HEALTH CATALYSTS

Diagnostics Year in Review 2020

Mara G. Aspinall

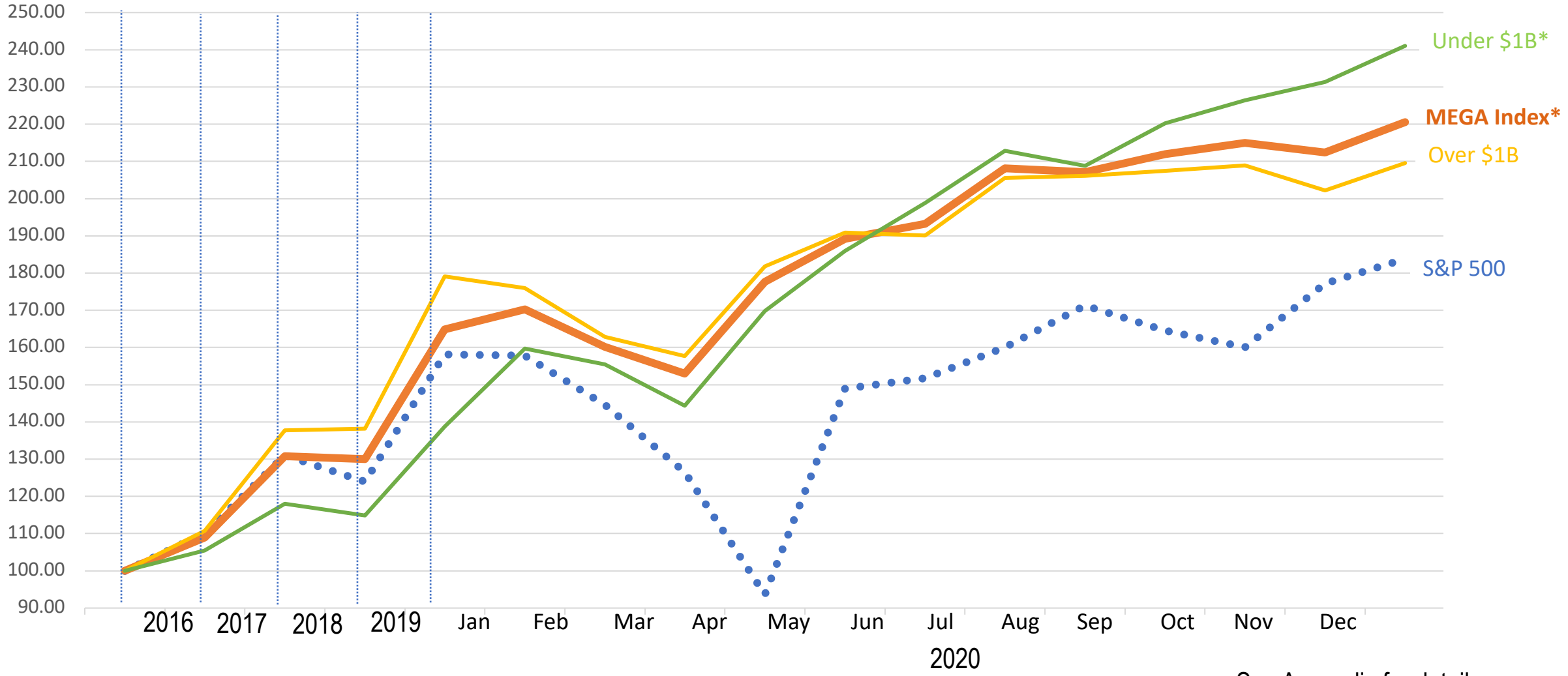
CEO, Health Catalysts Group

Managing Director, BlueStone Venture Partners

The Diagnostics World 2020

- Diagnostics in the Public Markets – The MEGA Index
- Diagnostic IPO's
- Diagnostic Mergers & Acquisitions
- Diagnostic Products Marketplace - Genetic Tests
- TestingCommons.com Overview of COVID Testing

The MEGA Diagnostics Index (2016-2020)

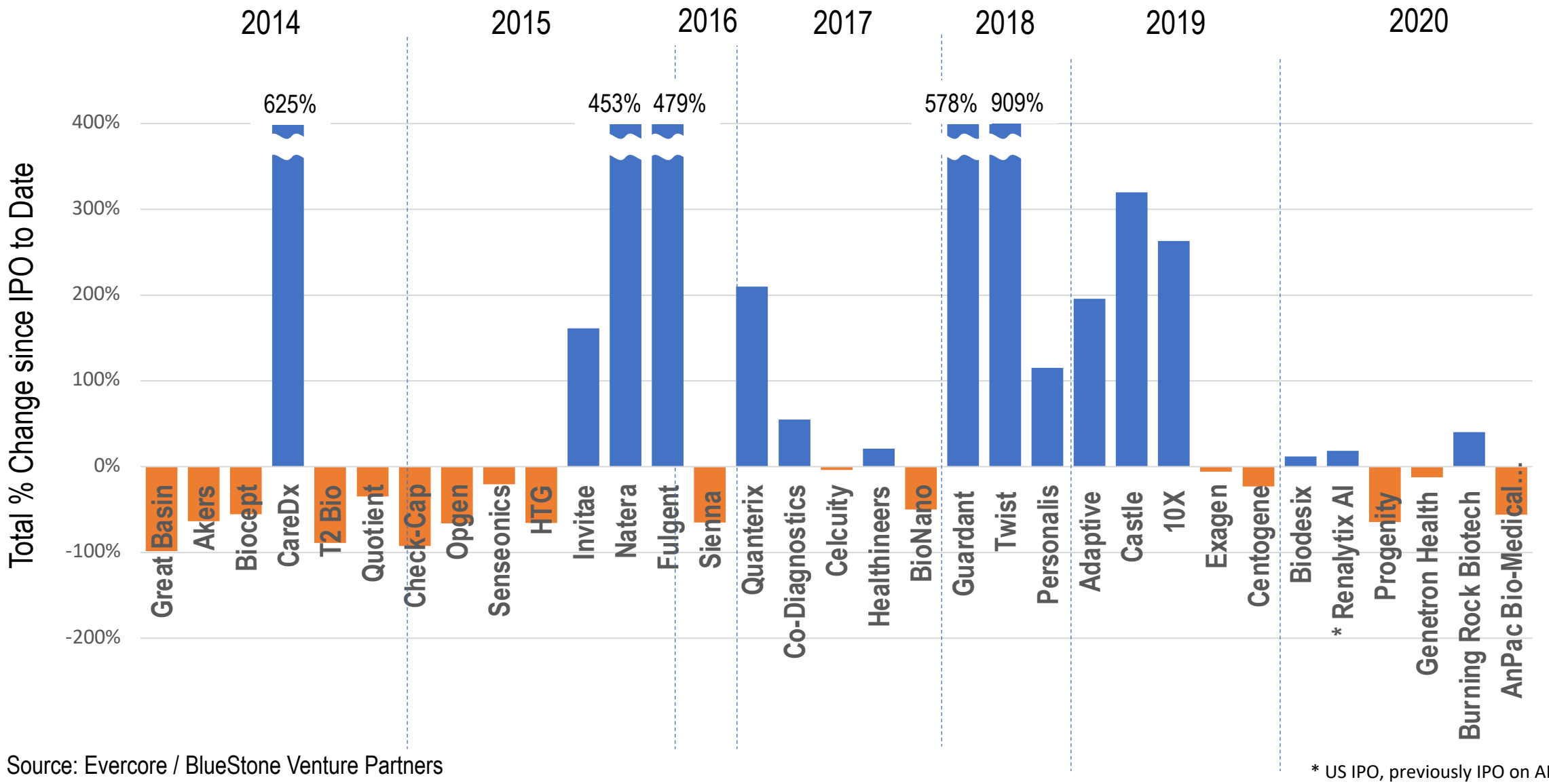


Source: Health Catalysts Group

* = Excludes BGI 2017/18 bubble

See Appendix for details.

