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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.

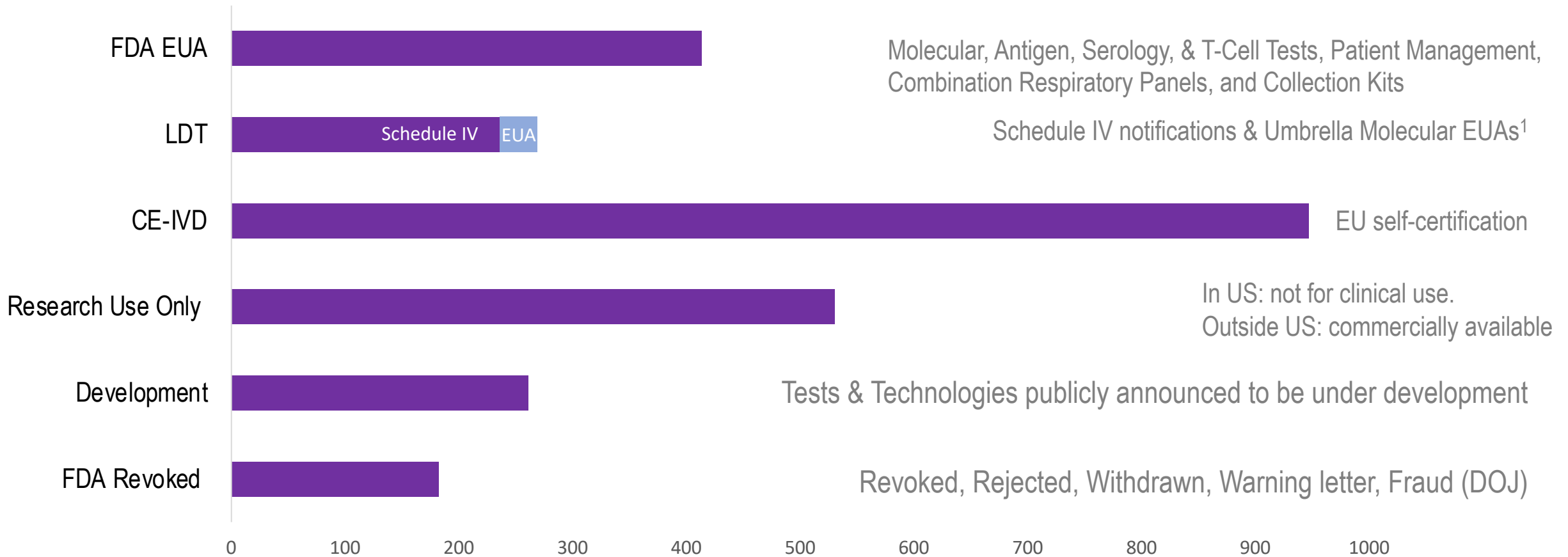
TestingCommons.com, part of COVID Diagnostics Commons initiative,
at Arizona State University's College of Health Solutions
Testing Commons is made possible with support from The Rockefeller Foundation



Insights, trends, and updates from Q3:

- Overall EUA activity from the FDA is down, with
 - 28 new EUA's in Q3 2021 vs.
 - 45 EUA's in Q2 and 41 EUA's in Q1
- Authorizations for pooled testing and serial screening both continued to roll out slowly
 - Neither trend has gained significant momentum despite the April 2021 introduction of a new amendment for Pooling and Screening aimed at further facilitating the authorization of molecular tests for “screening asymptomatic individuals using pooled anterior nasal respiratory specimens in serial testing programs”
- CE-IVD / Research Use Only (RUO) tests continue to show increase in Serology/Antibody tests

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

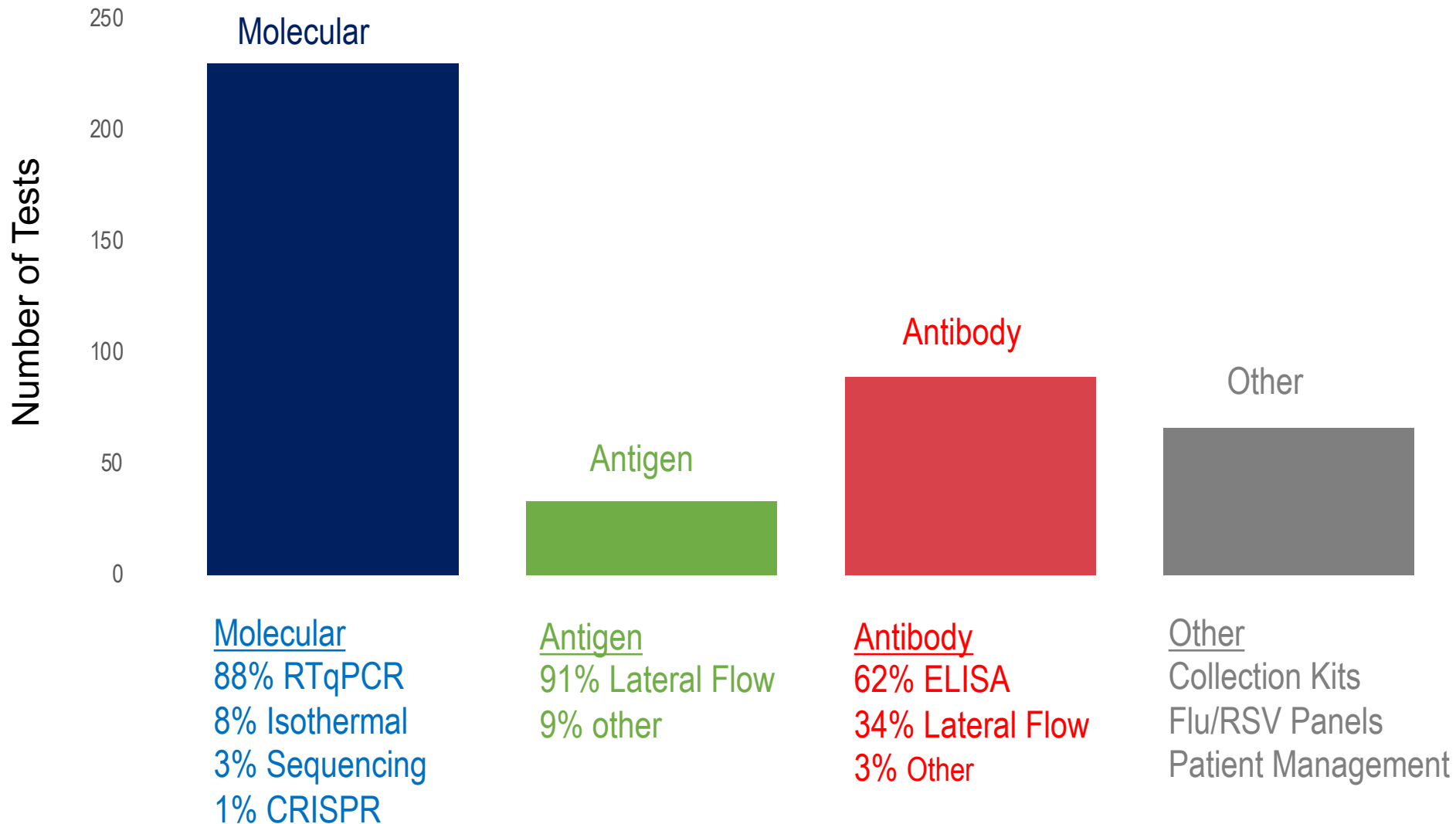
Pandemic Total through 9/30/21

US FDA EUA Test Classifications



- Tests:
 - Molecular Tests (including Appendix A LDTs and Flu panels)
 - Antigen Tests (including Flu panels)
 - Patient Management Tests (IL6)
 - Serology (Antibody) Tests (including cellular immunity)
- Collection Kits
 - Home Collection Kits (Nasal Swabs or Saliva)
- Test Attributes:
 - Test Location (Lab vs. POC vs. Home)
 - Screening (Asymptomatic)
 - Serial Screening
 - Pooling
 - OTC vs Prescription

