FDA

Identifying Short-Term Strategies to Enhance Laboratory Capabilities, Capacities, and Coordination: Acceleration, Surge, and Long-Term Response

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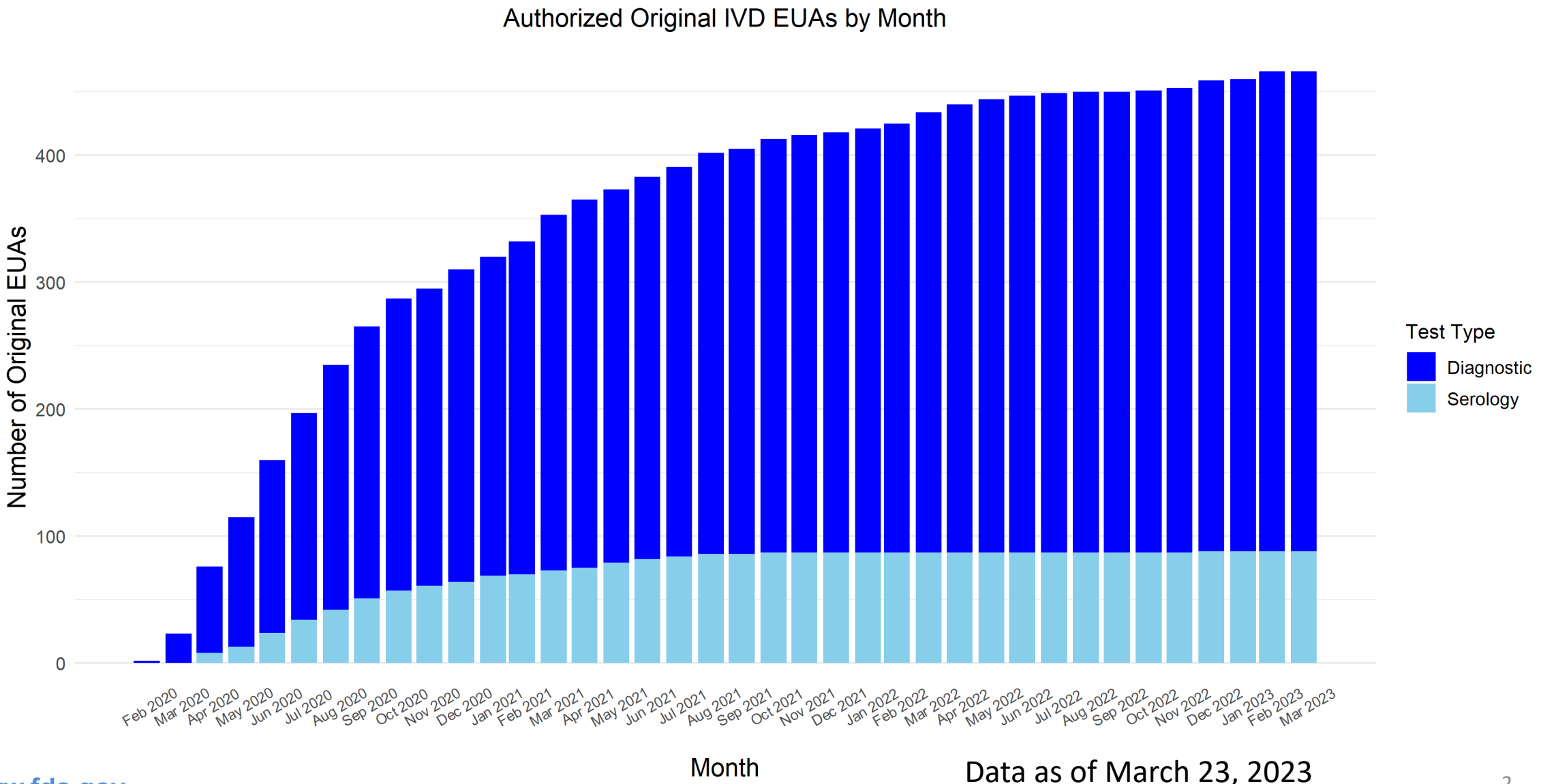
Tim Stenzel, M.D., Ph.D.
Director, Office of In Vitro Diagnostics
Food and Drug Administration

COVID-19 EUA Authorizations



Data as of March 23, 2023

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

Potential strategies to improve acceleration, surge, and long-term response capabilities, capacities, and coordination within the next 3-5 years

- FDA is reaching out to stakeholders to get input on both EUA generic guidance and generic recommended validations
  - This effort will be followed by pathogen specific work
- FDA is planning formal guidance for the preparedness work though timing of final guidance is unknown
- Will go through draft guidance with comment period
- Then review of comments and final guidance drafting and clearance
- FDA is participating in the future preparedness planning within the USG and is welcoming of participate in forums like this

What strategies, models, regulatory mechanisms, policies, systems, partnerships, and incentives either exist or should be considered to enhance surge capabilities within laboratory systems?

- FDA COVID-19 policies from February 29, 2020 to present day are a source of learnings
- FDA MPOX policies are another source
- FDA is currently engaged with stakeholders on their feedback on FDA responses to COVID-19 and MPOX in preparation for the next emergencies

What practical, impactful actions can be taken in the near term to address issues related to: maintaining standing excess test capacity, rapid expansion of test capacity, and rapid development of new test methods?

- This is highly dependent on USG leadership
- Items to consider are National Stockpile of tests and testing supplies, etc
- Prearranging key developers and processes to validation and review tests perhaps with the help of a third party such as NIH
  - Independent Test Assessment Program (ITAP) would be ideal
- Prepared validation recommendations for key potential pathogens

What strategies can be implemented to resolve unmet needs during response?

- FDA will stay engaged throughout with stakeholders by various means including Town Halls and the FDA website
- FDA will support efforts related to supply issues

What strategies can be implemented to ensure that laboratory testing is made available in an equitable manner during response?

- Prearrangements with selected high volume test manufacturers so they are immediately ready to begin test development, know what is needed to validate the tests and are ready to manufacture tests in high volumes
- Reagent and test supplies need to be planned for as well

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!