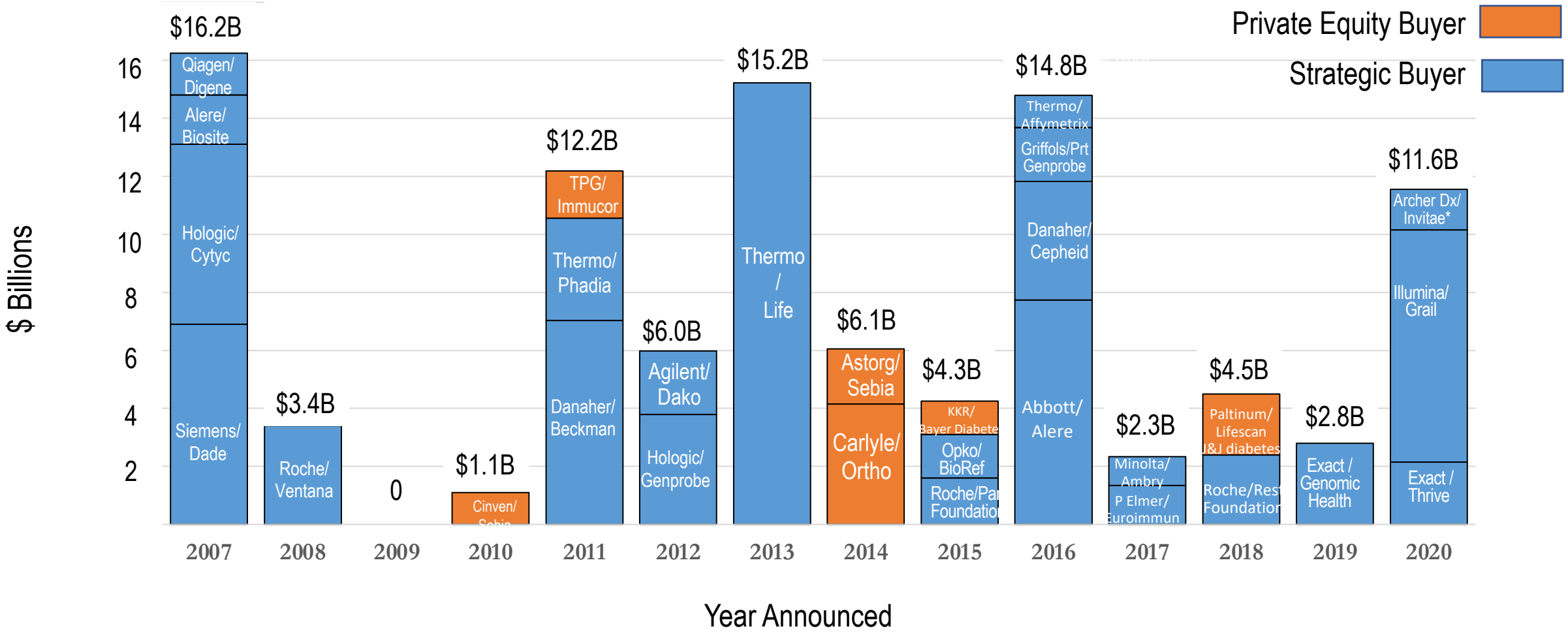
Diagnostic IPOs: Price Performance from IPO through 2020



Source: Evercore / BlueStone Venture Partners

* US IPO, previously IPO on AIM in 2018

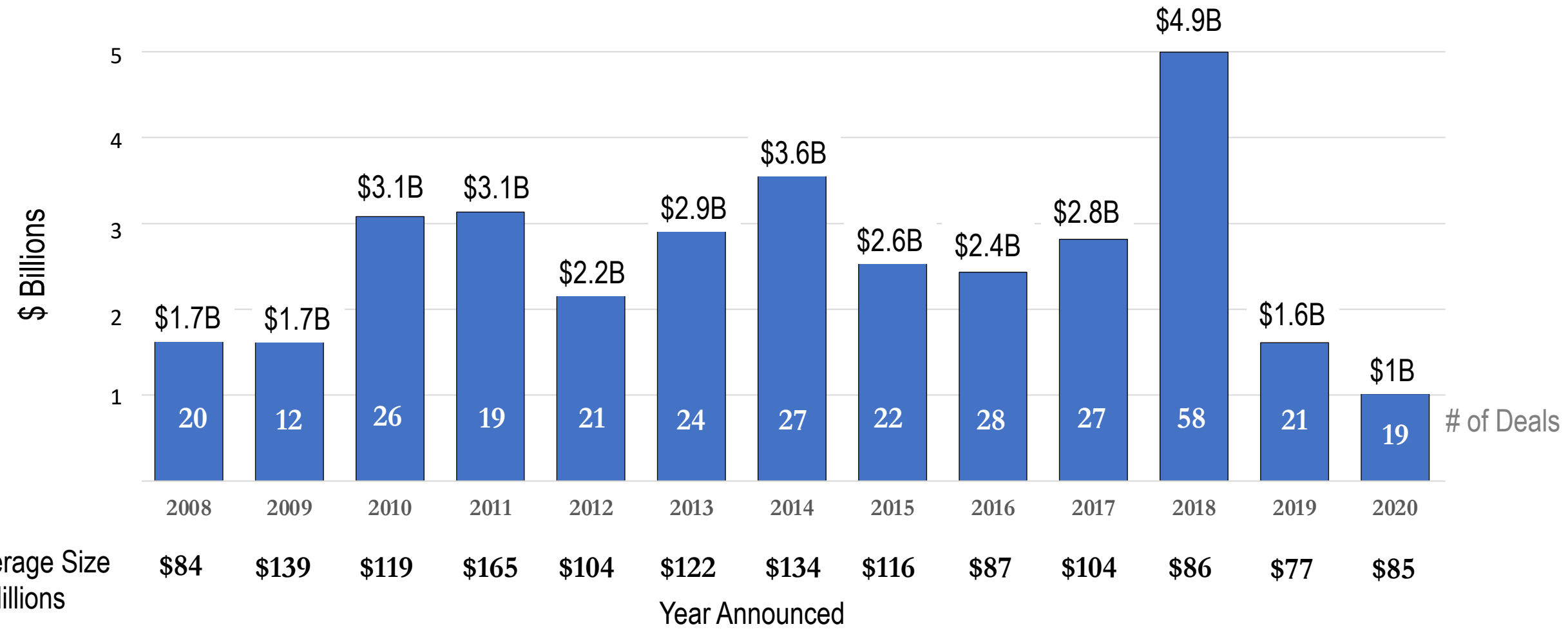
Diagnostic Industry Transforming Acquisitions (>$1 Billion)



Source: Evercore / BlueStone Venture Partners

* ArcherDx up to $2.7 billion with earnouts. See Appendix for details.