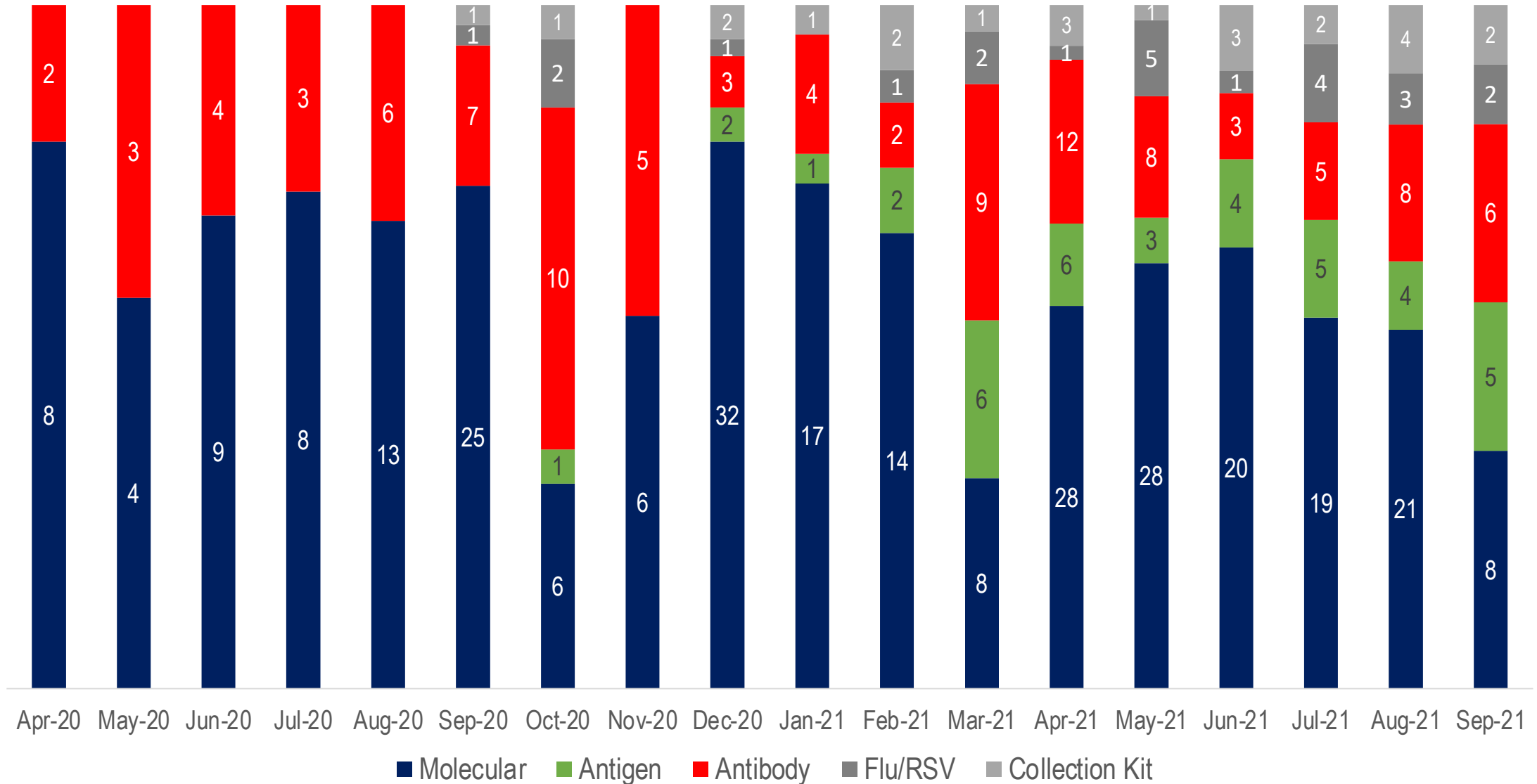
US FDA Emergency Use Authorizations



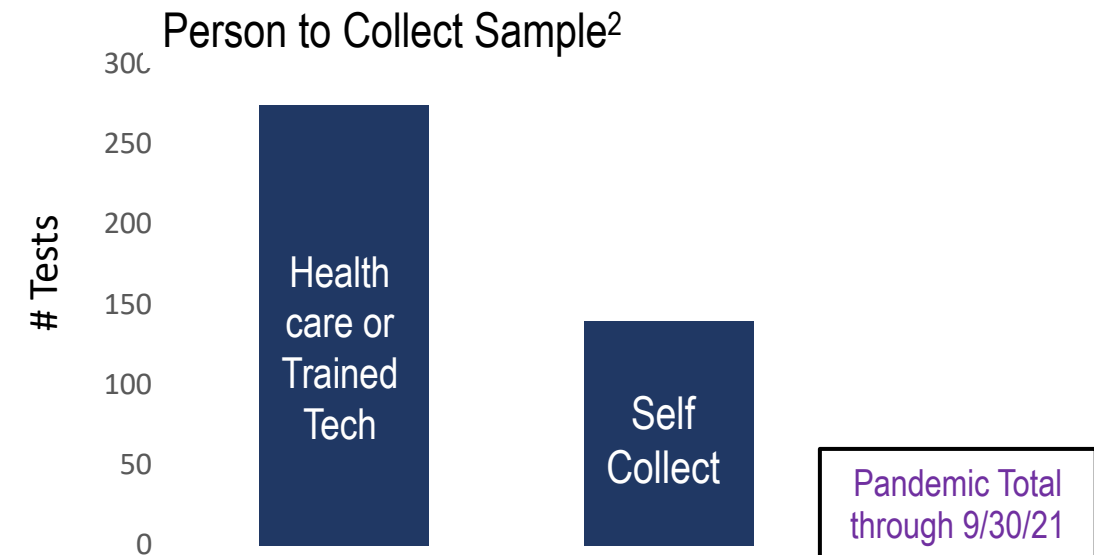
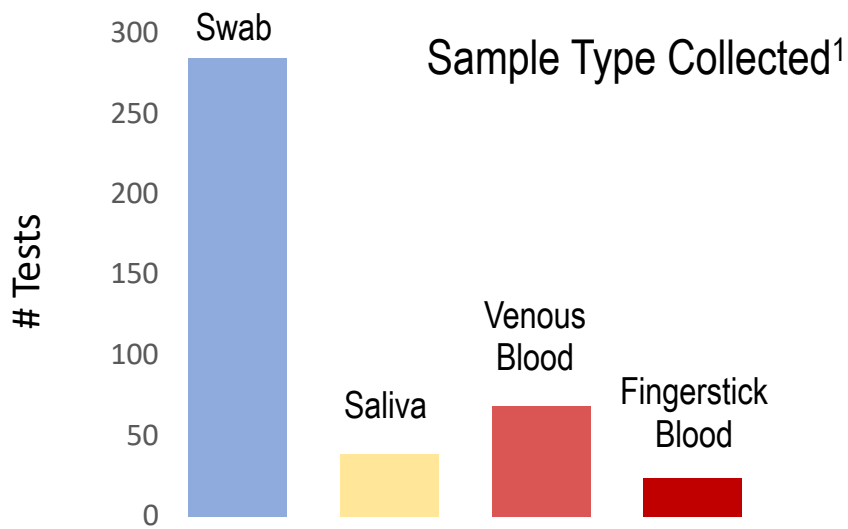
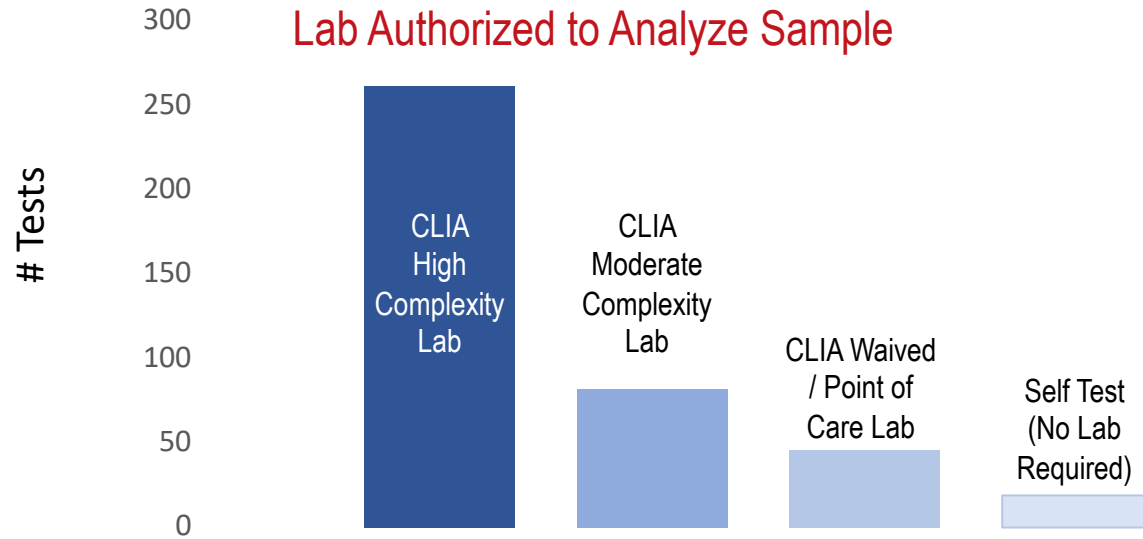
Pandemic Total
through 9/30/21

Timeline of EUA Issuances and Amendments by Type

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Profile of US FDA EUA's



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)

13 EUA's for Comprehensive At-Home Tests



MOLECULAR TESTS (3)

ANTIGEN TESTS (10)

RX TESTS (4)

- Lucira COVID-19 All-In-One Test Kit

- Abbott BinaxNOW COVID-19 Ag Card Home Test
- OraSure InteliSwab COVID-19 Rapid Test Rx
- Quidel QuickVue At-Home OTC COVID-19 Test

OTC TESTS (9)

