FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

CDRH Presentation

Microbiology Devices Panel of the Medical Devices Advisory Committee to Discuss IVD Pandemic Preparedness and Response

September 8, 2023

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Center for Devices and Radiological Health

Opening Remarks and Agenda

Purpose

Background

Panel Questions for Discussion

Preparing for Future Pandemics

- Lessons learned by CDRH from COVID-19 pandemic and mpox outbreak can be applied to prepare for and respond to future pandemics involving in vitro diagnostic (IVDs) devices

- Actual or potential emergencies for infectious diseases in which FDA exercised EUA authority to authorize IVDs include: influenza A H1N1 (2009), avian influenza A H7N9 (2013), MERS-CoV (2013), Ebola (2014), Enterovirus D68 (2015), Zika (2016), COVID-19 (2020), and mpox (2022)

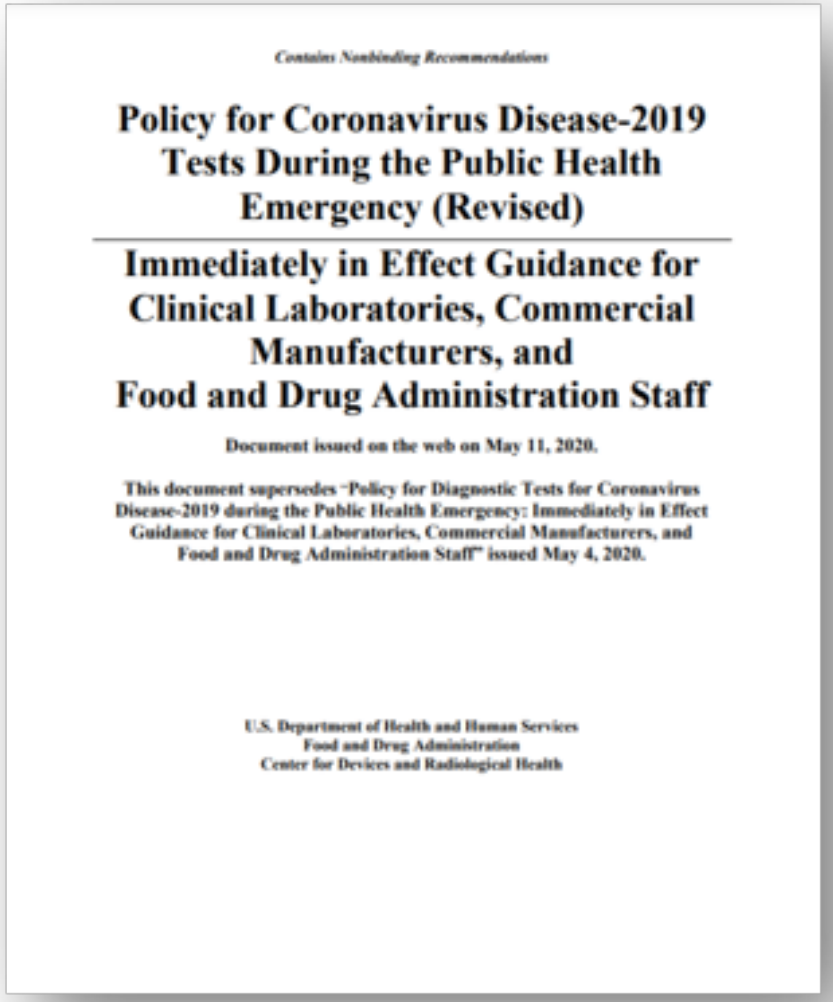
- **Objective**: Further improve CDRH's ability to prepare for and respond to IVD testing needs in future pandemics.

COVID-19 Background

- On January 31, 2020 - Public Health Emergency declared under section 319 of the Public Health Service Act.
- On February 4, 2020 - HHS issues Emergency Use Authorization (EUA) declaration under section 564 of the Federal Food, Drug, and Cosmetic Act
- On February 4, 2020 – first EUA issued for SARS-CoV-2 diagnostic test.
- Emergency Use Authorization (EUA) authority
  - **Statutory Criteria for Issuance Include:**
    - Serious or life-threatening disease or condition caused by agent
    - Medical product "**may be effective**" to diagnose, prevent or treat the condition
    - Known and potential **benefits outweigh** known and potential risks
    - No adequate, approved, and available alternative; unavailable includes insufficient supplies of the approved alternative

