FDA Update

CLIAC
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Timothy Stenzel, M.D., Ph.D.
Director, Office of In Vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)
CDRH | Food and Drug Administration

FDA and Medical Device Industry have reached an agreement on proposed recommendations for MDUFA V

On Tuesday April 19, FDA will host a virtual public meeting to discuss recommendations for the reauthorization of the Medical Device User Fee Amendments for fiscal years 2023 through 2027 (MDUFA V).

MDUFA V Commitment Letter

"The agreement underscores the continued commitment by the FDA and medical device industry to prioritize innovation and increase patient access to safe and effective medical devices. In addition, MDUFA V represents a substantial investment in the future of the agency's medical device program and would provide for important improvements, including new hiring targets, greater engagement with developers of innovative technologies based on lessons learned from the pandemic, broadened international harmonization efforts and expanded opportunities to ensure patient perspectives are an integral part of medical device development."

- Jeff Shuren, M.D., J.D., Director, Center for Devices and Radiological Health (CDRH)

Challenges and Solutions to Workload Impact

Looking Ahead to 2022 as FDA's Center for Devices and Radiological Health Manages a Sustained Increase in Workload

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By: Jeff Shuren, M.D., J.D., Director, Center for Devices and Radiological Health (CDRH) and William Maisel, M.D., MPH, Director, Office of Product Evaluation and Quality (OPEQ), CDRH

- The unprecedented number of EUA and pre-EUA submissions significantly impacted CDRH's workload, particularly the ability to review IVD submissions not related to COVID-19.
  - CDRH has been reviewing IVD 510(k), De Novo and PMA premarket submissions for some time now but under extended review timelines.
  - IVD Pre-Submissions (Q-subs) are also currently being reviewed when related to COVID-19, companion diagnostics, a product that will likely be reviewed as a De Novo or PMA, a breakthrough device designation request, or have a significant public health impact. IVD Pre-Submissions (Q-subs) for 510(k)s will resume as soon as possible later this fiscal year. IVD pre-submissions currently being reviewed do have an extended timeline, though **we expect to transition toward normal MDUFA timelines during the course of 2022.**

https://www.fda.gov/news-events/fda-voices/looking-ahead-2022-fdas-center-devices-and-radiological-health-manages-sustained-increase-workload

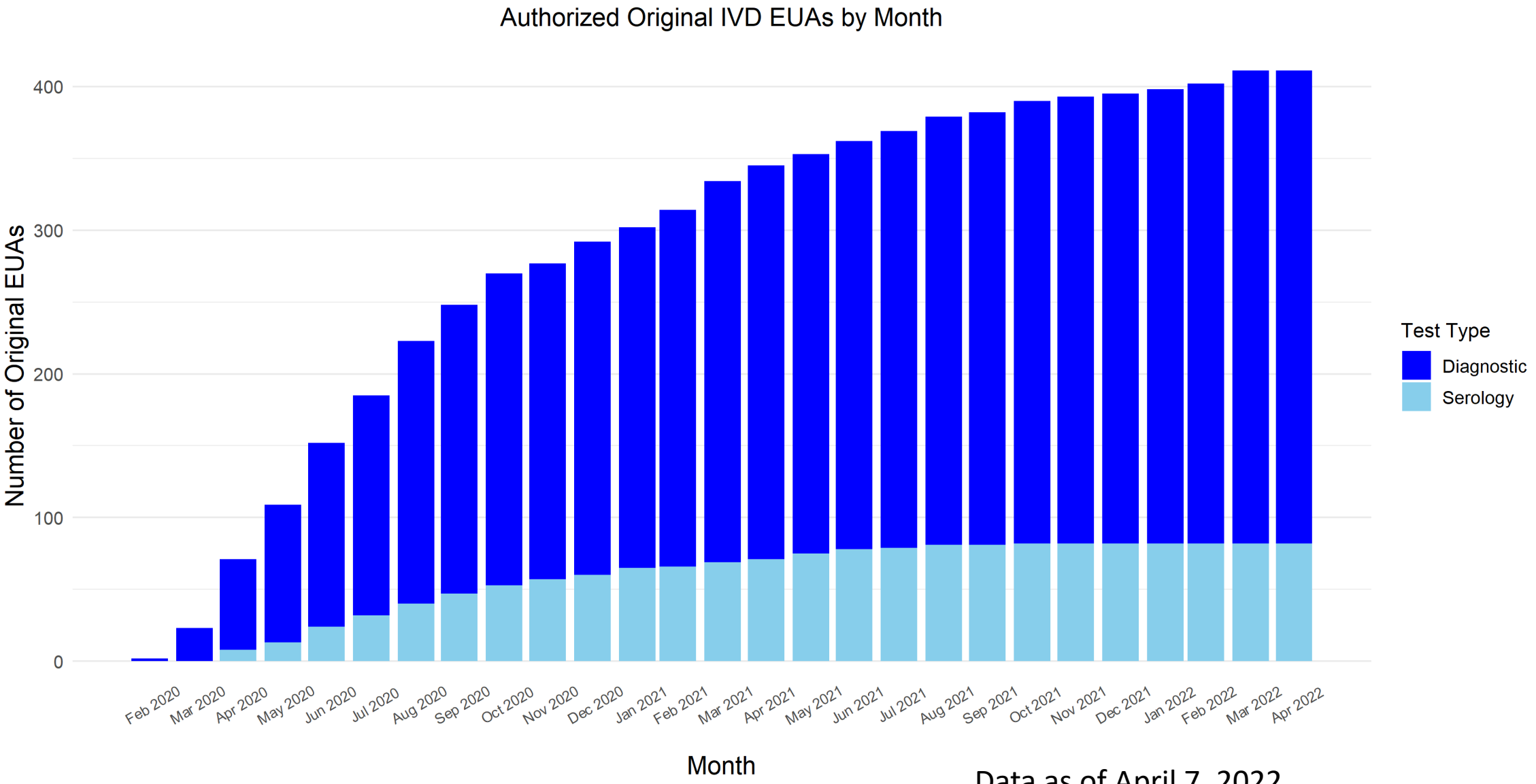
Collaborative Communities: Addressing Health Care Challenges Together