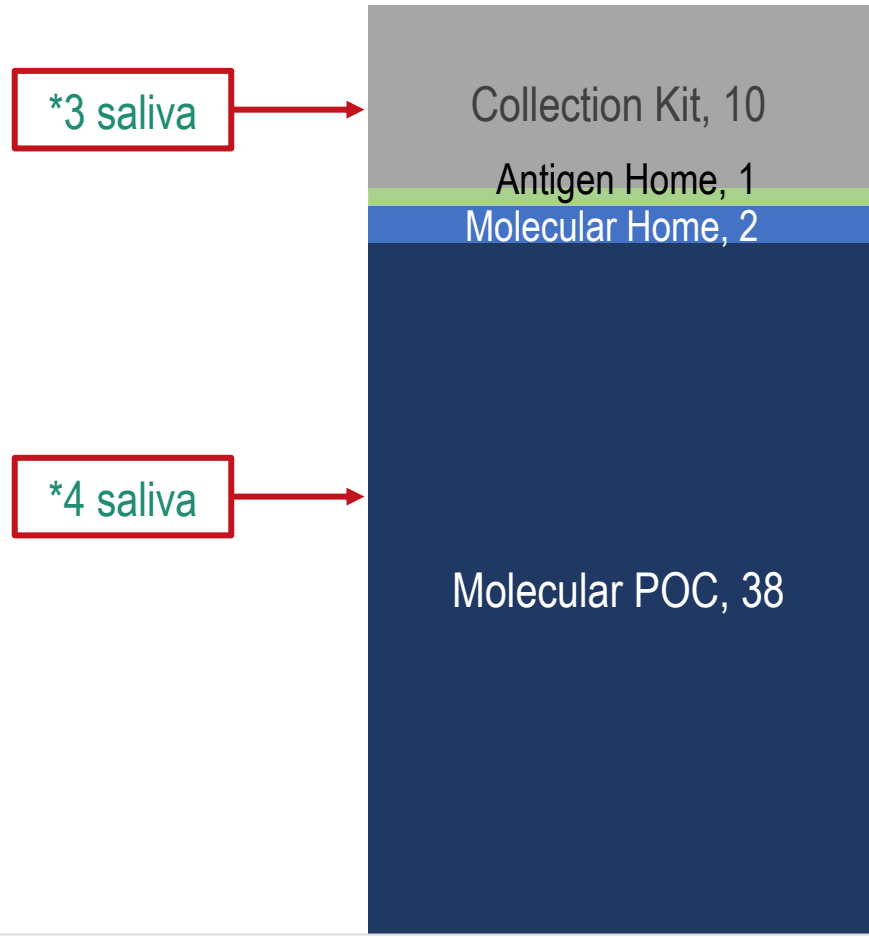
- Cue COVID-19 Test for Home and Over The Counter (OTC) Use
- Lucira CHECK-IT COVID-19 Test Kit

- Abbott BinaxNOW COVID-19 Ag Card 2 Home Test
- **Abbott BinaxNOW COVID-19 Antigen Self Test***
- **Access Bio CareStart COVID-19 Antigen Home Test***
- BD Veritor At-Home COVID-19 Test
- Ellume COVID-19 Home Test
- OraSure InteliSwab COVID-19 Rapid Test
- Quidel QuickVue At-Home OTC COVID-19 Test

New Q3*

Pandemic Total
through 9/30/21

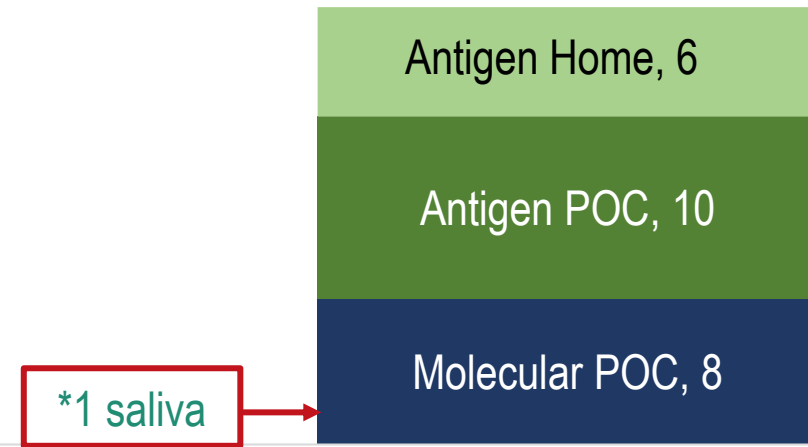
EUA's for Asymptomatic Screening & Serial Screening



Screening (51)



Serial Testing – 2 tests in 24-48 hours



Serial Screening (24)

Pandemic Total through 9/30/21

35 Antigen Tests with EUAs

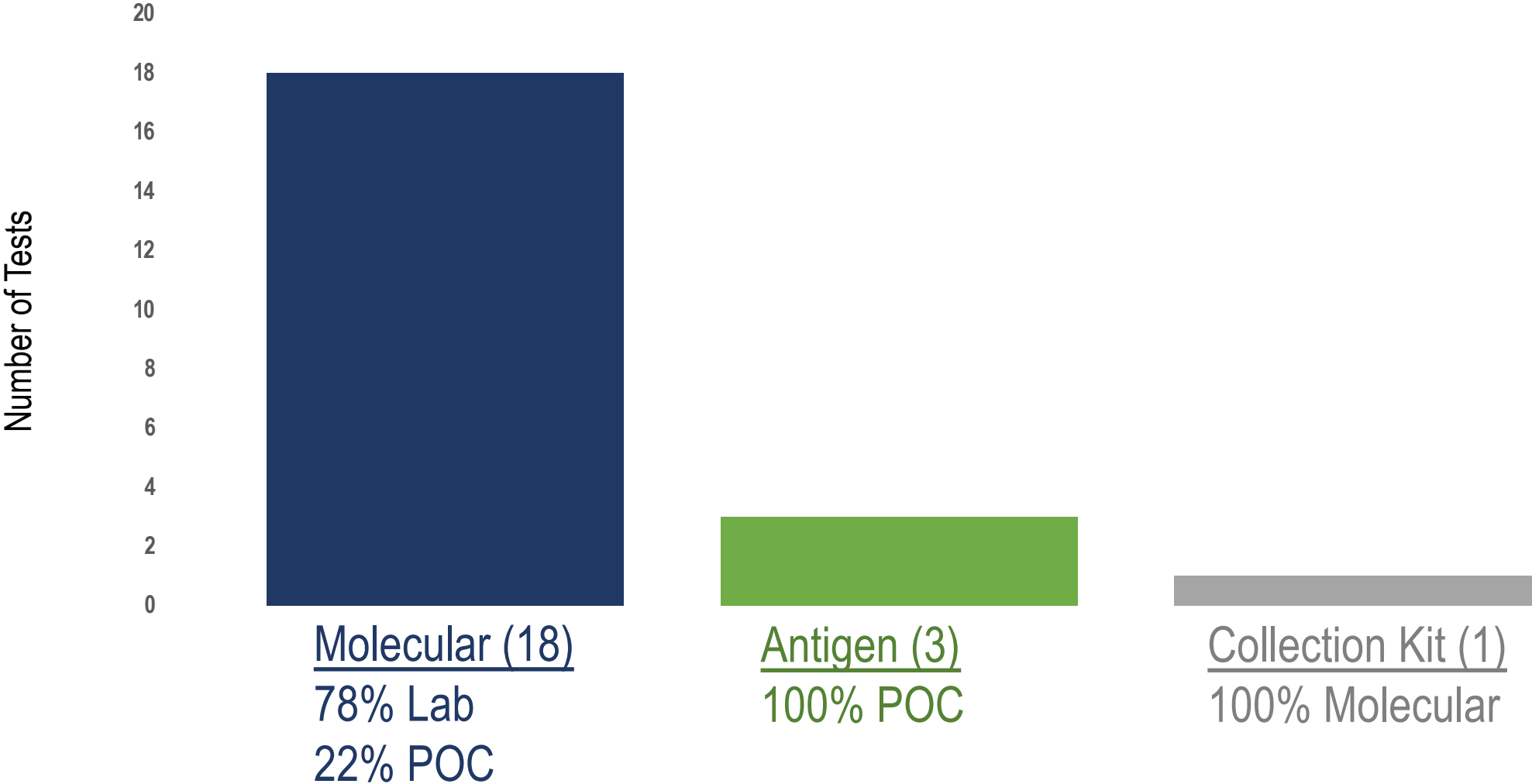
Instrument read

| | CLIA High/Moderate (Laboratory) | CLIA Waived (Physician Office) | Home |
|-----------------|--|--|--|
| Instrument read | Celltrion Sampinute DiaSorin LIAISON Ortho VITROS Qorvo Omnia QIAGEN QIAreach* Quanterix Simoa | BD Veritor BD Veritor + Flu A/B Ellume* Luminostics Clip LumiraDx Quidel Sofia FIA Quidel Sofia2+Flu | BD Veritor* Ellume OTC |
| Visual read | | Access Bio CareStart ANP Technologies NIDS* BinaxNOW Card BinaxNOW 2 Card Celltrion DiaTrust GenBody COVID-19 Ag* InBios SCoV-2 OraSure Inteliswab Pro PHASE Scientific INDICAID* Princeton Status+Flu Salofa Sienna-Clarity Quidel QuickVue | Access Bio CareStart* BinaxNOW Home Rx BinaxNOW Self OTC BinaxNOW Telehealth OraSure Inteliswab RX OraSure Inteliswab OTC Quidel QuickVue Rx Quidel QuickVue OTC |

New Q3*

Pandemic Total
through 9/30/21

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



Pandemic Total through 9/30/21

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



Molecular Respiratory Combination Tests (18)

