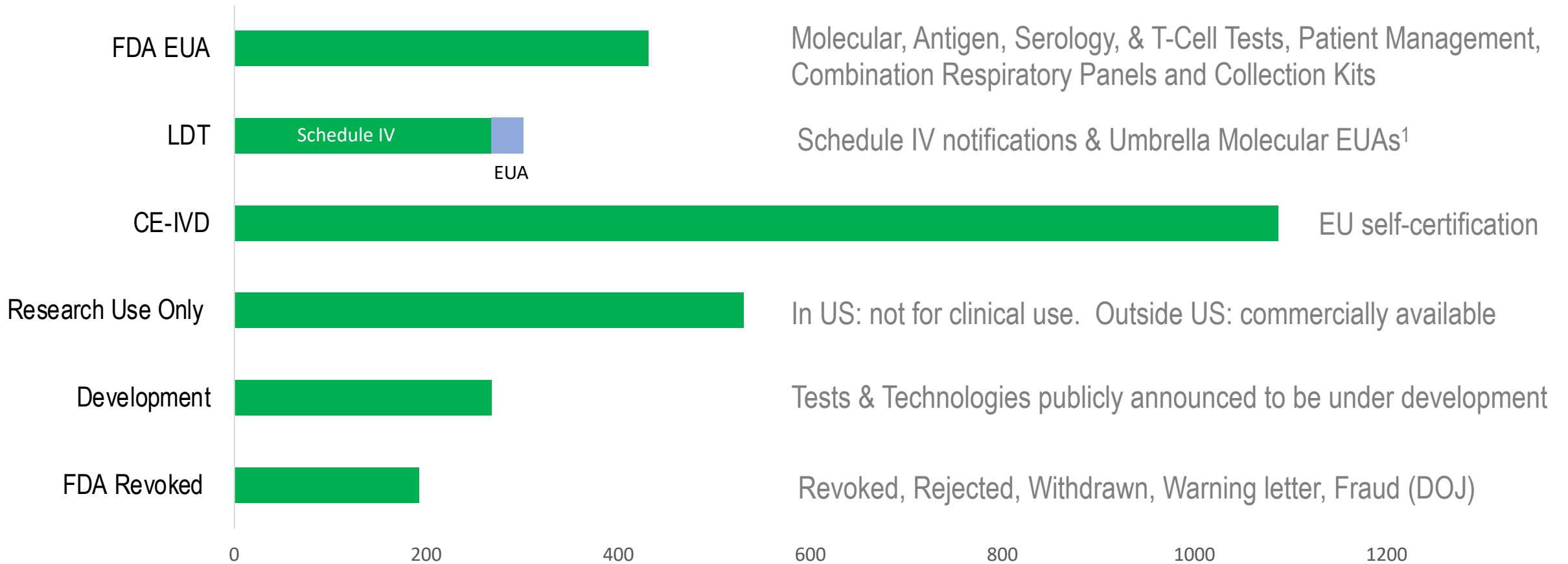


Pandemic Total
through 12/31/21



- Total EUA activity
 - 133 EUA's in 2021 vs. 188 EUA's in 2020
- Antigen Rapid Self-Test EUA activity
 - 2021 Q1 through Q3 – 6 new EUA's
 - 2021 Q4 – 6 new EUA's (ACON, Celltrion, InBios, iHealth, SD BioSensor (Roche), Siemens)
- Molecular EUA activity
 - 2021 3 Rapid Molecular [Cue in Q1, Lucira in Q2, Detect in Q4]
 - 2021 Lab Based Molecular – 43 new EUAs [for COVID assays, excludes multi-analyte panels and collection kits]