Smaller Diagnostic Acquisitions (<$1 Billion)

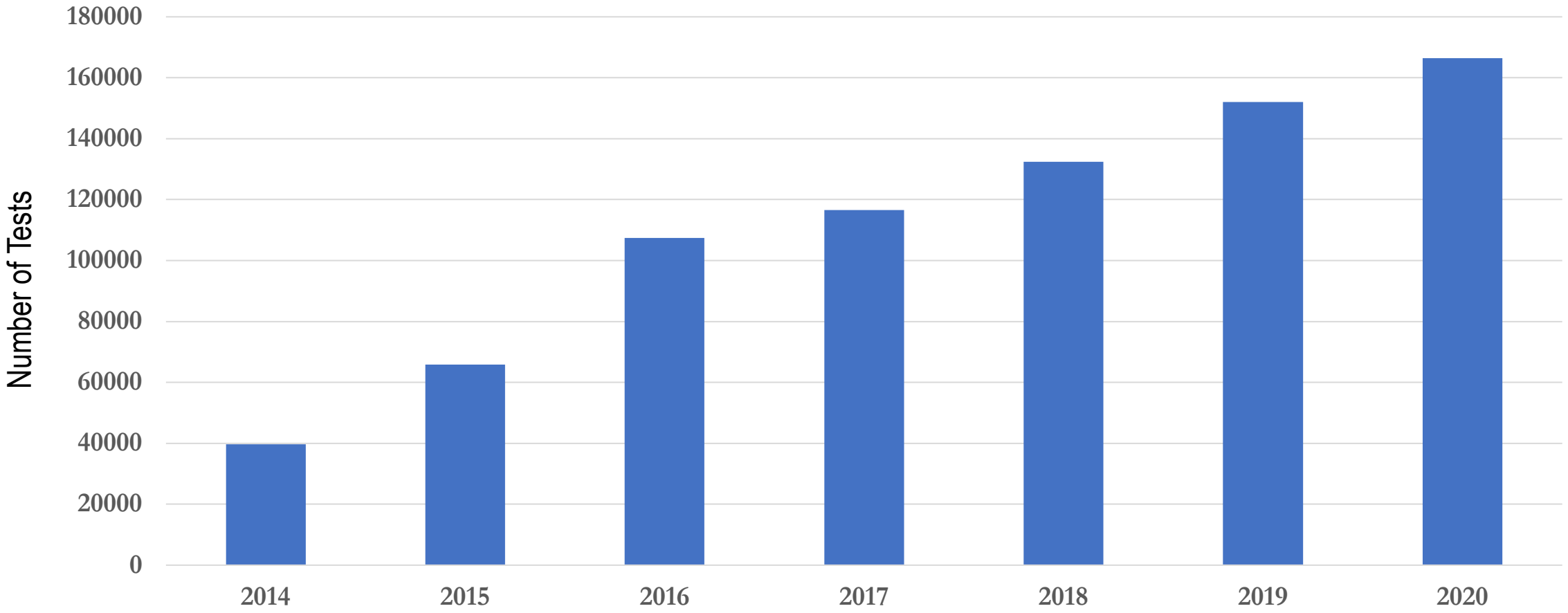


Source: Evercore / BlueStone Venture Partners

See Appendix for details.

Clinically Available Genomic Tests

Compound Annual Growth Rate 22.6%



Source: Concert Genetics Test Database

Diagnostics:

The Beginning, Middle and End of the Pandemic

COVID-19 TESTING COMMONS

ASU Arizona State University

WITH SUPPORT FROM The ROCKEFELLER FOUNDATION

Workplace Commons | Testing Commons | Evidence Commons | T3 Blog | Meet Our Team | Webinars | Media | Get Involved

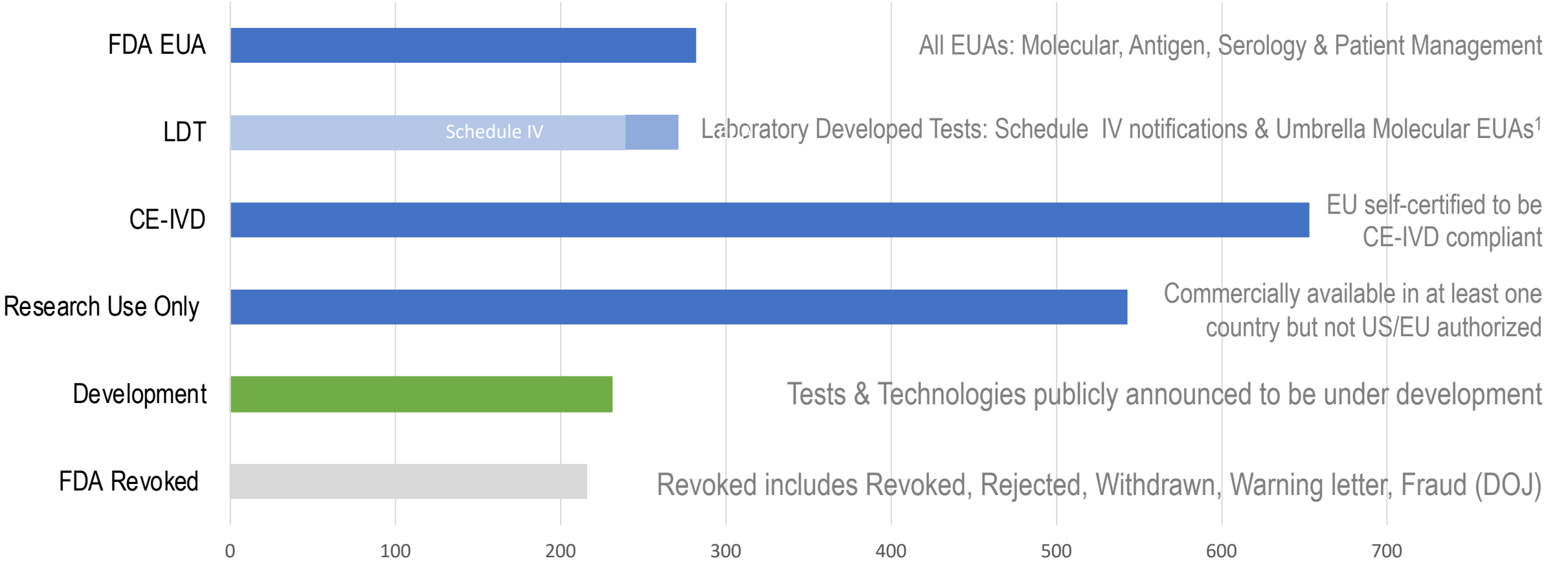
A one-stop reliable source for comprehensive information about COVID-19 tests worldwide. Search all tests in the market and in the pipeline by multiple parameters including test type, technology, regulatory status, country of origin and more.

COVID-19 Testing Commons, 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

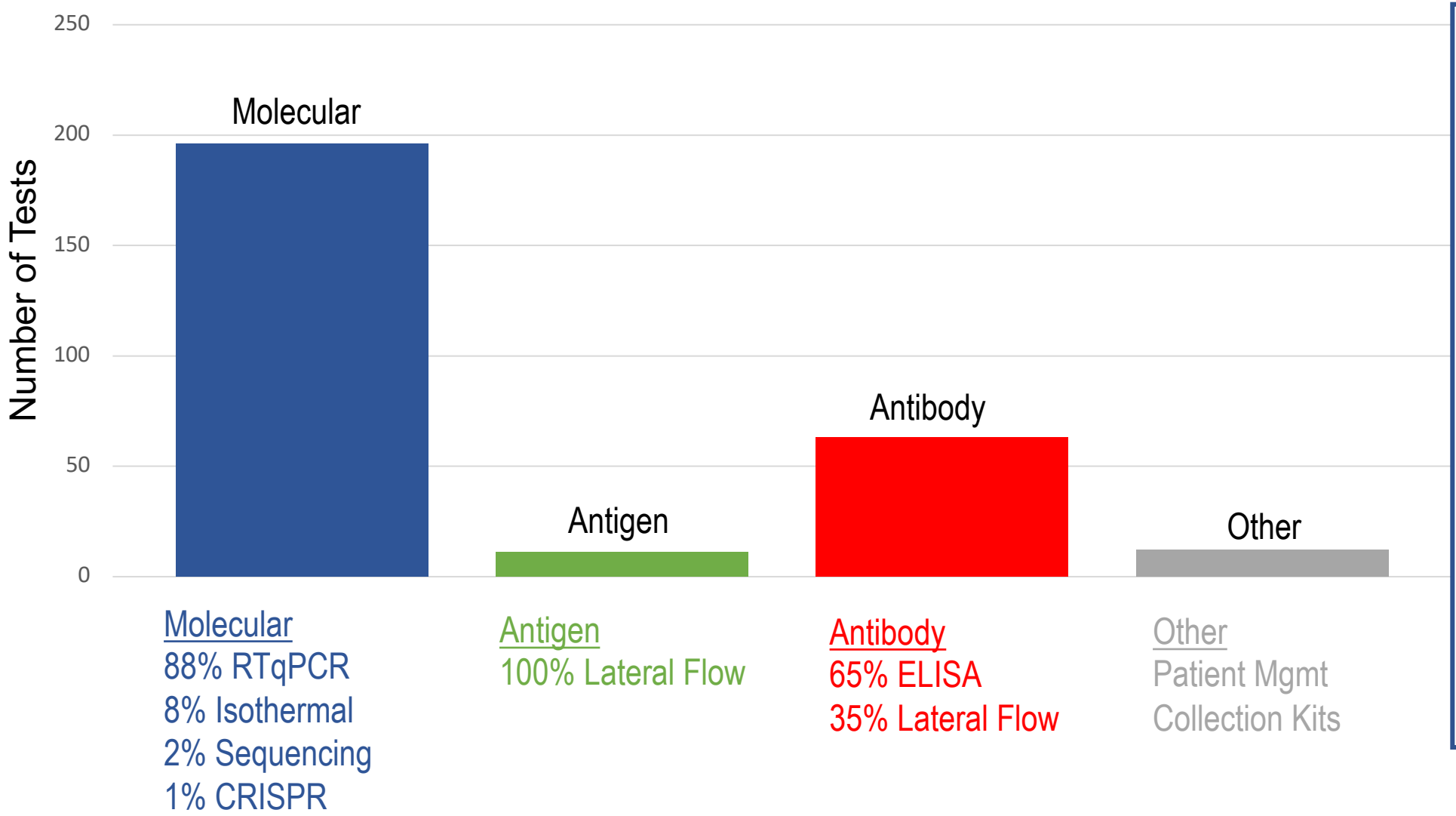
TestingCommons.com Year in Review 2020: *2,232 tests*