- Abbott Alinity m Resp-4-Plex
- BD for BD MAX system
- BioFire Diagnostics Respiratory Panel 2.1 EZ
- Bio-Rad Reliance
- CDC Flu C2 Multiplex Assay
- Cepheid Xpert Xpress Flu/RSV
- Cepheid Xpert Xpress Flu/RSV Plus
- Exact Science Laboratories COVID-Flu Multiplex
- GenMark ePlex Respiratory Pathogen Panel 2
- Hologic Aptima
- Labcorp SARS-CoV-2 & Influenza A/B Assay
- Luminex NxTAG Respiratory Pathogen Panel + SARS-CoV-2
- NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay
- QIAGEN GmbH QIAstat-Dx Respiratory SARS-CoV-2 Panel
- Quest RC COVID-19+Flu RT-PCR
- Roche cobas
- Roche cobas for use with Liat system
- Thermo Fisher TaqPath

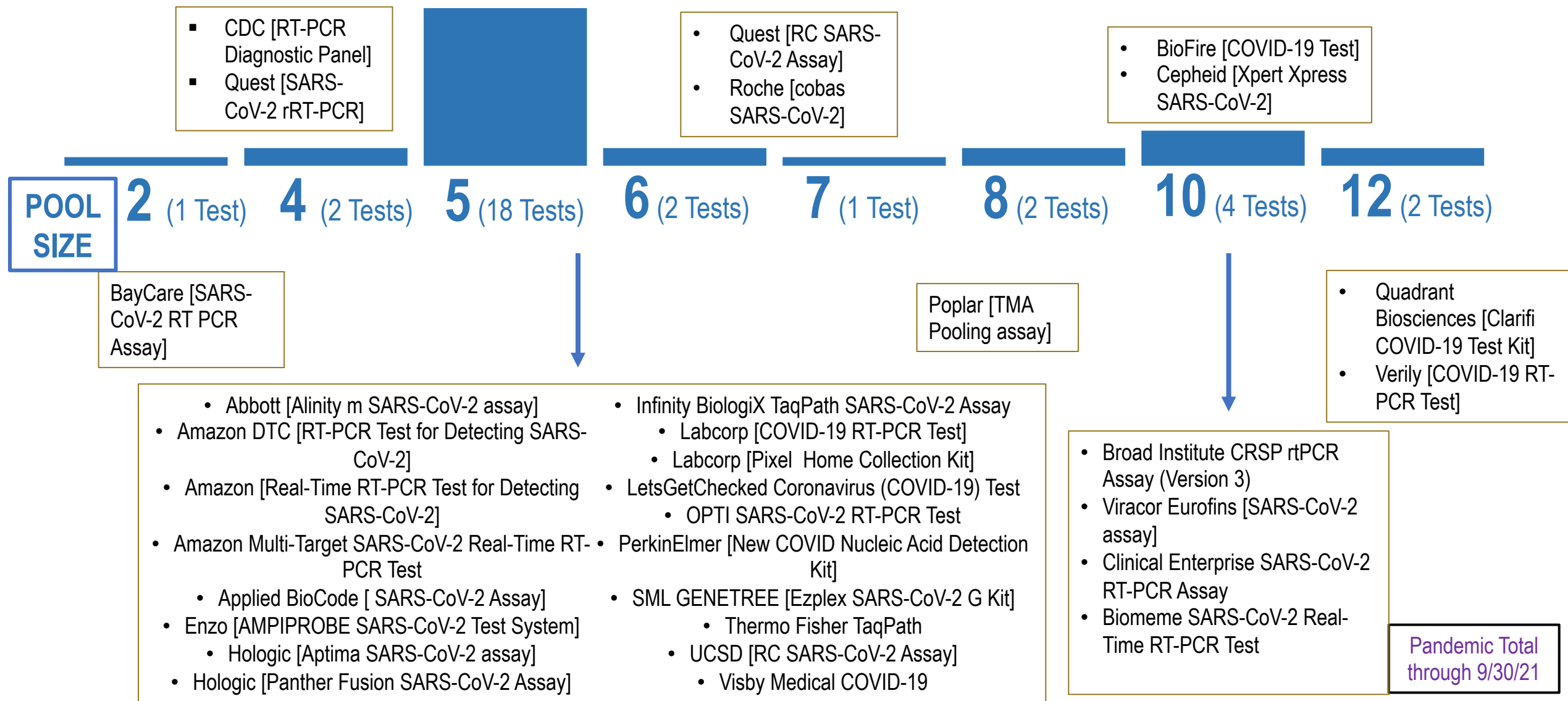
Molecular Respiratory Combination Collection Kits (1)

- Everlywell COVID-19 & Flu Test Home Collection Kit

Antigen Respiratory Combination Tests (3)

- BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B
- Princeton BioMeditech Corp. Status COVID-19/Flu
- Quidel Sofia 2 Flu + SARS Antigen FIA

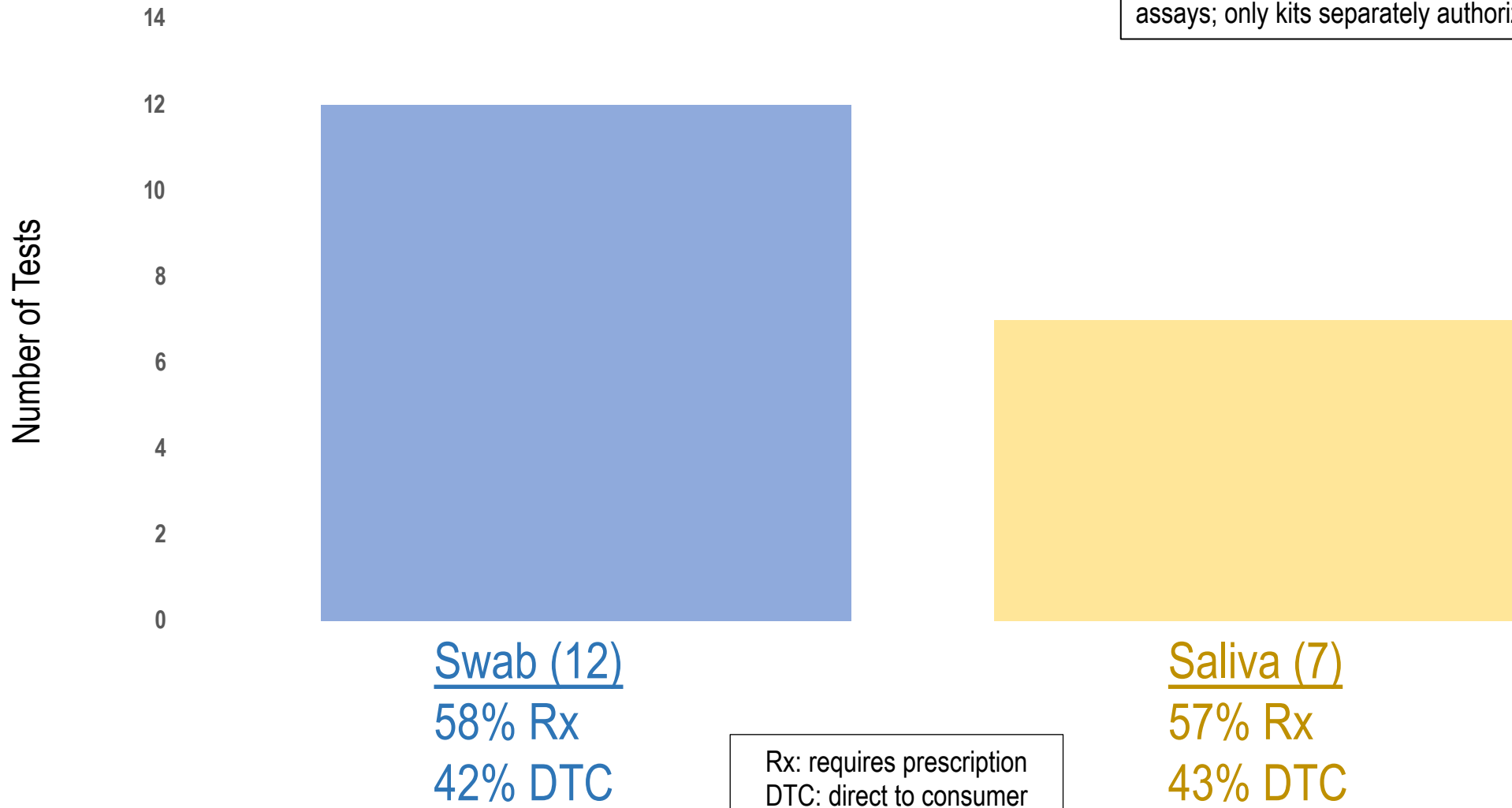
32 EUA's for Testing of Pooled Samples



19 EUA's for Independent Home Specimen Collection Kits



Note: Does not include collection kits included with proprietary assays; only kits separately authorized with independent EUA's



Rx: requires prescription
DTC: direct to consumer

Pandemic Total through 9/30/21



Note: Does not include collection kits included with proprietary assays; only kits separately authorized with independent EUA's

Swab Collection Kits (12)

- binx health At-Home Nasal Swab COVID-19 Sample Collection Kit
- Clinical Enterprises EmpowerDX COVID-19 Home Collection Kit DTC
- Color COVID-19 Self-Swab Collection Kit
- Color COVID-19 Self-Swab Collection Kit DTC
- Color COVID-19 Self-Swab Collection Kit with Saline
- Everlywell COVID-19 Test Home Collection Kit
- Everlywell COVID-19 Test Home Collection Kit DTC
- Everlywell COVID-19 & Flu Test Home Collection Kit
- GetMyDNA COVID-19 Test Home Collection Kit
- Kroger Health COVID-19 Test Home Collection Kit
- Kwokman Diagnostics COVID-19 Home Collection Kit
- RapidRona Self-Collection Kit

