FDA

THE CURRENT LANDSCAPE OF THE NATION'S LABORATORY SYSTEMS FOR PUBLIC HEALTH EMERGENCY PREPAREDNESS AND RESPONSE

National Academies

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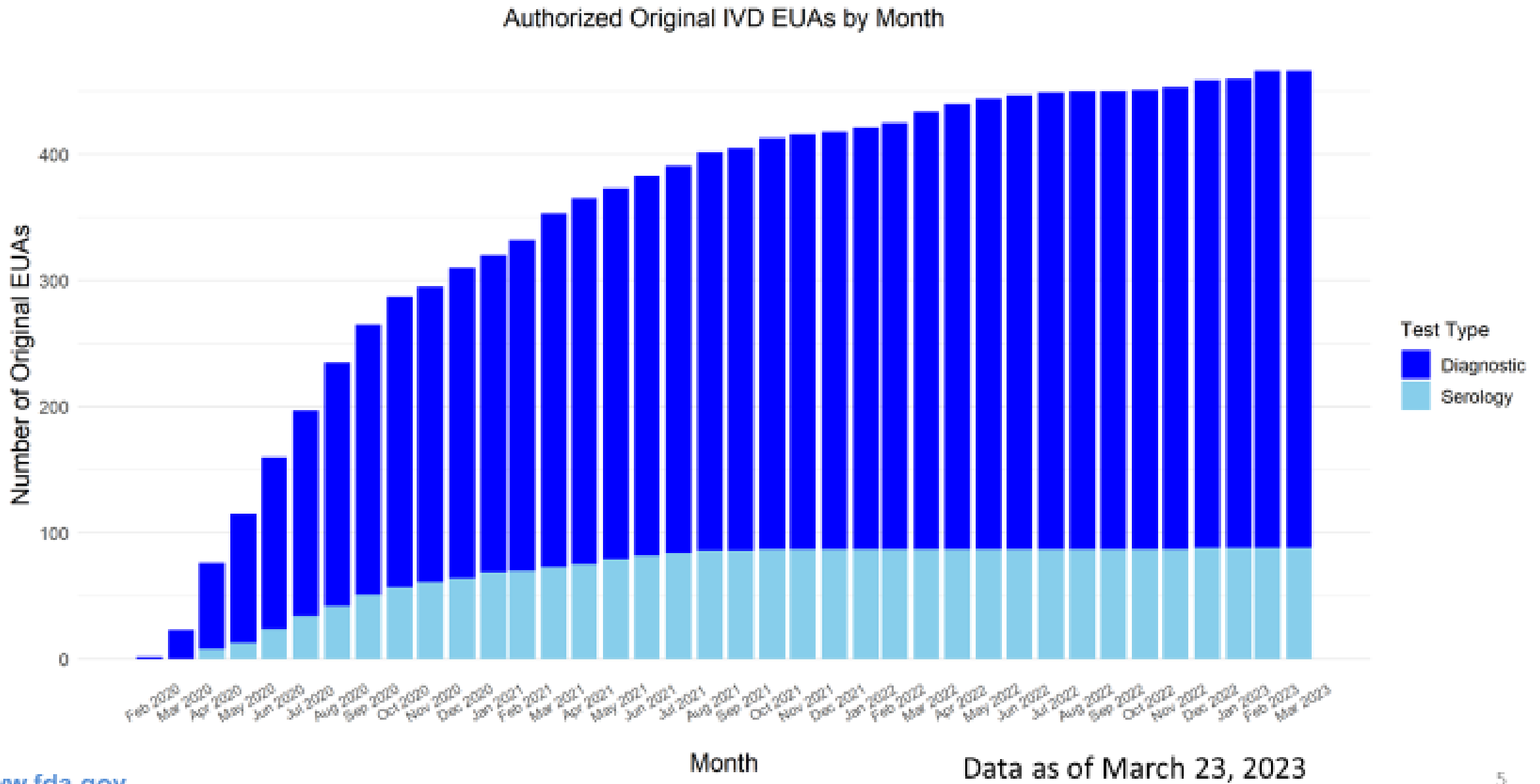
COVID-19 EUA Authorizations