19% of global commercially-available tests have been authorized for US use



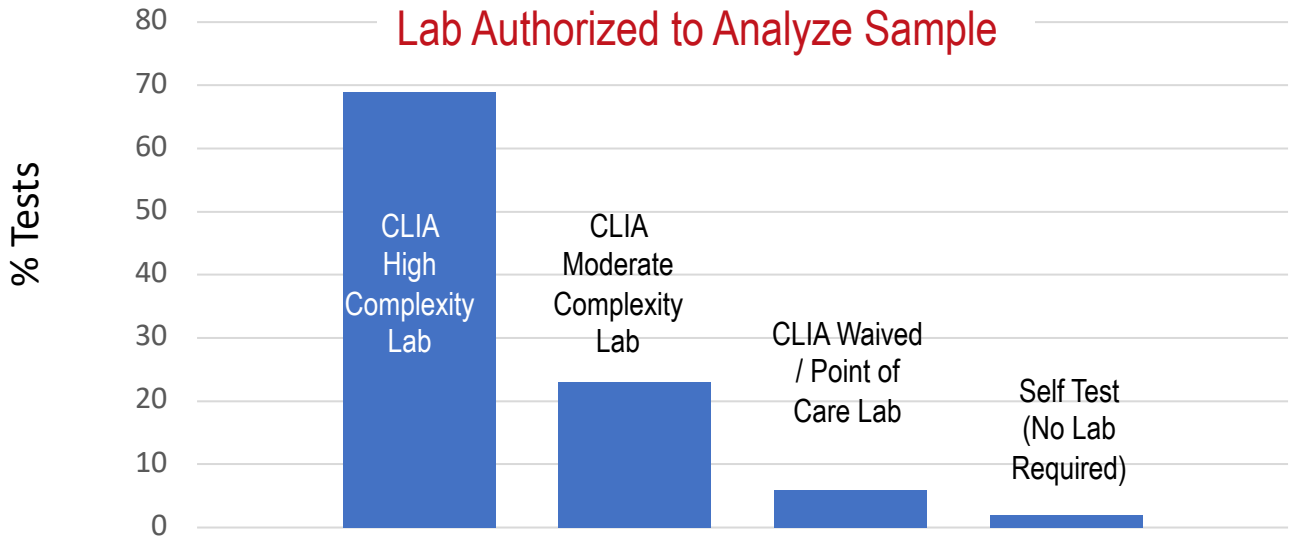
1. Incomplete list after 10/7/20 when HHS/FDA announced policy to not require authorization for any LDT

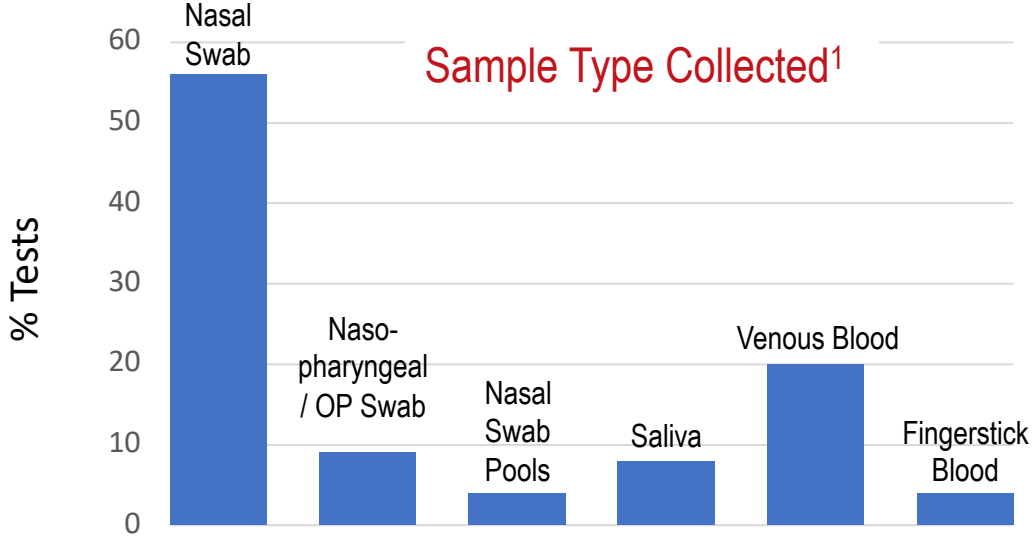
US FDA Emergency Use Authorizations

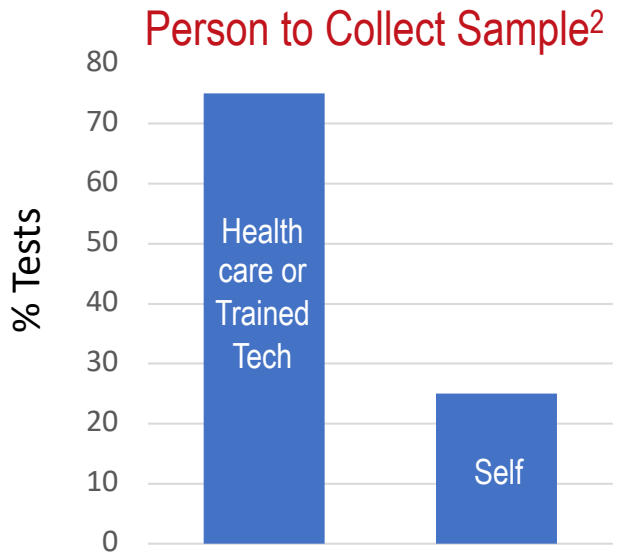


- All early EUA's were central Lab RTqPCR and ELISA Antibody tests for clinical care.
- Number of tests is less important than capacity per test – many EUA's have small manufacturing volumes and little distribution.
- FDA backlog of potential new tests has delayed faster/ simpler tests needed for pandemic control.