Saliva Collection Kits (7)

- DNA GenoTech OMNIgene·ORAL OM-505 and OME-505 (OMNIgene·ORAL) Saliva Collection Device
- DNA GenoTech ORAcollect·RNA OR-100 and ORAcollect·RNA ORE-100 Saliva Collection Device
- Phosphorus Diagnostics LLC Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC
- Spectrum Solutions SDNA-1000 Saliva Collection Device
- WREN Laboratories COVID-19 Saliva Test Collection Kit DTC
- Yale School of Public Health SalivaDirect
- Yale School of Public Health SalivaDirect DTC

Pandemic Total
through 9/30/21

CE-IVD Certified Tests (Mostly Europe)



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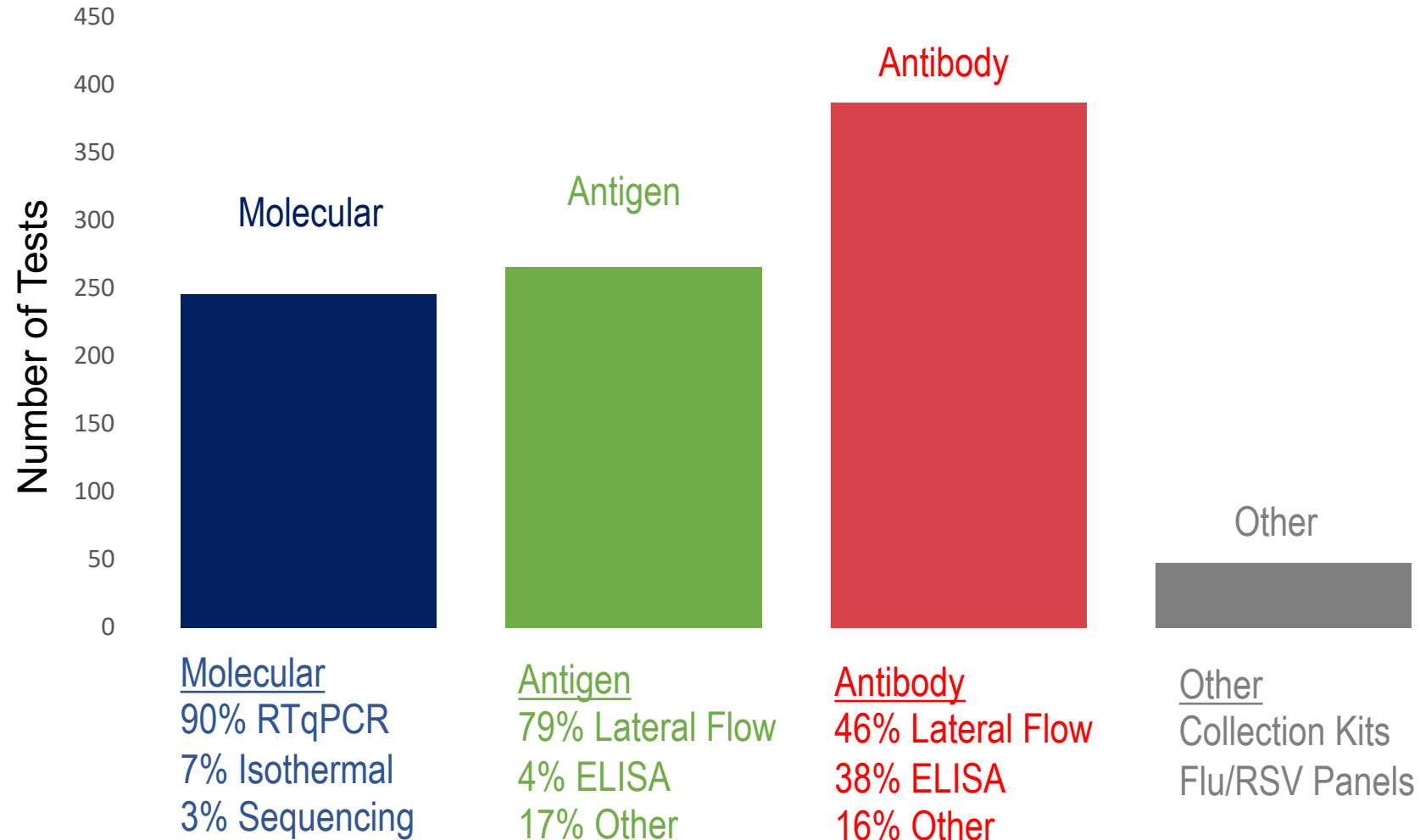
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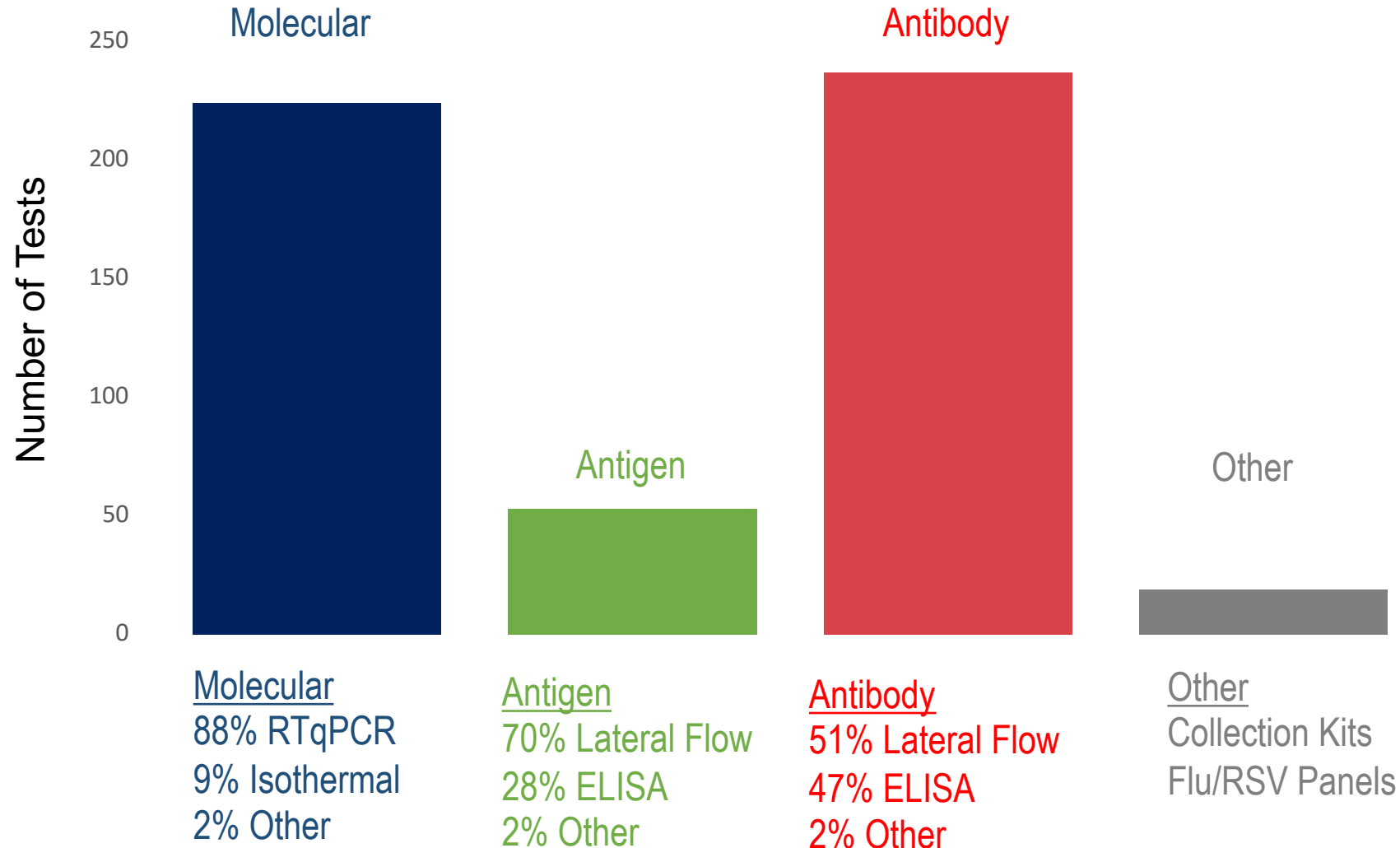
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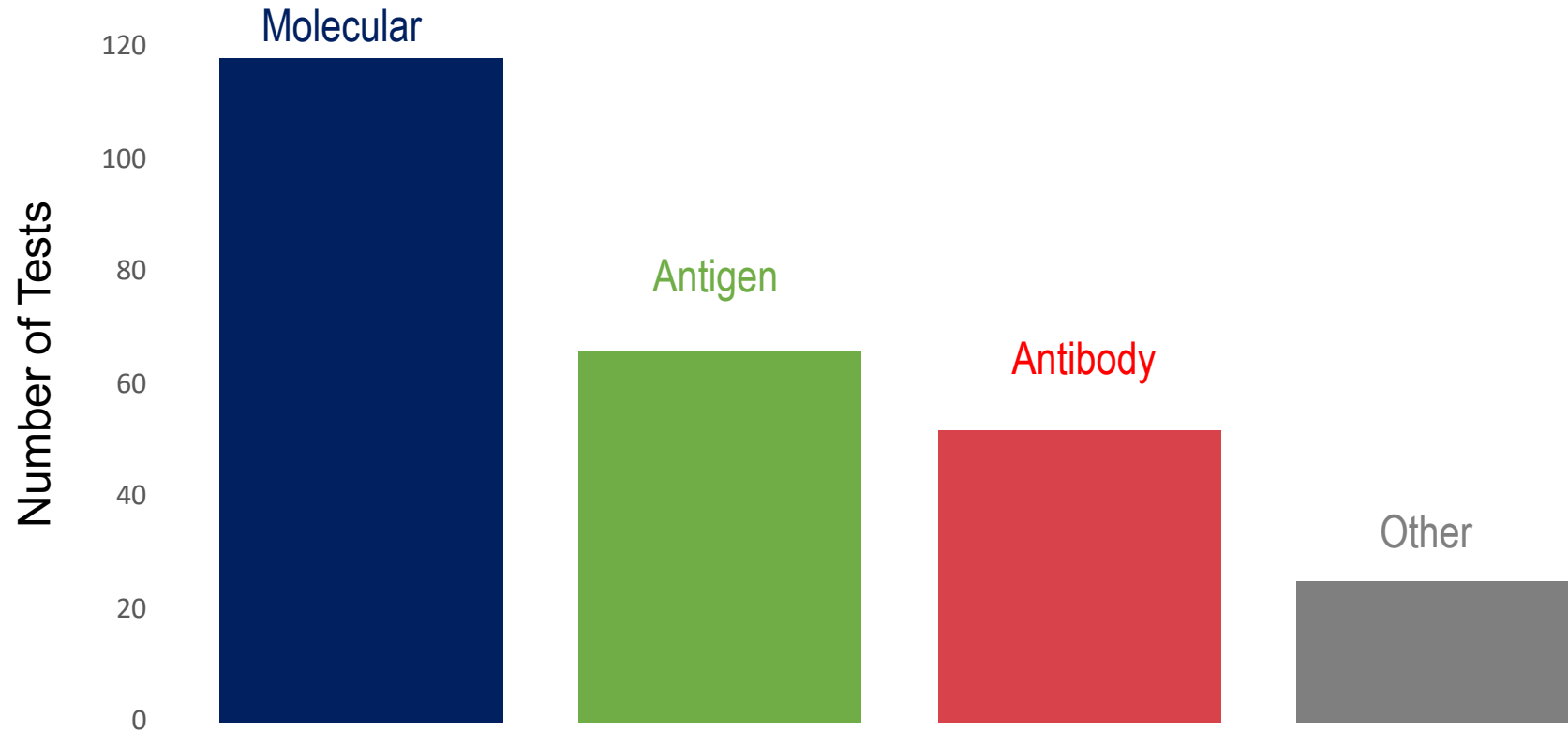
Pandemic Total
through 9/30/21