FDA's COVID-19 Test Policy

- Initially published on CDRH's website on February 29, 2020
- Was updated throughout the pandemic as the situation evolved
- CDRH's EUA request review priorities and enforcement policies for COVID-19 Tests
- By February 28, 2021, CDRH had received over 730 EUA requests related to COVID-19 tests



Contains Nonbinding Recommendations

Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)

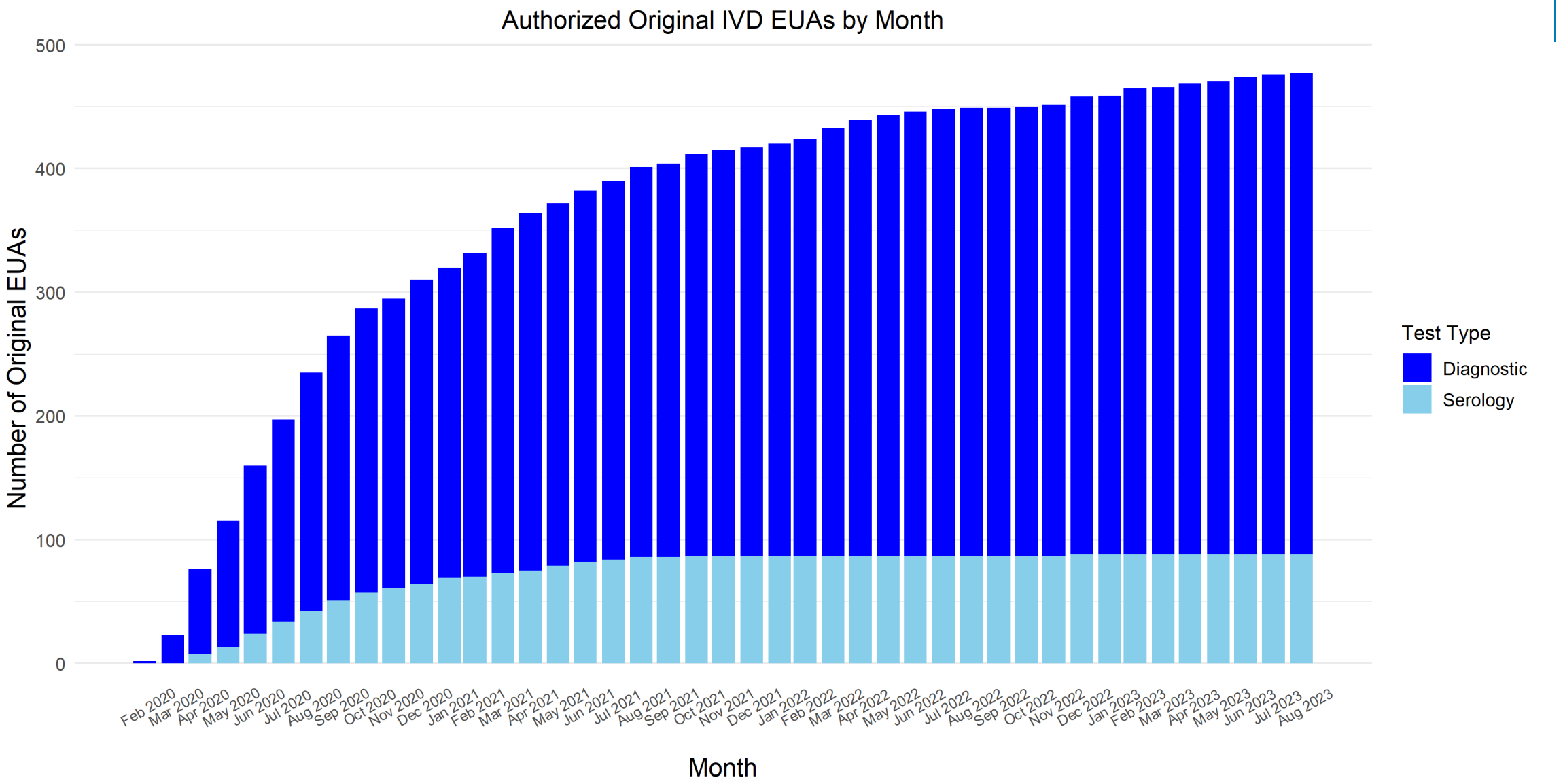
Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff

Document issued on the web on May 11, 2020.