Profile of US FDA EUA's





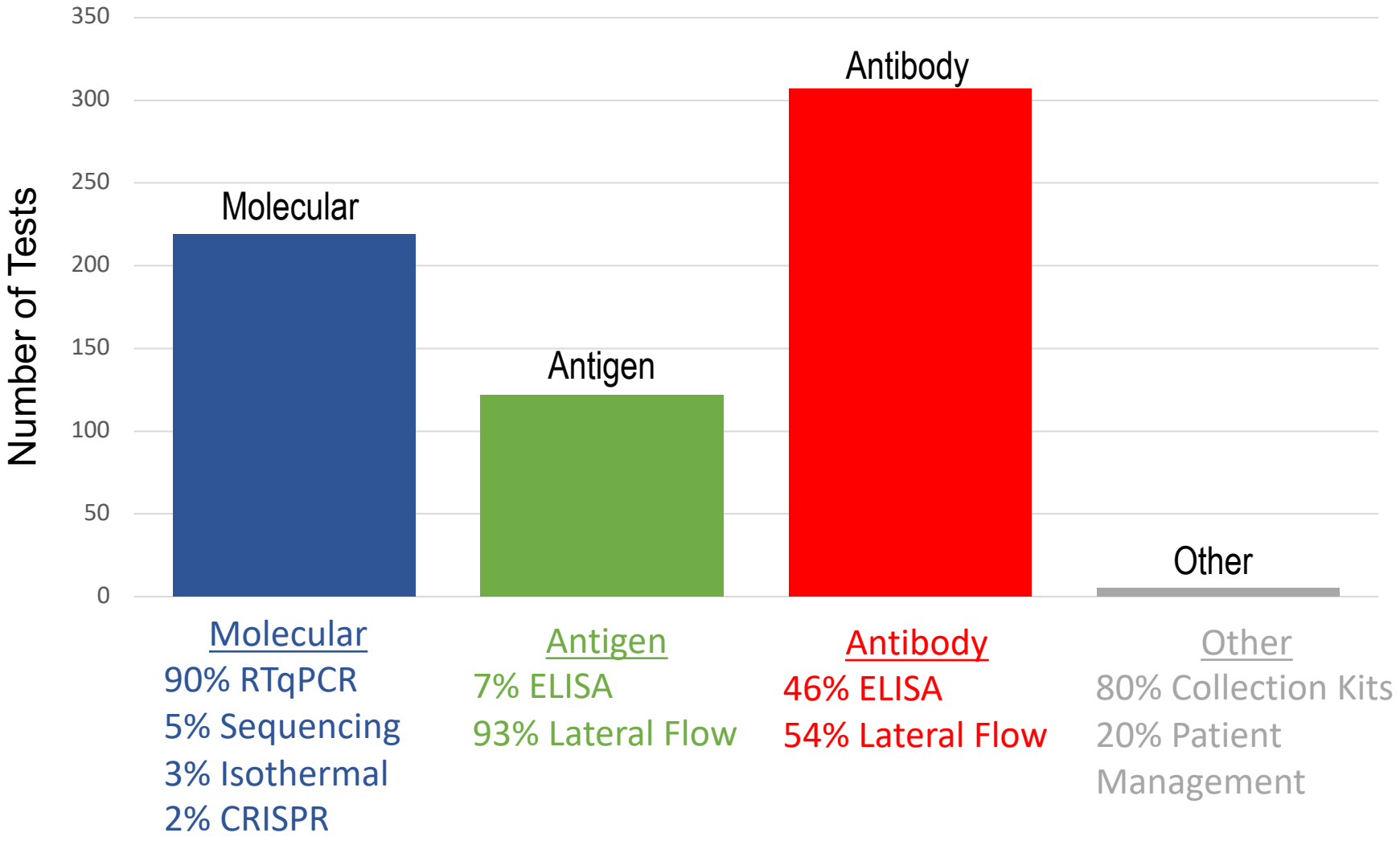


- CLIA High Complexity Labs required by the preponderance of early test EUAs
- Designing simpler tests for POC/Self testing required longer engineering effort, only recently achieving EUAs
- Anterior nasal swaps (or Saliva) have eclipsed Nasopharyngeal swabs (NP) – a more invasive, risky viral collection method
- Self collection (AN swab or saliva) set to become dominant methods in 2021

1. Only a single Swab type per test counted here, in least to most invasive priority order: Saliva; ANS; lastly NPS/OPS. All PCR tests are sensitive enough to work with nearly all of these swab types: later authorizations specify ANS in addition to other swab methods. 2. No specific Healthcare Professional training is required by the EUA (at Laboratory discretion)

Profile of CE-IVD Certifications (ex US)

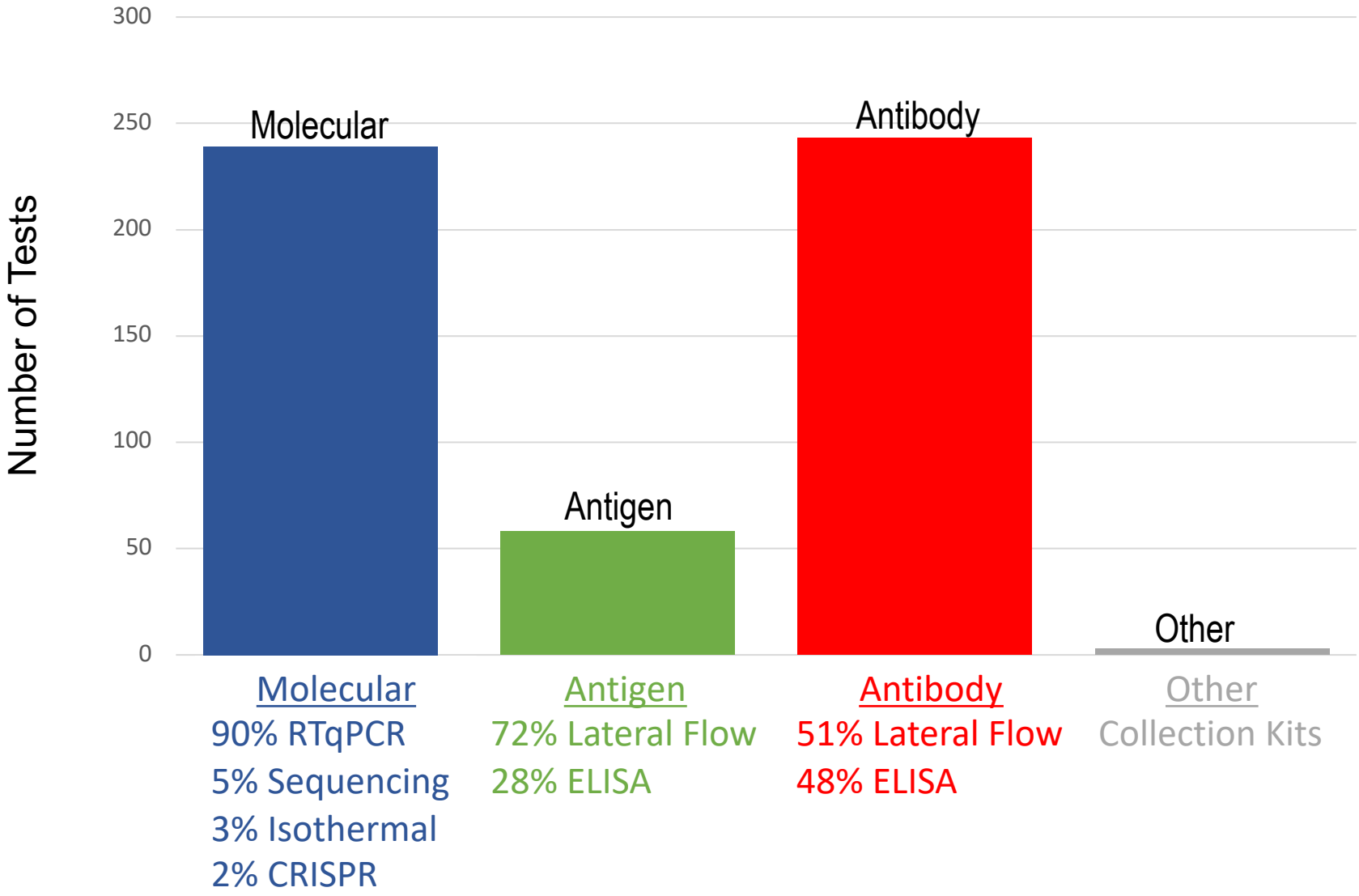
COVID-19 TESTING COMMONS | Arizona State University | WITH SUPPORT FROM The Rockefeller Foundation