Research Use Only Tests



Pandemic Total
through 9/30/21

Tests in Development Worldwide



Molecular
40% RTqPCR
24% Isothermal
14% CRISPR
14% Sequencing
10% Other

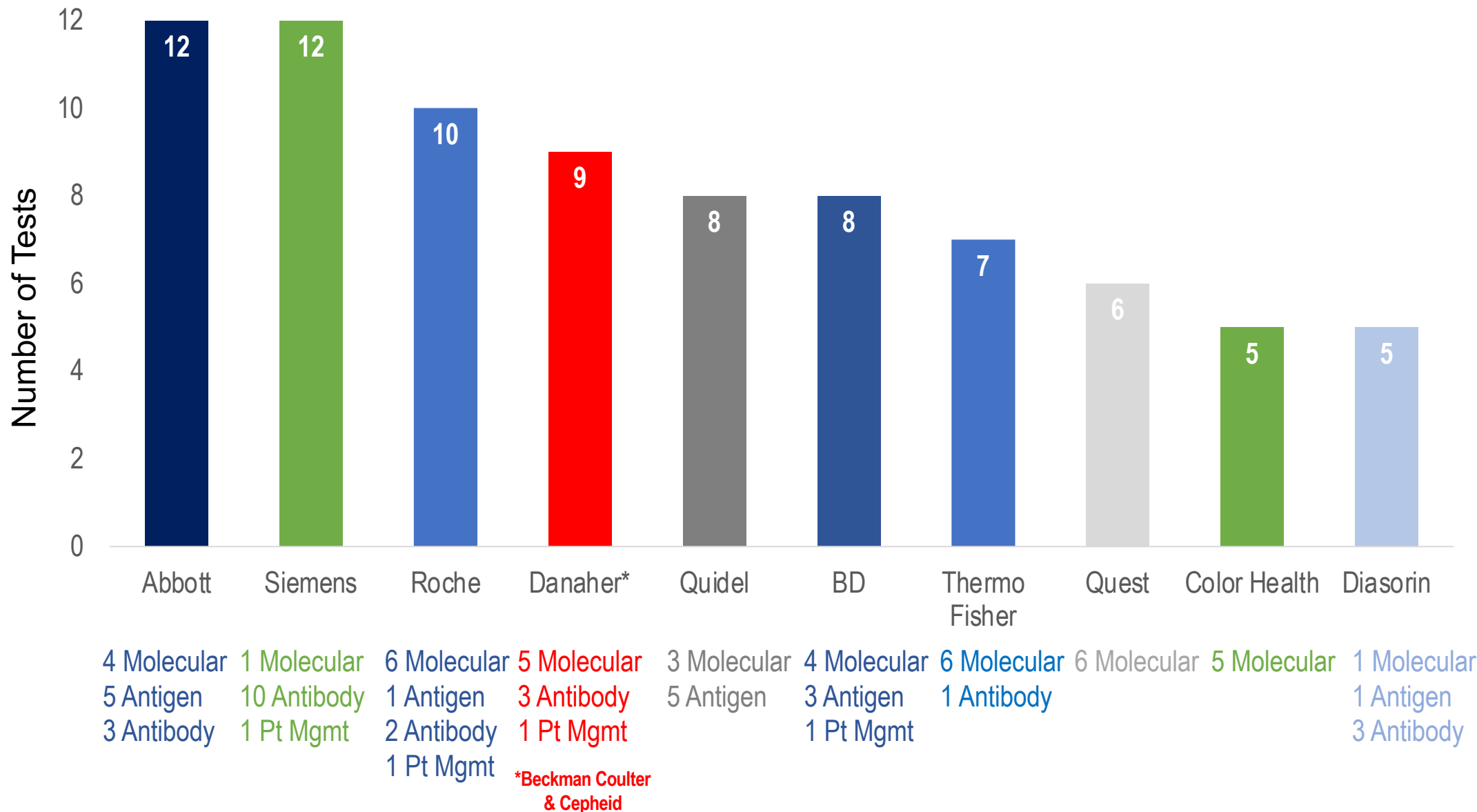
Antigen
59% Lateral Flow
20% ELISA
9% Breath
12% Other