TestingCommons.com Pandemic Review



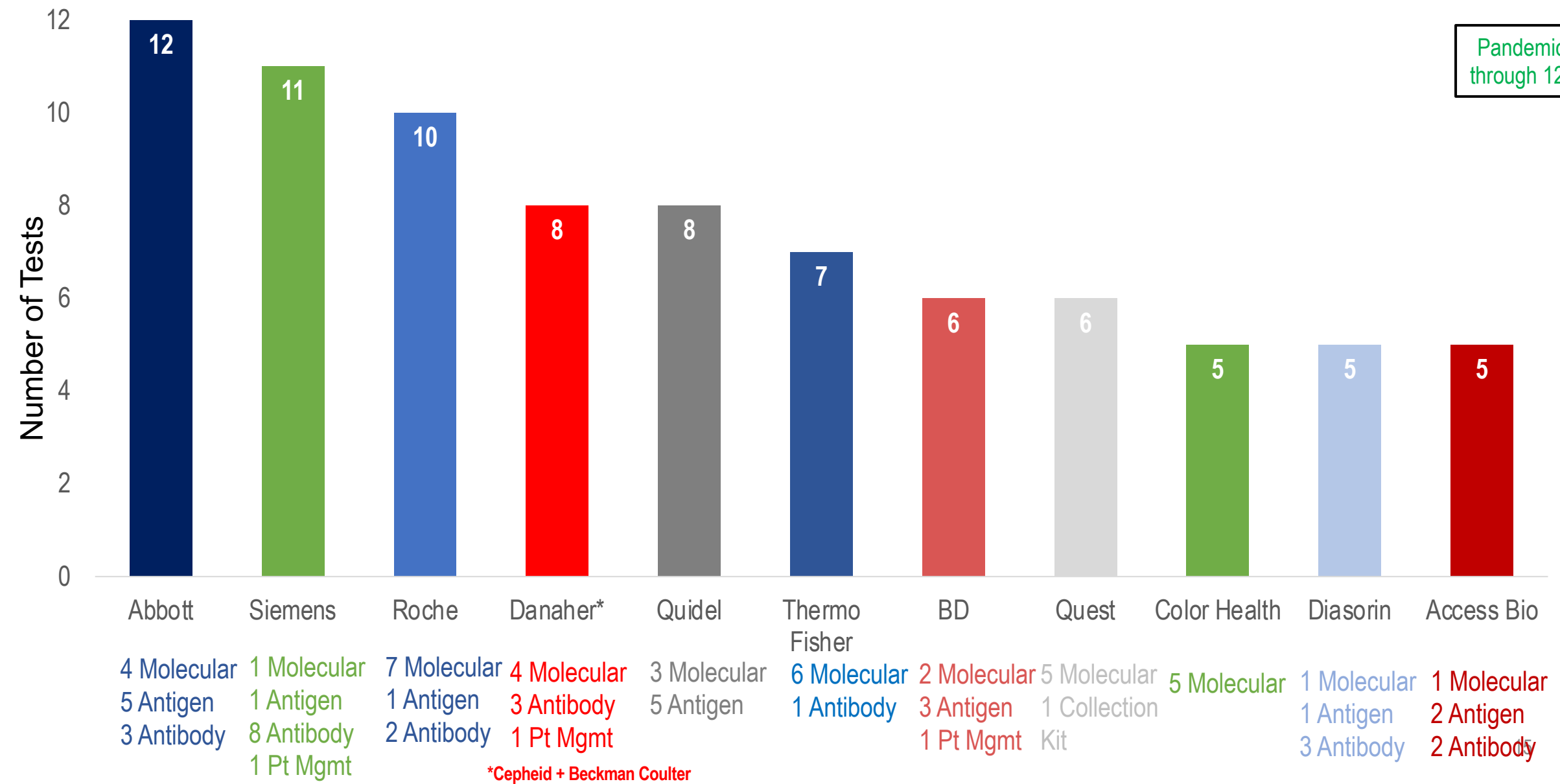
1. Discontinued after 10/7/20 when HHS/FDA announced policy to not require authorization for COVID LDT