- The primary choice outside of the US has been the cheaper, quicker, simpler but less sensitive Lateral Flow technology for both Antigen and Antibody tests.
- Antibody tests were initially proposed for disease detection but proved ineffective since antibodies only detectable after the infectious period
- Antigen tests using Lateral Flow technology displaced Antibodies for detection, but are much more difficult to develop
- Molecular tests remain essential for confirmation and clinical care

Research Use Only Tests (excluding US & EU)

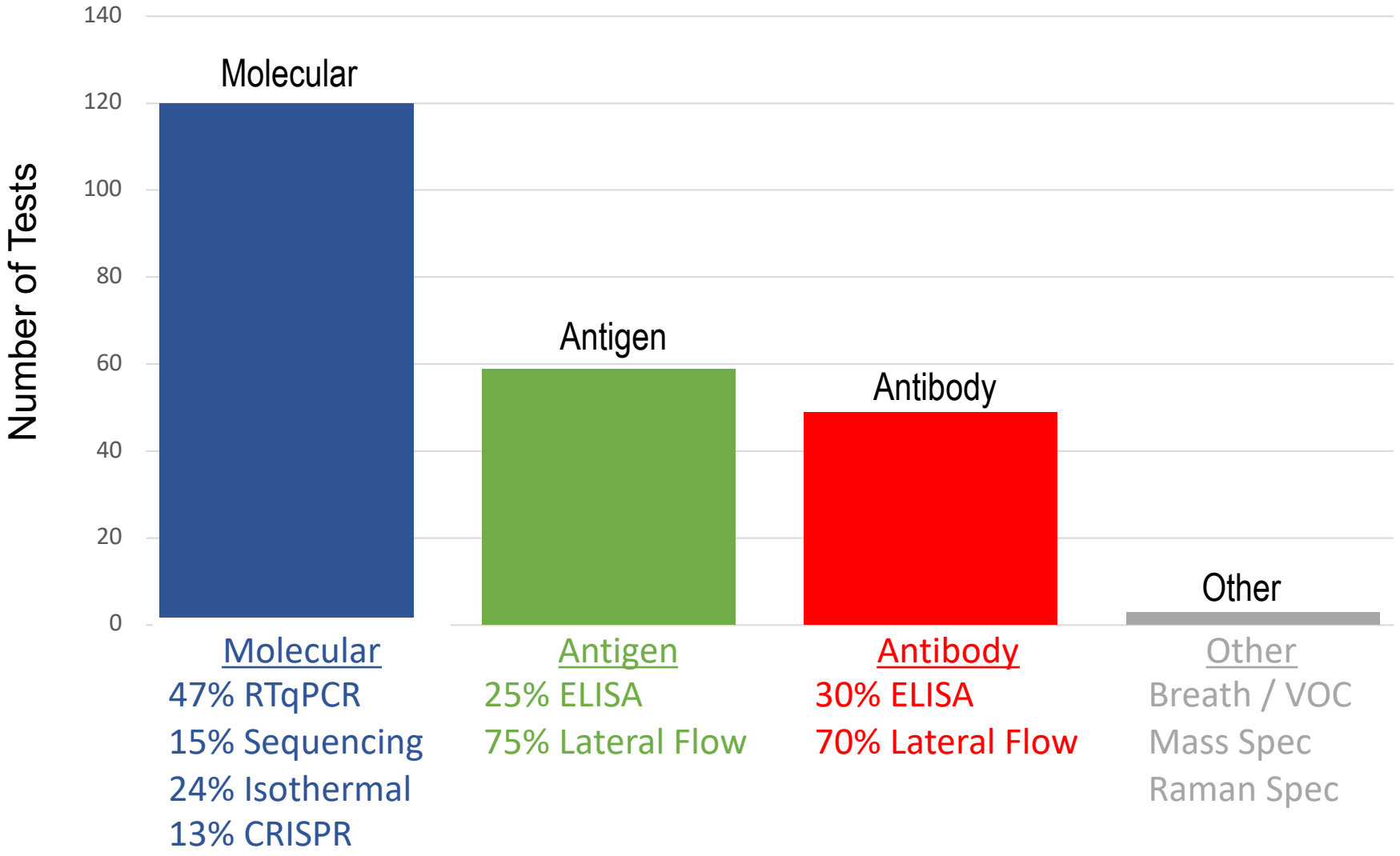
COVID-19 TESTING COMMONS | Arizona State University | WITH SUPPORT FROM The ROCKEFELLER FOUNDATION



- Technology mix of RUOs reflects that of CE-IVD Lateral Flow focus outside of the US.
- These are primarily of two types: either: “local” manufacturers/labs with me-too tests without global aspirations and/or who may or may not meet minimum CE-IVD certification requirements or: newer tests that are in the process of approval, frequently in the home country first (primarily China and further-Asia), then CE-IVD, then US.
- Strong innovative products are being introduced from China, Korea and Singapore.