Antibody
63% Lateral Flow
30% ELISA
7% Other

Other
Breath / VOC
Mass Spec
Raman Spec

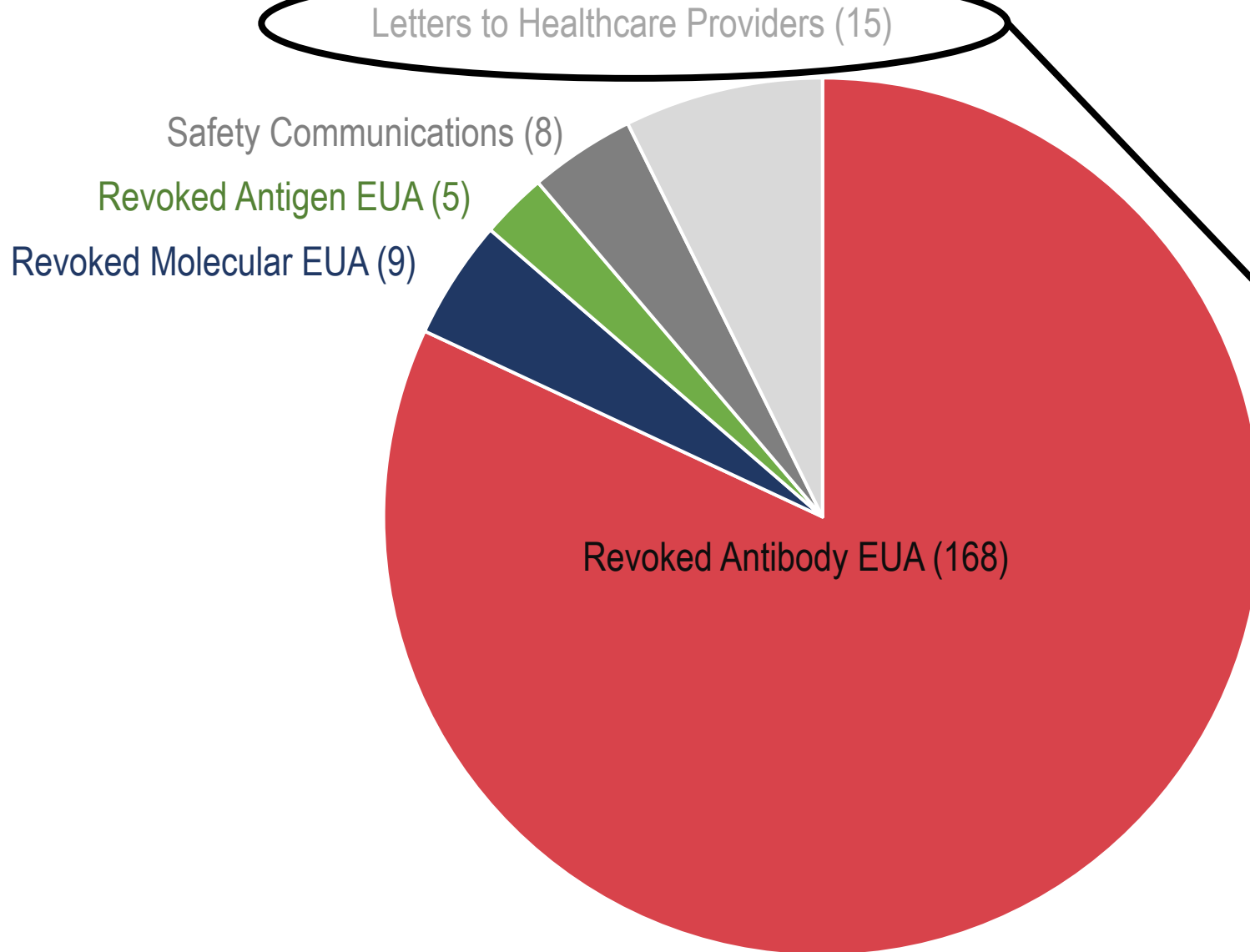
Pandemic Total
through 9/30/21

Companies with the largest number of EUAs



Pandemic
Total
through
9/30/21

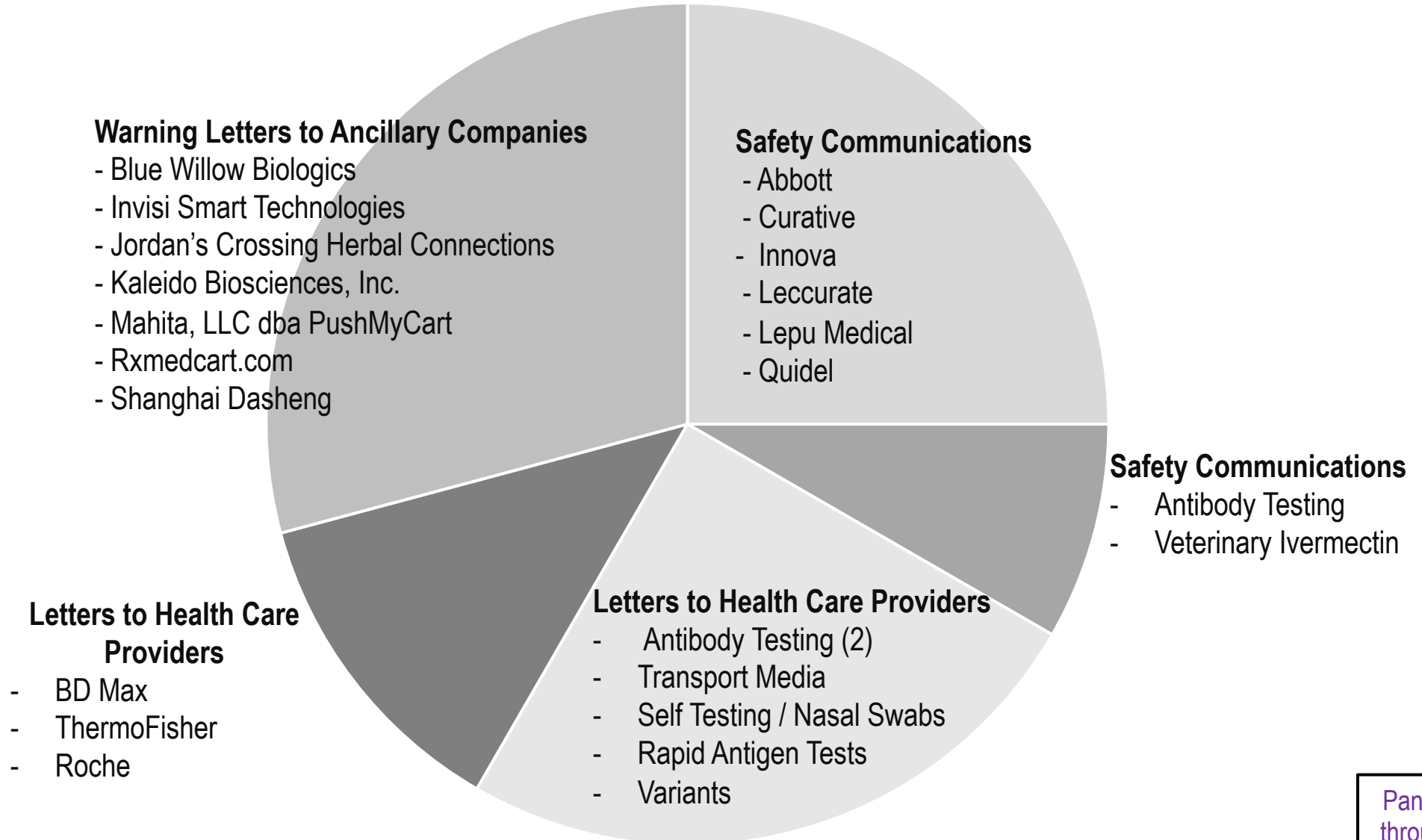
FDA Revoked EUA's & Other Safety Communications



- **Safety Communications:** FDA posts Medical Device Safety Communications to describe FDA's analysis of a current issue and provide specific regulatory approaches and clinical recommendations for patient management.
- **Letters to Healthcare Providers:** FDA posts the letters it sends to health care providers about safety concerns with medical devices used in health care facilities.

Pandemic Total through 9/30/21

Other FDA Safety Communications by Subject



Pandemic Total
through 9/30/21

EUA's for Management of COVID-19 Patients



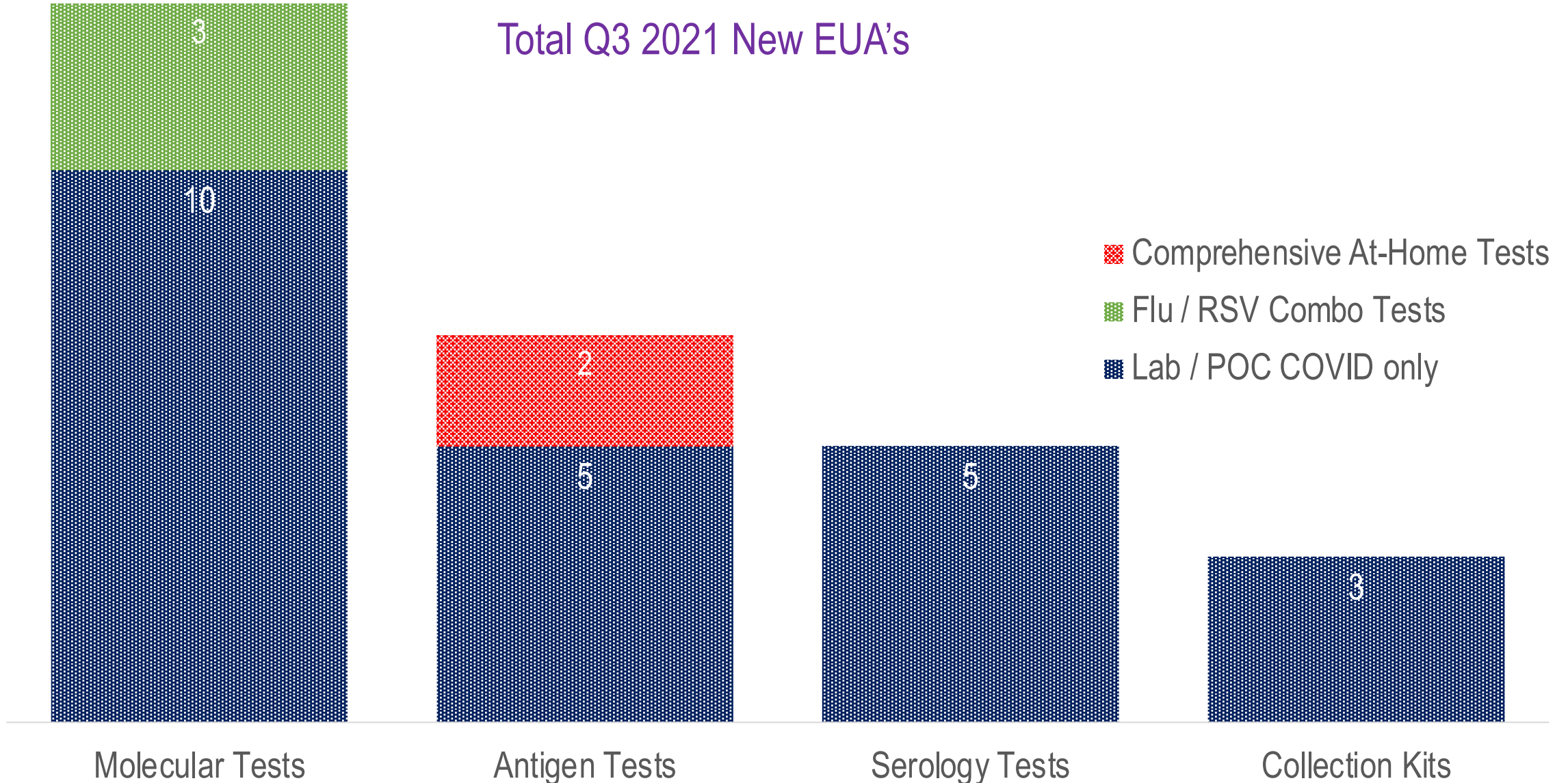
IVDs for Management of COVID-19 Patients (4)