COVID-19 Tests Authorized as of March 23, 2023

300

Molecular diagnostic tests

- 34 Pooling
- 70 Asymptomatic single use screening
- 8 Serial screening
- 28 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 25 Point-of-care
- 78 Home collection
  - 16 Direct-to-consumer
  - 6 Multi-analyte
  - 15 Saliva home collection
- 21 Standalone home collection kits
- 3 Standalone saliva collection devices
- 1 Prescription at-home test
- 5 Over-the-counter (OTC) at-home tests

60

Antigen diagnostic tests

- 54 Point-of-care
- 2 Prescription at-home tests
- 28 Over-the-counter (OTC) at-home tests
- 45 Serial Screening
- 3 Serial Testing
- 3 Multi-Analyte

84

Serology and other immune response tests

- 13 Point-of-care
- 3 Neutralizing antibody tests
- 16 Semi-quantitative
- 1 Quantitative
- 1 Home collection

FDA Interactions, Collaborations, Contributions

- FDA interacted early and often with all stakeholders including laboratories and will do in the future
- FDA directly involved with individual laboratories and laboratory networks to solve issues as well has kit manufacturers and reagent suppliers
- Data is an increasingly important role
- MDRs allowed FDA to monitor test performance and address concerns with they arise
- FDA created and maintains vigilant work on mutations and variant assessments on test performance in collaboration with NIH and CDC

Response Phases - Early

- Future: Prepositioned pathogen agnostic test(s) for surveillance for potential pathogens and after identification could be used for diagnosis immediately
  - Likely low throughput automated molecular assays
- Current: Followed quickly by high volume though low to medium throughput tests that can be widely distributed and used
  - Likely molecular assays that can be quickly developed, validated and manufactured by high volume manufacturers that can be performed on commonly used clinical laboratory instrumentation

Response Phases – Highly Automated, High Throughput Tests

- Utility or requirements for tests changed or may change – COVID-19 vs MPOX
- Next up for laboratories, if test orders increase dramatically, is the need for nearly or complete automation on high throughput instruments already in place in many laboratories
  - Clinical laboratories do have workforce issues and automation is/was clearly needed to address this issue
- Also as test orders increase dramatically, this can lead to shortages of key and sometimes common test reagents and supplies
  - FDA has served as a resource to laboratories and manufacturers on which substitutions make sense and posted those on the FDA website
  - FDA used and can use other forms of communication as well such as IVD Town Halls

Response Phases – Point of Care

- Point of Care (POC) tests were widely used for COVID-19 and are beginning to be used for MPOX
- POC tests are usually more challenging to develop and validate as assessment of performance by non laboratory personnel is important
- Near patient, manufactured in extremely high volumes, and widely distributed
- Low throughput

Response Phases – Over the Counter Tests

- Over the counter tests (OTC) played an important role in the COVID-19 response
- Decentralization of testing played an important role for COVID-19 and is likely to be a key part of future widespread responses
- Pan Flu, Sars, or other pathogen tests have played a role in COVID-19 and previous influenza (Flu) responses and are likely to play key roles going forward
- Simple to use tests that need to be evaluated in patient hands can take the longest to develop and validate
- These tests, especially antigen tests, can be manufactured in extremely high volumes and distributed to nearly all US households

References

- **NEJM:** Covid-19 Molecular Diagnostic Testing — Lessons Learned | NEJM
- **NEJM:** The FDA's Experience with Covid-19 Antibody Tests | NEJM
- **Health Affairs:** Bending The Arc Of COVID-19 Test Development To Increase Access And Ensure Reliability—Now And In The Future | Health Affairs
- **Health Affairs:** South Korea's Implementation Of A COVID-19 National Testing Strategy | Health Affairs

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Thank You!