This document supersedes "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency: Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff" issued May 4, 2020.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

EUA Authorizations



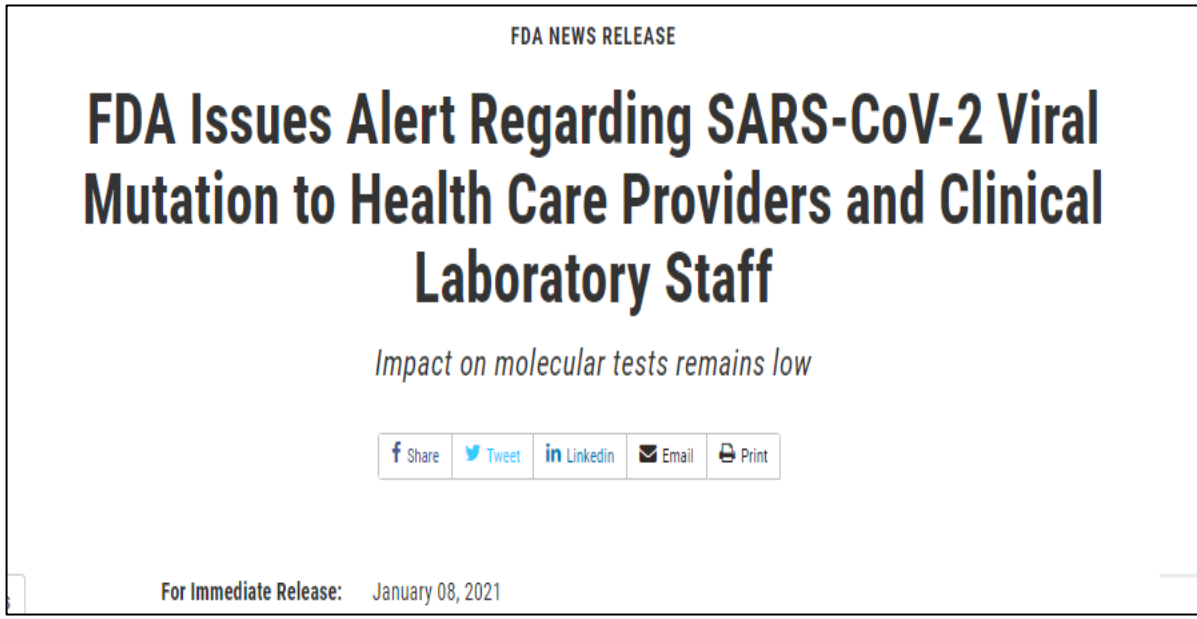
Data as of August 3, 2023

Approaches during COVID-19 pandemic

- Early versions of the COVID-19 Test Policy guidance provided a policy for certain developers and tests to market their tests without first obtaining EUA authorization (“notification”)
- Independent evaluation of tests to enable laboratory-based evaluation and provide reasonable estimates and confidence intervals for test performance given limited sample availability
- The Independent Test Assessment Program (ITAP) in order to accelerate regulatory review and availability of high-quality, accurate, and reliable over-the-counter COVID-19 tests to the public
- Pioneering the use of umbrella EUAs allowed for a streamlined approach to the authorization of tests that meet specified criteria
- A study of serial testing conducted by UMass, NIH, and FDA showed that antigen tests benefited from serial testing of both symptomatic and asymptotic patients. This was applied to all antigen tests

Additional COVID-19 Activities

- Shortage Mitigation of certain diagnostic supplies (e.g., swabs, VTM)
- EUA request templates for developers
- External Communications
  - SARS-CoV-2 FAQ on CDRH's website
  - Virtual Town Halls
  - Dedicated COVID-19 test inbox for questions
  - Safety communications
- Monitoring variant impact, with the Variant Task Force (VTF) in collaboration with NIH and Emory University
- FDA support of and collaboration with the NIH RADx and ITAP programs



FDA NEWS RELEASE

FDA Issues Alert Regarding SARS-CoV-2 Viral Mutation to Health Care Providers and Clinical Laboratory Staff

Impact on molecular tests remains low

Share Tweet LinkedIn Email Print

For Immediate Release: January 08, 2021

Engagement as of August 10, 2023

373 **Frequently Asked Questions**

- 3D Printing
- Diagnostic Testing
- Face Masks (Non-Surgical)
- Shortages of Medical Gloves
- Home-use Blood Glucose Meters Utilized Within Hospitals
- Shortages of Surgical Masks and Gowns
- EUAs for Devices
- Personal Protective Equipment (PPE)
- Non-NIOSH Approved Respirators
- Ventilators