A collaborative community is a continuing forum in which private- and public-sector members, which can include the FDA, work together on medical device challenges to achieve* common *objectives and outcomes

Collaborative Communities with CDRH Participation

- Collaborative Community on Ophthalmic Imaging
- National Evaluation System for health Technology Coordinating Center (NESTcc) Collaborative Community
- Standardizing Laboratory Practices in Pharmacogenomics Initiative (STRIPE) Collaborative Community
- International Liquid Biopsy Standardization Alliance (ILSA)
- Xavier Artificial Intelligence (AI) World Consortium
- Case for Quality Collaborative Community
- Heart Valve Collaboratory (HVC)
- Wound Care Collaborative Community
- Pathology Innovation Collaborative Community (PICC)
- RESCUE (REducing SuiCide Rates Amongst IndividUals with DiabEtes) Collaborative Community)
- MedTech Color Collaborative Community
- Digital Health Measurement Collaborative Community (DATAcc)

EUA Authorizations



Data as of April 7, 2022

Tests Authorized as of April 11, 2022

294

Molecular diagnostic tests

- 37 Pooling
- 54 Asymptomatic single use screening
- 9 Serial screening
- 21 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 18 Point-of-care
- 74 Home collection
  - 16 Direct-to-consumer
  - 3 Multi-analyte
  - 14 Saliva home collection
- 19 Standalone home collection kits
- 3 Standalone saliva collection devices
- 1 Prescription at-home test
- 3 Over-the-counter (OTC) at-home tests

50

Antigen diagnostic tests

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

84

Serology and other immune response tests

- 13 Point-of-care
- 2 Neutralizing antibody tests
- 17 Semi-quantitative
- 1 Quantitative
- 1 Home collection

FDA Updates Test Policies to Help to Ensure Accuracy and Reliability of Tests and Increase Access to At-Home Tests

November 15, 2021: Key Policy Highlights

- Statement by HHS Secretary Xavier Becerra on Withdrawal of HHS Policy on Laboratory Developed Tests: *"Effective today, HHS no longer has a policy on LDTs that is separate from FDA's longstanding approach in this area."*
- Updated policies regarding tests, including LDTs, currently being offered prior to or without authorization (i.e. end to notification policy). Moving forward, FDA expects submission of an EUA request prior to tests being offered
- Updated modification policies relating to EUA-authorized COVID-19 test
- Updated policies regarding the types of tests on which the FDA intends to focus its review