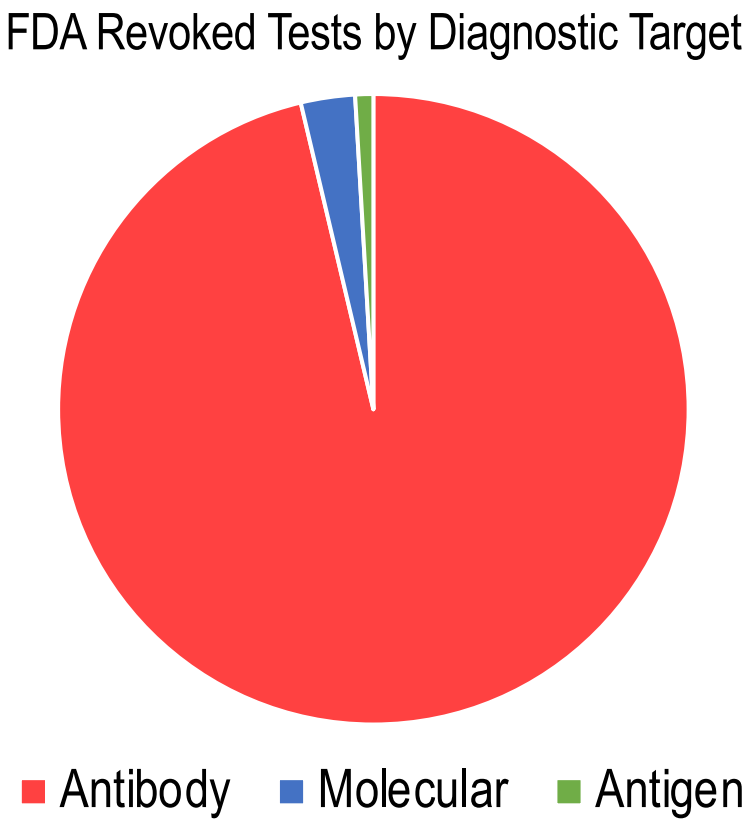
Tests in Development

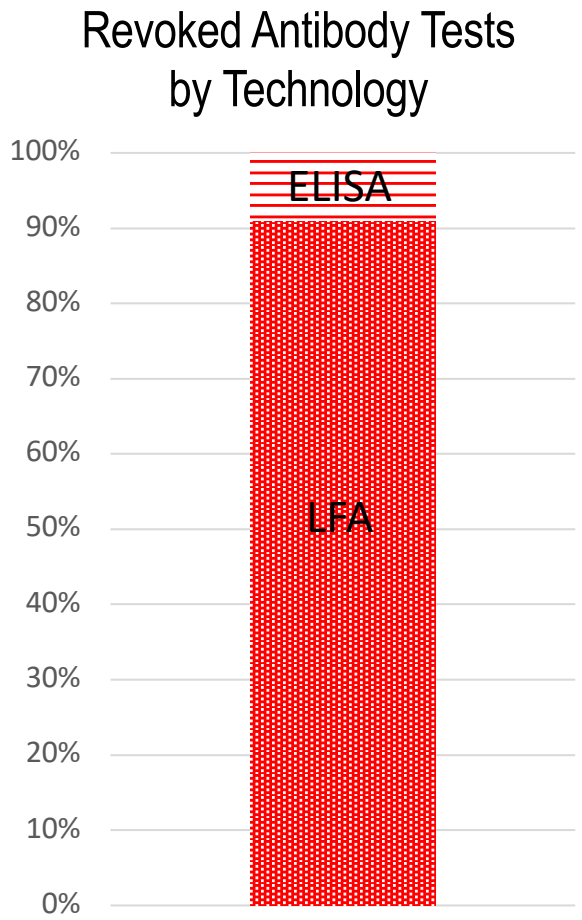
COVID-19 TESTING COMMONS | Arizona State University | WITH SUPPORT FROM The Rockefeller Foundation



- There are many innovative molecular technologies efforts to replace PCR in development. Many have potential to be lower cost, closer to the patient and with near PCR accuracy.
- Lateral Flow Antigen tests are the future of pandemic large-scale screening/surveillance representing ~20% of all new development.
- Antibody tests are an already overcrowded field with very limited demand today but may grow in importance if vaccine effectiveness becomes an issue.

All FDA Revoked Tests

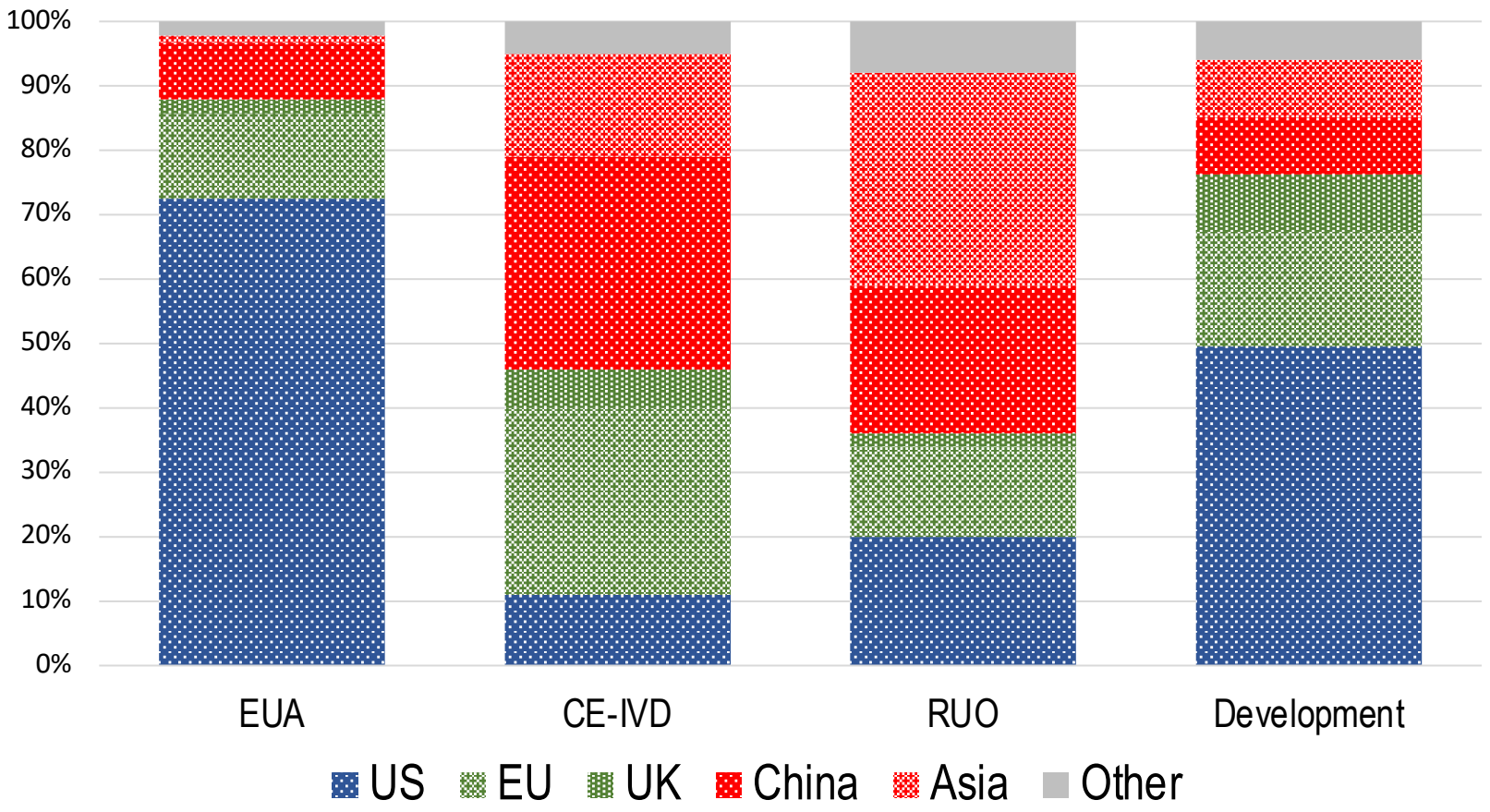




- The cheap, quick and simple Lateral Flow Antibody tests from China/Asia were available in bulk quantities in Q1 2020 – many authorities placed early multi-million quantity orders but were quickly disappointed. These early tests were not effective technologically and when they did function - antibody testing was poor at diagnosing new disease. This led to an extensive culling of the herd.
- As viral load and transmissibility came into greater focus later in the year, a new generation of Lateral Flow technology adapted to Antigen tests has proven more accurate and reliable.