24 **Letters to Healthcare Providers & Safety Communications**

- Diagnostic Tests
- Antibody Tests
- PPE
- Ventilators

445,000 **Inquiries addressed through**

- 17 mailboxes
- 2 phone lines

127 **Webinars & Virtual Town Halls**

- 106 Diagnostic Tests
- 19 PPE
- 2 other

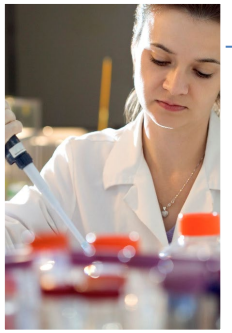
13 **Templates**

- 10 Diagnostic Tests
- 3 other

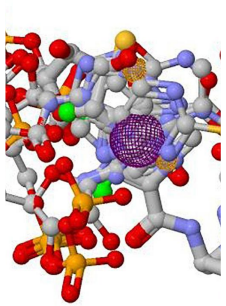
RADx **Participation in NIH's RADx and ITAP**

Monitoring for Impact of Variants on Test Performance

FDA monitors global databases for emerging variants



FDA requires tests developers to conduct own surveillance and analyses as condition of authorization



FDA conducts in silico analyses of target sequences for all authorized molecular tests

FDA provides information on specific tests for which FDA has identified potential impacts on performance due to genetic mutations

FDA provides recommendations to clinical lab staff and healthcare providers using tests for which FDA identified potential performance impacts due to genetic mutations

FDA collaborates with NIH's RADx program on Variant Task Force (VTF), studying performance of COVID tests with different variants (most recently for omicron variant)

Assessments of CDRH's COVID-19 Tests Response

- Several external assessments with recommendations:
  - Office of Inspector General (OIG) report titled "FDA Repeatedly Adapted Emergency Use Authorization Policies To Address the Need for COVID-19 Test"
  - US Government Accountability Office (GAO) report titled "FDA Took Steps to Make Tests Available for Future Public Health Emergencies Needed" available at https://www.gao.gov/assets/gao-22-104266.pdf
  - Booz Allen Hamilton report titled "Emergency Use Authorization Assessment – Final Report" available at https://www.fda.gov/media/152992/download.

- CDRH's own experiences learned through the COVID-19 pandemic
  - Value of regulatory flexibility
  - Power of engagement

Key Lessons Learned

Premarket Review

Importance of review of tests before clinical use, and consideration of potential alternative approaches, such as prior certification of developers

Agile Organization

Ability to quickly respond and adapt to changes, pivoting to focus on immediate needs and challenges as they arise

Pre-position Commercial Developers

Establish contracts to pre-position handful of commercial developers to be ready for outbreak response

De-risk the Enterprise

De-risk test development through guarantees of minimum purchases, reimbursement and production funding support

Centralized Performance Validation

Establish centralized clinical validation program to support test development and validation (e.g., ITAP for at-home tests)

Sample Sharing

Establish more effective mechanisms for sample sharing in outbreaks to facilitate test development and validation

Invest in Novel Technologies

Continue investment in novel test development, particularly point-of-care (POC) and at-home technologies

Regulatory Flexibility

Regulatory flexibility and extensive engagement with developers is critical

Questions for Panel Discussion

1. How can test developers (including both commercial manufacturers and laboratory test developers) best interact with CDRH when preparing for a future pandemic? What steps can CDRH take to strengthen its communication strategies in future pandemics with test developers, laboratories performing tests, and other stakeholders such as patients and clinicians? Were any methods of communication (town halls, telephone hotline, website FAQ, email boxes for stakeholders, EUA templates) more advantageous than others and what might CDRH consider doing differently in future pandemics?

Questions for Panel Discussion (Cont.)

2. What types of educational resources or communications from CDRH would be most valuable to aid test developers with respect to test development in preparation for a future pandemic?

3. Are there certain types of instrument manufacturers or test component manufacturers with whom CDRH should collaborate in preparation for a future pandemic response to ensure test availability in a future pandemic. For example, would earlier engagement from CDRH to work with manufacturers of high throughput systems help ensure that well-designed, high-throughput tests can be made available at an appropriate volume to meet the needs of any future outbreak?

Questions for Panel Discussion (Cont.)

4. Are there certain types of tests or developers that should be prioritized for review in the early stages of a future pandemic? Examples include certain test types (e.g., diagnostic and high throughput), test protocol development for sharing with any laboratory, manufacturing capacity, or experienced test developers.

5. What are key features of tests or are there certain test designs that would be helpful in a future pandemic?

6. What other lessons from the recent COVID-19 pandemic and mpox emergencies might CDRH take into consideration in preparing for future pandemics?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