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

EUA Review Priorities

- *Details in Section IV.A of the COVID-19 Test Policy

- FDA generally intends to focus its review on EUA requests for the following types of tests (please see the guidance for additional details for each of these types of tests):
  - **At-home** and **point-of-care** (POC) **diagnostic** tests for use with or without a prescription and that can be manufactured in high volumes;
  - Certain **high-volume, lab-based molecular diagnostic** tests (and home collection kits for use with such tests) that **expand testing capacity or accessibility** such as through **pooling** of specimens to increase throughput, testing **specimens collected at home** and shipped to the lab, **screening** asymptomatic individuals, or detecting **multiple different respiratory viruses** at once;
  - Certain lab-based and POC high volume antibody tests that can measure the amount of antibodies (**fully quantitative antibody tests**) or the amount of **neutralizing antibodies**; and
  - Tests for which the request is from, or supported by, a **U.S. government stakeholder**, such as the Biomedical Advanced Research and Development Authority or the National Institutes of Health's Rapid Acceleration of Diagnostics (RADx).

Independent Test Assessment Program (ITAP) provides support for FDA authorization of rapid at-home COVID-19 tests

- The National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) initiative has established 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.

Tests with Emergency Use Authorization (EUA) after being evaluated through ITAP

- SD Biosensor distributed by Roche
- Siemens
- Maxim Biomedical
- Osang, LLC
- Xiamen Boson Biotech Co., Ltd

- These authorizations are due to a unique program of collaboration between the FDA and the NIH RADx program. Combined, it is estimated these companies can produce about 200 millions of tests per month for use in the U.S. with more companies in the pipeline.
- This program is incredibly beneficial to increasing access to rapid tests by quickly and consistently gathering the critical data companies need to request EUA and subsequently enter the U.S. market once authorized.

OTC EUA Requests and Authorizations

20 Authorized OTC Tests

Abbott Diagnostics Scarborough, Inc.*
Access Bio, Inc.
ACON Laboratories, Inc
Becton, Dickinson and Company (BD)
Celltrion USA, Inc.
Ellume Limited
iHealth Labs, Inc.
InBios International Inc.
Maxim Biomedical, Inc.
OraSure Technologies, Inc.
Quidel Corporation
SD Biosensor, Inc.
Siemens Healthineers
Cue Health Inc. (Molecular)
Detect, Inc. (Molecular)
Lucira Health, Inc. (Molecular)
Phase Scientific International, Ltd.
Osang, LLC
Xiamen Boson Biotech Co., Ltd

*Two EUAs for one test with and without telehealth proctors

- Current Review Priorities include:
  - POC or at-home tests with 500k+/week manufacturing capacity
  - EUA request is from (or supported by) a US government stakeholder

- OTC tests being evaluated by ITAP

- FDA web page provides List of Authorized At-Home OTC COVID-19 Diagnostic Tests including links to home use instructions for each test

FDA issues multiple Safety Communications warning people not to use certain COVID-19 Ag Rapid Tests

The following tests have not been authorized, cleared, or approved by the FDA for distribution or use in the United States:

- Celltrion DiaTrust COVID-19 Ag Rapid Test
- SD Biosensor Inc. STANDARD Q COVID-19 Ag Home Test
- ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)
- E25Bio COVID-19 Direct Antigen Rapid Test
- LuSys Laboratories COVID-19 Antigen Tests (Nasal/Saliva) and COVID-19 IgG/IgM Antibody