Commercialized Tests by Manufacturer's HQ Country

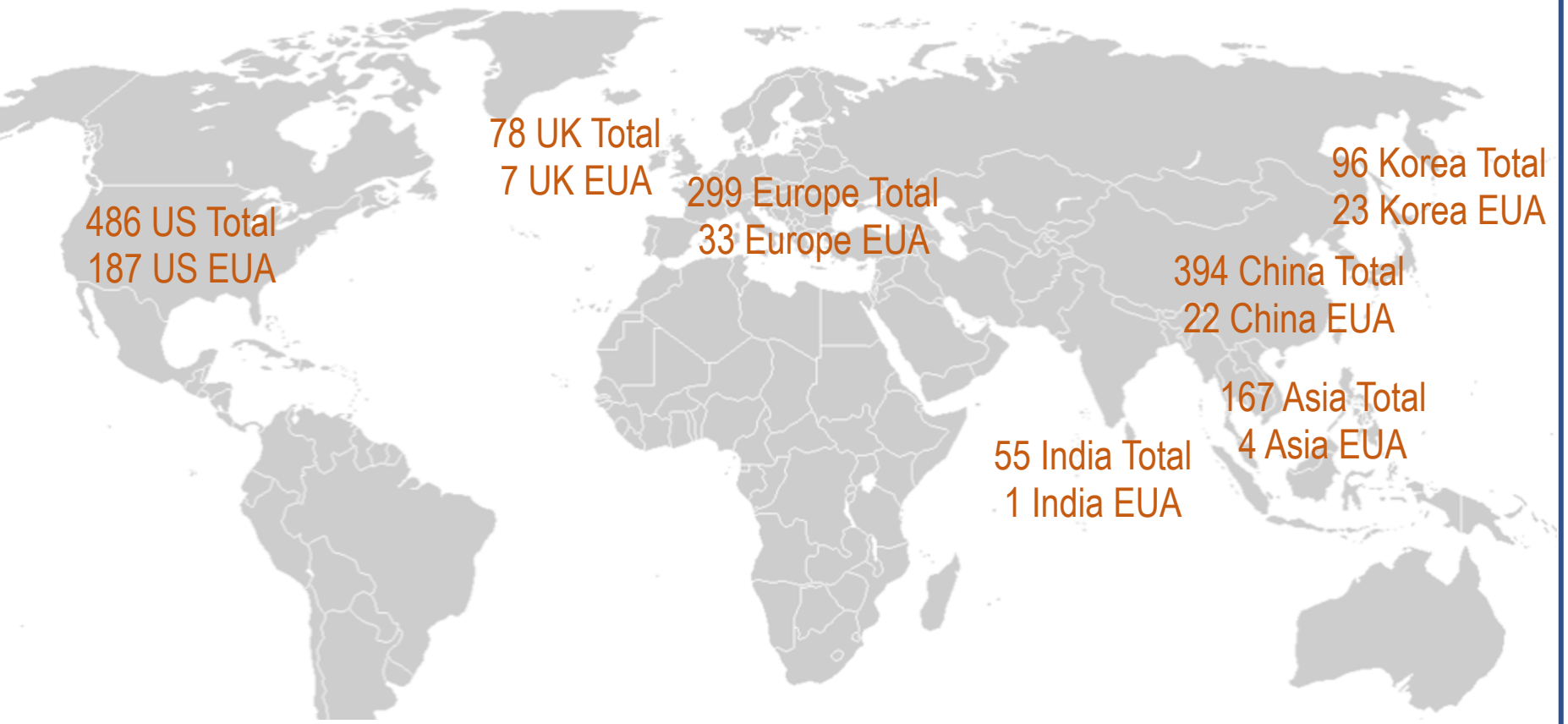
COVID-19 TESTING COMMONS | Arizona State University | WITH SUPPORT FROM The Rockefeller Foundation



- The US FDA has maintained a "clinical grade" approach that delayed the introduction of "surveillance grade" tests (e.g., pooling, antigen and isothermal techniques)
- US diagnostic innovation has accelerated dramatically and 2021 will see many novel accurate and cheap technologies brought to market for clinical and screening applications
- China, Korea and Singapore (and others) were the fastest to introduce less complex, decentralized testing that has proven highly effective

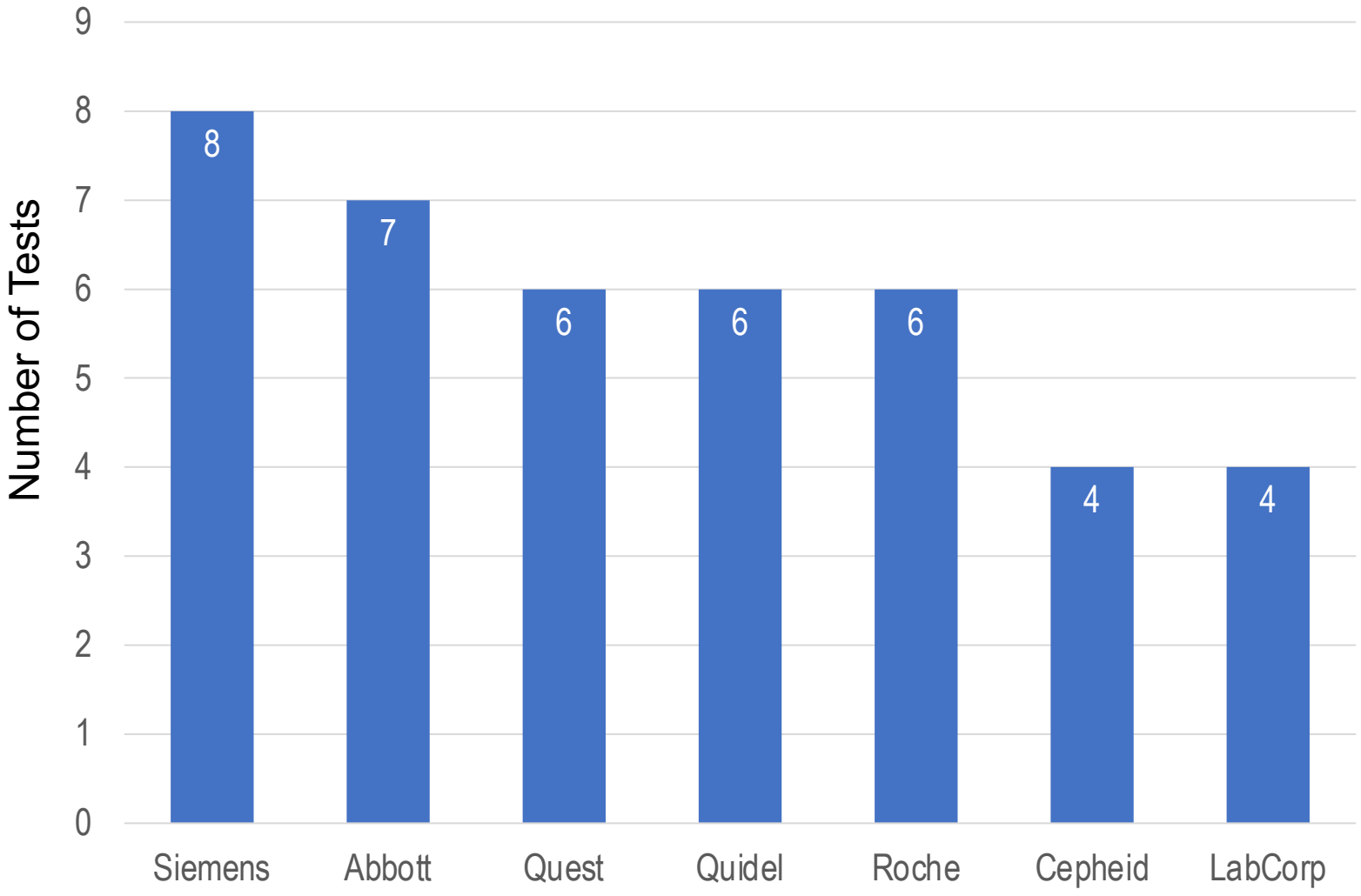
How well does the US marshal global resources?

COVID-19 TESTING COMMONS | Arizona State University | WITH SUPPORT FROM The ROCKEFELLER FOUNDATION



- 38% of US originated tests have received an EUA versus 11% of those from Europe
- China, with the longest experience of COVID19, has achieved US EUA status for just 6% of its tests. For Korean companies, 24% of their tests have achieved US EUAs.

Companies with the largest number of EUAs



- The US In-Vitro Diagnostic industry has long been highly concentrated. The critical question at the start of 2021 is whether they can fulfill the promise of ramping up manufacturing supply.

Acknowledgements

I would like to thank the following people & organizations for their help and support:

- For HCG Diagnostics Year in Review 2020
  - Evercore for their data and analysis including Bernhard Sakmann and Justin Reed
  - BlueStone Venture Partners especially Chris Burwell who was the primary architect for the Report's analysis
- For COVID Testing Commons:
  - Arizona State University's Decision Theater team including Sri Kandala and Kayleigh Steele
  - ASU's College of Health Solutions team including Dean Deborah Helitzer, Sarah Igoe and Nate Wade
  - Advisors including Simon Johnson, MIT and Melea Atkins, Covid-19 Policy Alliance
  - Testing Commons was made possible by a grant from The Rockefeller Foundation. Special thanks to Dr. Jono Quick and Leah Perkinson.

Mara G. Aspinall

Managing Director, Health Catalysts Group; mara.aspinall@healthcatalysts.com

Co-Founder and Managing Director, BlueStone Venture Partners; mara.aspinall@bluestonevp.com