- Roche Diagnostics Elecsys IL-6 (June 2020)
- Beckman Coulter, Inc. Access IL-6 (October 2020)
- Siemens Healthcare Diagnostics Inc. ADVIA Centaur IL6 Assay (December 2020)
- BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) (August 2021)

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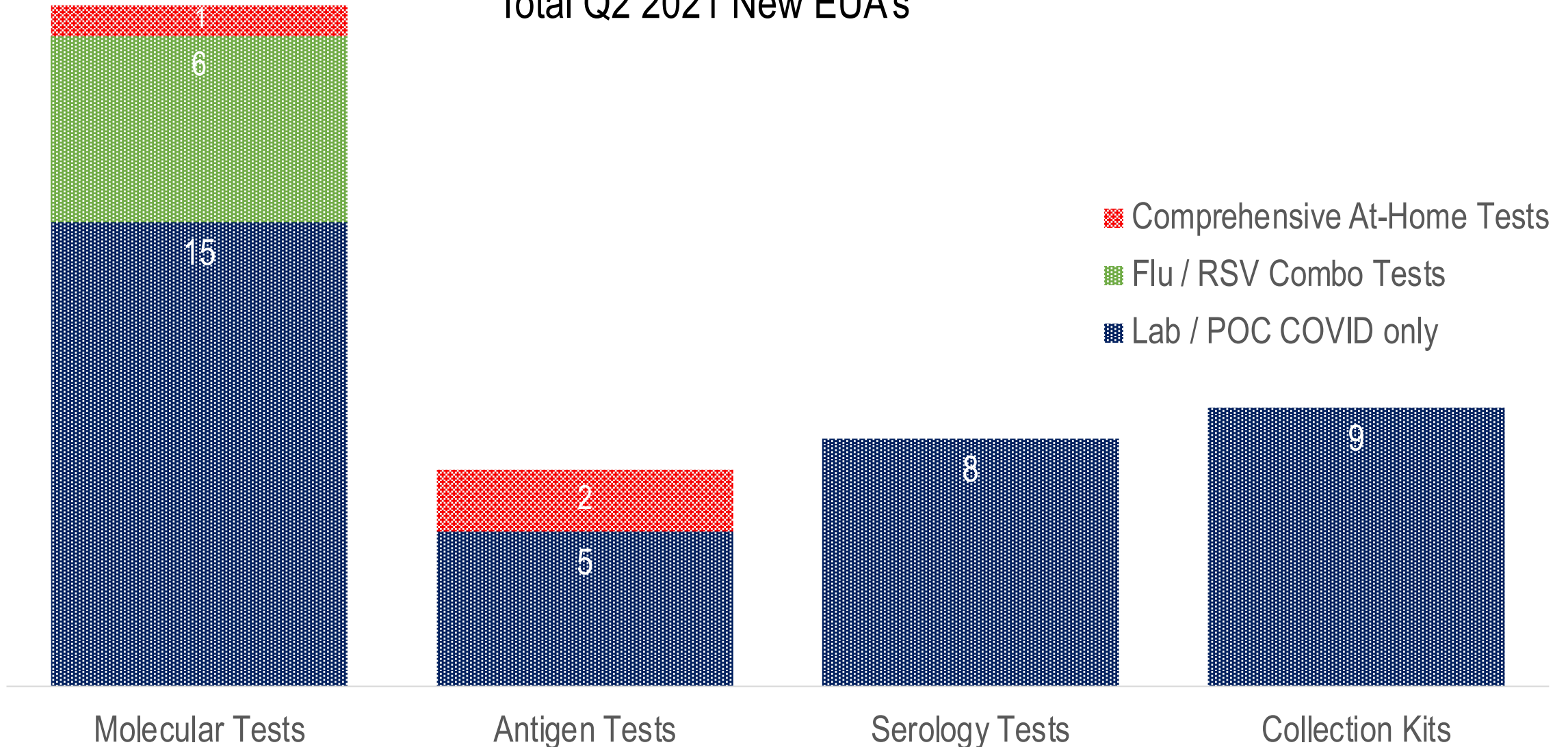
New EUAs by Technology Q3 2021 (n=28)

Total Q3 2021 New EUA's



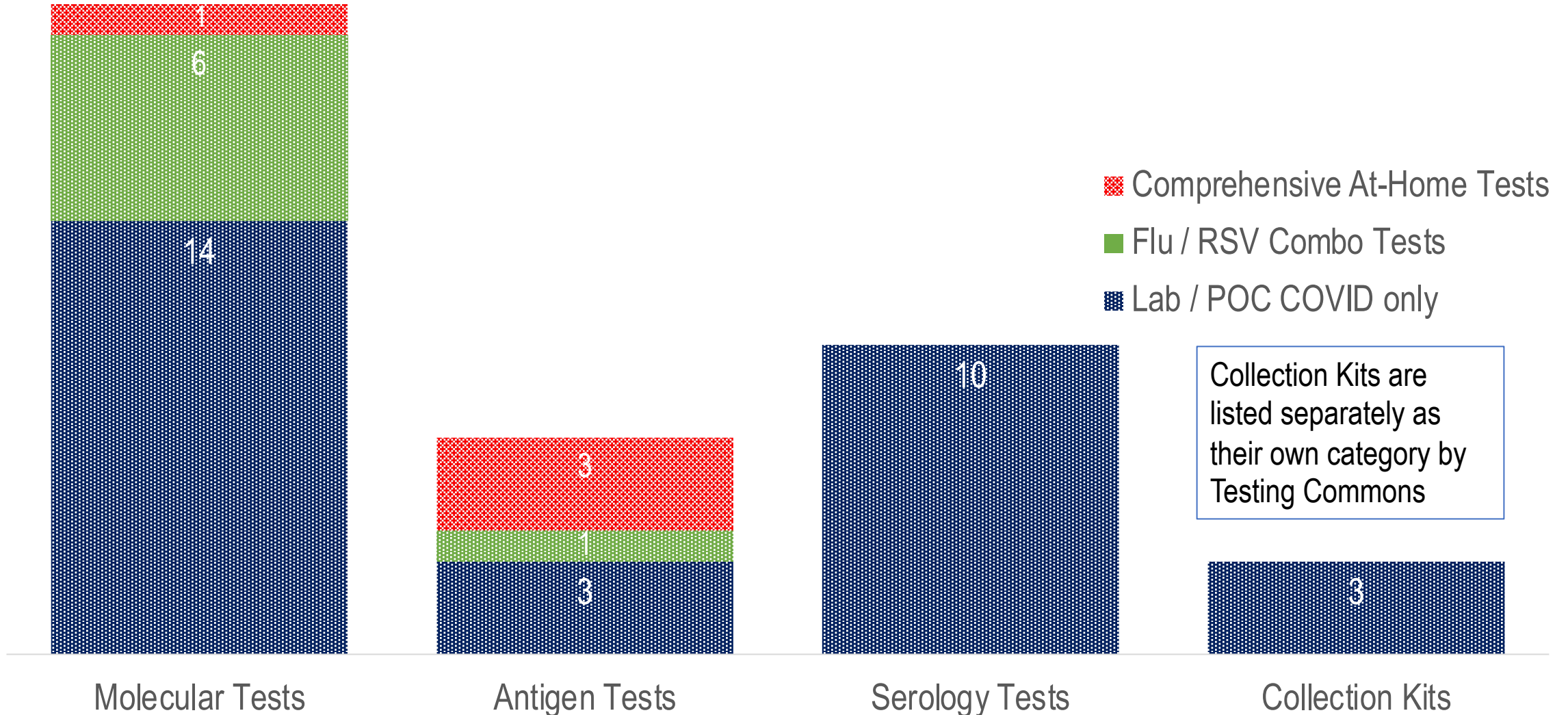
New EUAs by Technology Q2 2021 (n=45)

Total Q2 2021 New EUA's



New EUAs by Technology Q1 2021 (n=41)

Total Q1 2021 New EUA's





Special thanks to:

- ASU College of Health Solutions for leadership in Biomedical Diagnostics
 - *Sarah Igoe, MD for her great work on TestingCommons.com*
 - *Nate Wade, PhD, for his continued partnership on ASUCovidCommons.com*
- ASU Decision Theater
 - *The team's work is critical to the success of all of our systems*
- The Rockefeller Foundation
 - *For the enabling grant for TestingCommons.com and all parts of ASUCovidCommons.com*
 - *For continued commitment to education*