Questions: mara.aspinall@asu.edu

Pandemic Total through 12/31/21

Companies with the largest number of EUAs

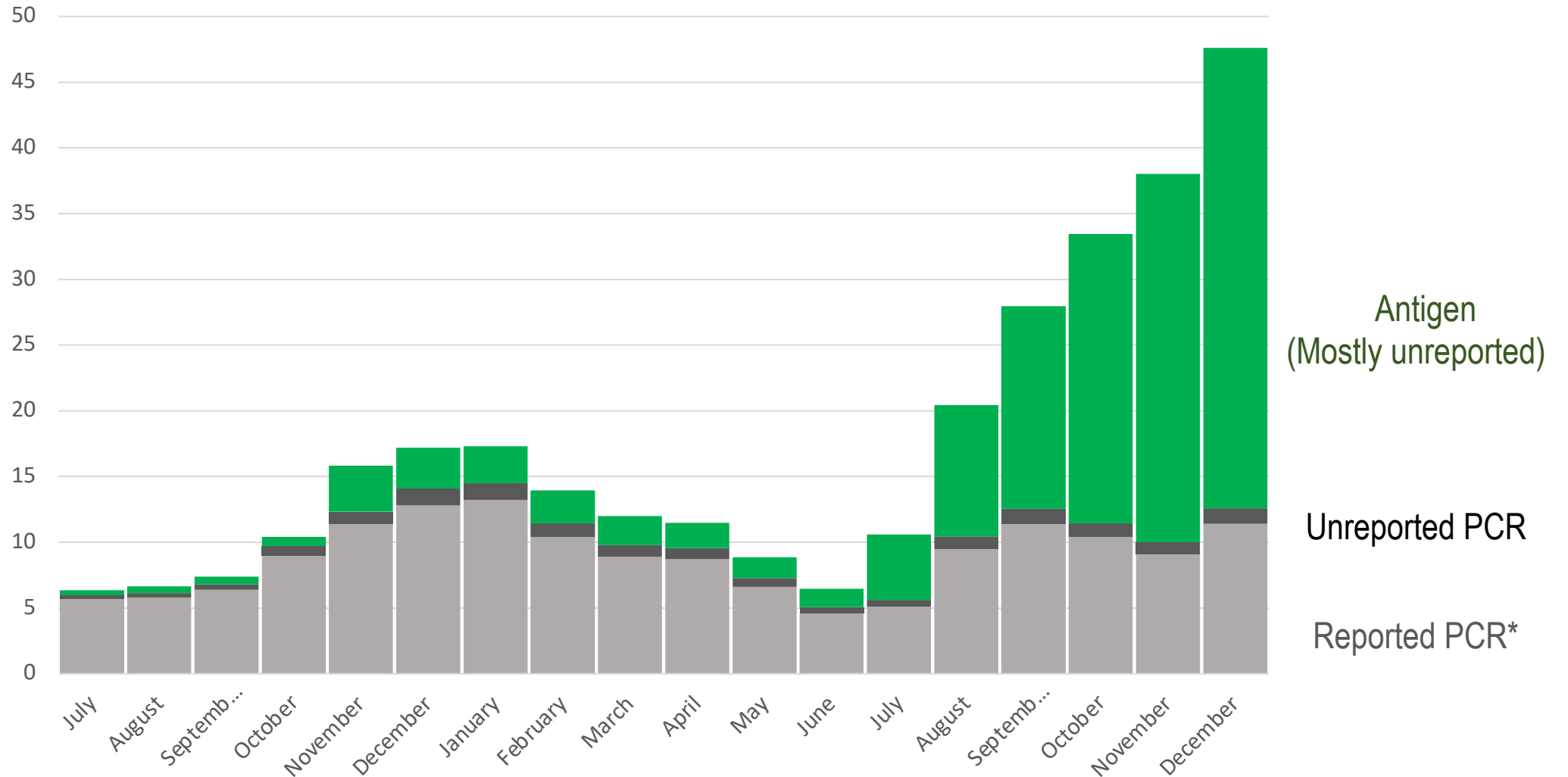
Pandemic Total through 12/31/21





COVID Test Volume – Reported and Unreported Estimates

Average weekly tests
Millions



Note: The COVID Tracking Project through February 2021, then CDC Data Tracker March to present PCR unreported by 10%



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