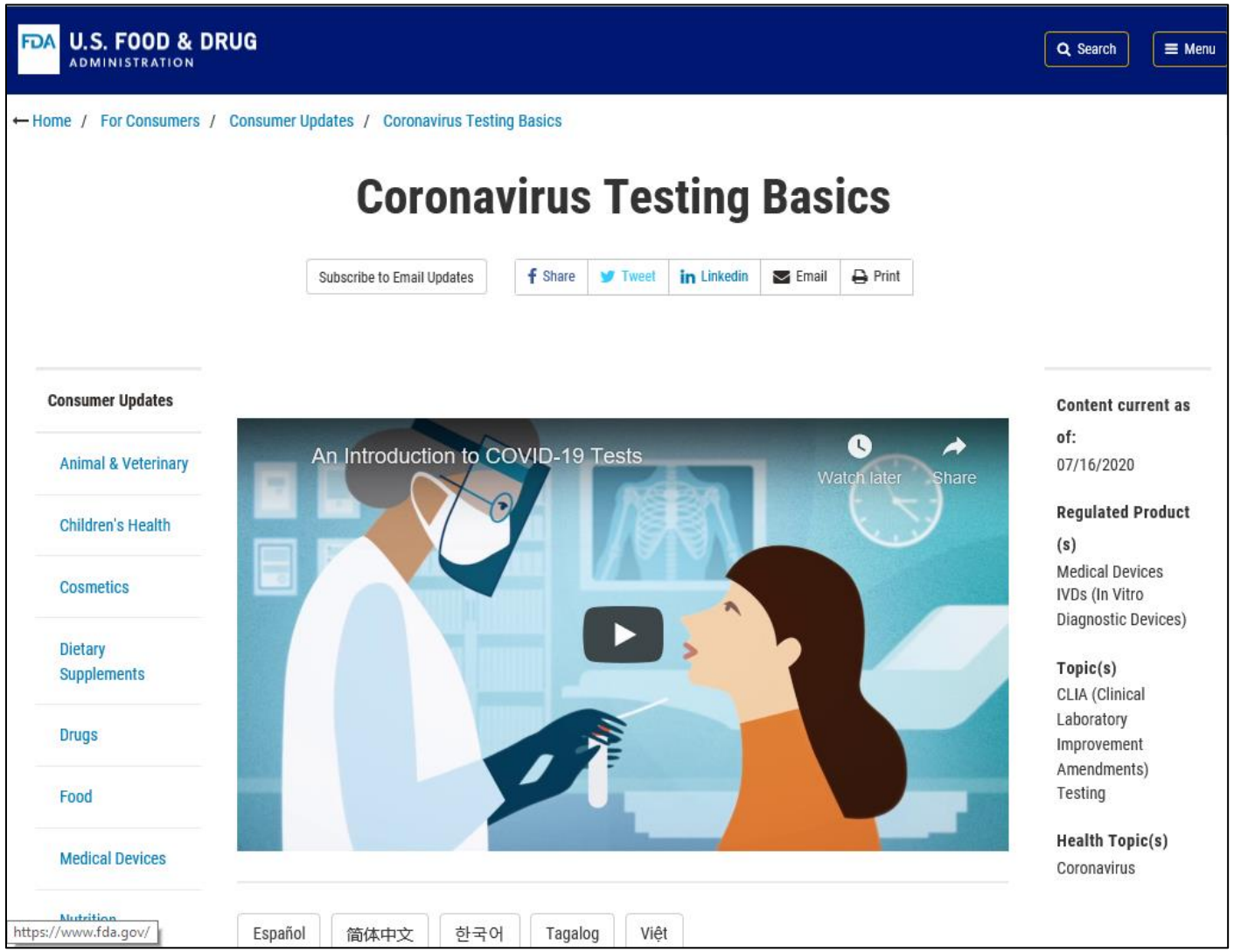
SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests

FDA web page provides information about the impact of viral mutations on COVID-19 tests, recommendations for clinical laboratory staff and health care providers, and information about certain tests for which the FDA has identified potential impacts on performance due to SARS-CoV-2 genetic mutations.

The FDA will update this page as significant new information becomes available.

On this page:

Outreach



- 85 Virtual Town Halls (>53,000 participants)
- FAQs on Testing for SARS-CoV-2
- Safety Communications
- Resources for Patients, Healthcare Providers, and Developers
- COVID-19 Diagnostics Mailbox (185,000+ inquiries)
- 2 stakeholder calls to discuss the guidance/policy
- 1 virtual town hall to discuss 3D Swabs

New FAQ addresses what happens to EUA tests after the public health emergency (PHE) expires

Q: What will happen with tests offered under EUA if the public health emergency expires and is not renewed? (4/6/22)

- Distinguishes between the PHE determination under section 319 of the Public Health Service Act (the PHE declaration) and the separate declaration under section 564 of the FD&C Act that enables the issuance of EUAs (the EUA declaration)
- FDA issued a draft guidance, Transition Plan for Medical Devices Issued EUAs During the COVID-19 Public Health Emergency, describing the steps FDA recommends manufacturers take to transition medical devices issued EUAs to full marketing authorization
- Acknowledges the need for an appropriate period to transition to normal operations when the emergency use declaration is no longer in effect

The 510(k) Pathway is Available for Molecular COVID-19 Tests

BioFire Respiratory Panel 2.1 (RP2.1), which had an Emergency Use Authorization (EUA), was granted marketing authorization using the De Novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type.

- With granting of the De Novo, the FDA also revoked the EUA for this device
- This EUA revocation and De Novo authorization do not impact the availability of other tests under EUA
- In addition to the De Novo, FDA has also cleared one COVID-19 molecular test using the 510(k) pathway. We welcome additional 510(k) submissions for molecular tests.

https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-sars-cov-2-diagnostic-test-using-traditional-premarket-review-process

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Thank You