FDA Update

Don St. Pierre
Deputy Director, New Product Evaluation
Office of In Vitro Diagnostics (OHT7)
FDA-Industry IVD Roundtable
August 3, 2022

Key Office IVD Activities

- Premarket – Pre-submissions, Breakthrough Designations, CLIA Waiver Reviews and complexity determinations, 510(k), De Novo, PMA, EUA, IDE, and HDE
- Relevant Guidance Documents
- Surveillance
- Compliance
- Community Outreach

OHT7: Office of In Vitro Diagnostics

Office Director: **Timothy Stenzel**
Deputy Director New Product Evaluation: **Donald St. Pierre**
Deputy Director Patient Safety & Product Quality: **Ryan Lubert** (Acting)
Deputy Director Personalized Medicine: **Wendy Rubinstein**
Associate Director for Regulatory Programs: **Toby Lowe**
Associate Director Strategic Initiatives: **Vacant**
Associate Director for Regulatory Counsel: **Vacant**
Associate Director for Medical Affairs: **Sara Brenner**
Associate Director for Professional Development: **Vacant**
Associate Director for Operations: **Crystal Genius**
OIR Immediate Office Staff:
Stacey Borenstein, Jennifer Campbell, Victoria Derbyshire, Daniel Edelman, Dina Jerebitski, Marina Kondratovich, Stephanie Krmenec, Kristofor Langlais, Mckenna Tennant, Thierry Vilboux, Amy Zale

Division of Chemistry and Toxicology Devices (DCTD)

Division Director **– Kellie Kelm**
Deputy Division Director **– Marianela Perez-Torres**

Division of Microbiology Devices (DMD)

Division Director **– Uwe Scherf**
Deputy Division Director **– Kristian Roth**

Division of Molecular Genetics and Pathology (DMGP)

Division Director **– Wendy Rubinstein** (Acting)
Deputy Division Director **– Donna Roscoe**

Division of Immunology and Hematology Devices (DIHD)

Division Director **– Lea Carrington**
Deputy Division Director **– Takeesha Taylor-Bell**

Division of Program Operations and Management (DPOM)

Division Director **– Rob Sauer**
Deputy Division Director **– Vacant**

Division of Chemistry & Toxicology Devices (DCTD)

Division Director: **Kellie Kelm**

Deputy Division Director : **Marianela Perez-Torres**

Chemistry Branch

Branch Chief **– Juliane Lessard**

Diabetes Branch

Branch Chief **– Yiduo Wu**

Toxicology Branch

Branch Chief **– Joseph Kotarek**

Cardio-Renal Diagnostics Branch

Branch Chief **– Paula Caposino**

Division of Immunology & Hematology Devices (DIHD)

Division Director: **Lea Carrington**

Deputy Division Director : **Takeesha Taylor-Bell**

Hematology Branch

Branch Chief **– Min Wu**

Immunology & Flow Cytometry Branch

Branch Chief **– Ying (Katelin) Mao**

Division of Microbiology Devices (DMD)

Division Director: **Uwe Scherf**

Deputy Division Director : **Kristian Roth**

Viral Respiratory & HPV Branch

Branch Chief – **Himani Bisht**

Deputy Branch Chief – **Joseph Briggs**

General Bacterial & Antimicrobial Susceptibility Branch

Branch Chief – **Ribhi Shawar** (On detail OHT7 IO)

Deputy Branch Chief – **Leroy Hwang**

General Viral & Hepatitis Branch

Branch Chief – **Maria Garcia**

Deputy Branch Chief – **Ryan Karsner**

Bacterial Respiratory & Medical Countermeasures Branch

Branch Chief – **Noel Gerald**

Deputy Branch Chief – **Brittany Goldberg**

Division of Molecular Genetics & Pathology (DMGP)

Division Director: **Wendy Rubinstein** (Acting)

Deputy Division Director : **Donna Roscoe**

Molecular Pathology & Cytology Branch

Branch Chief **– Soma Ghosh**

Deputy Branch Chief **– Shyam Kalavar**

Molecular Genetics Branch

Branch Chief **– Zivana Tezak**

Deputy Branch Chief **– Pamela Ebrahimi**

Division of Program Operations and Management (DPOM)

Division Director: **Rob Sauer**

Deputy Division Director : **Vacant**

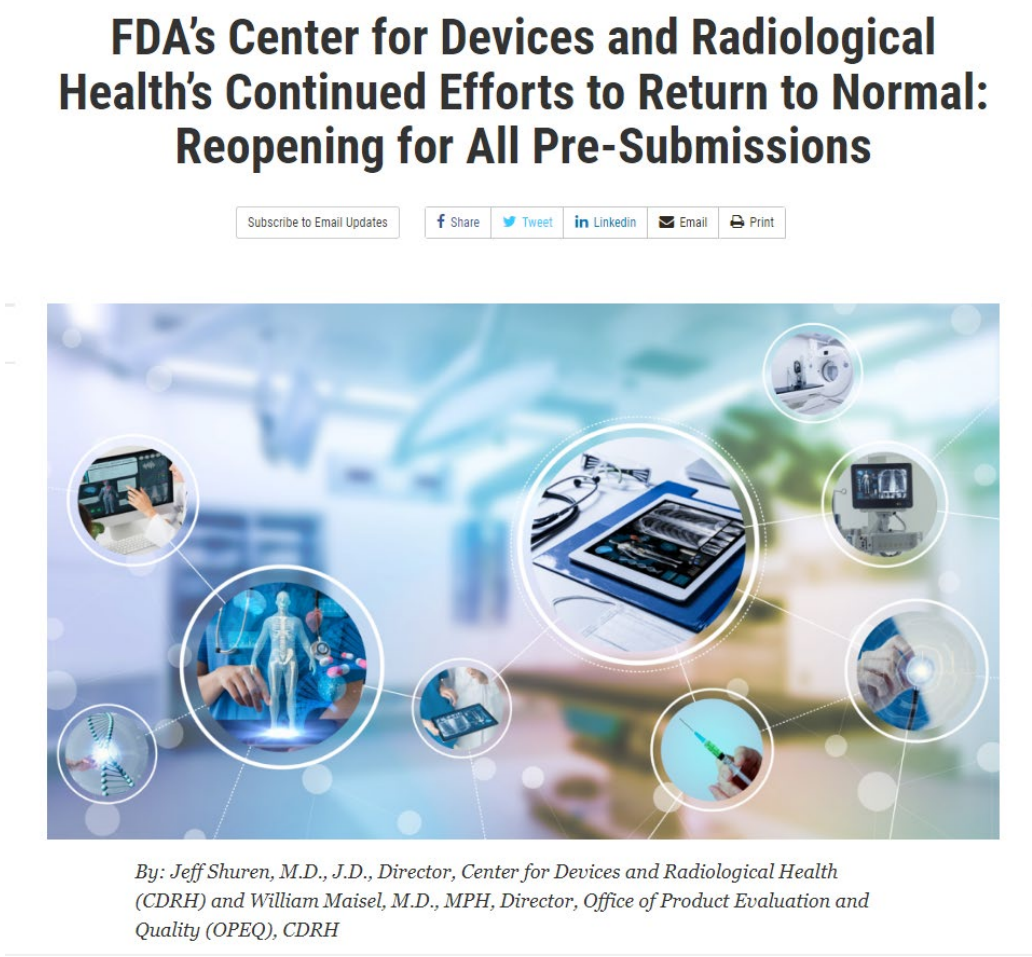
Laboratory Improvement, Outreach & Analysis Team

Branch Chief **– Andrew Grove**

Program Operations and Management Team

Branch Chief **– Vacant**

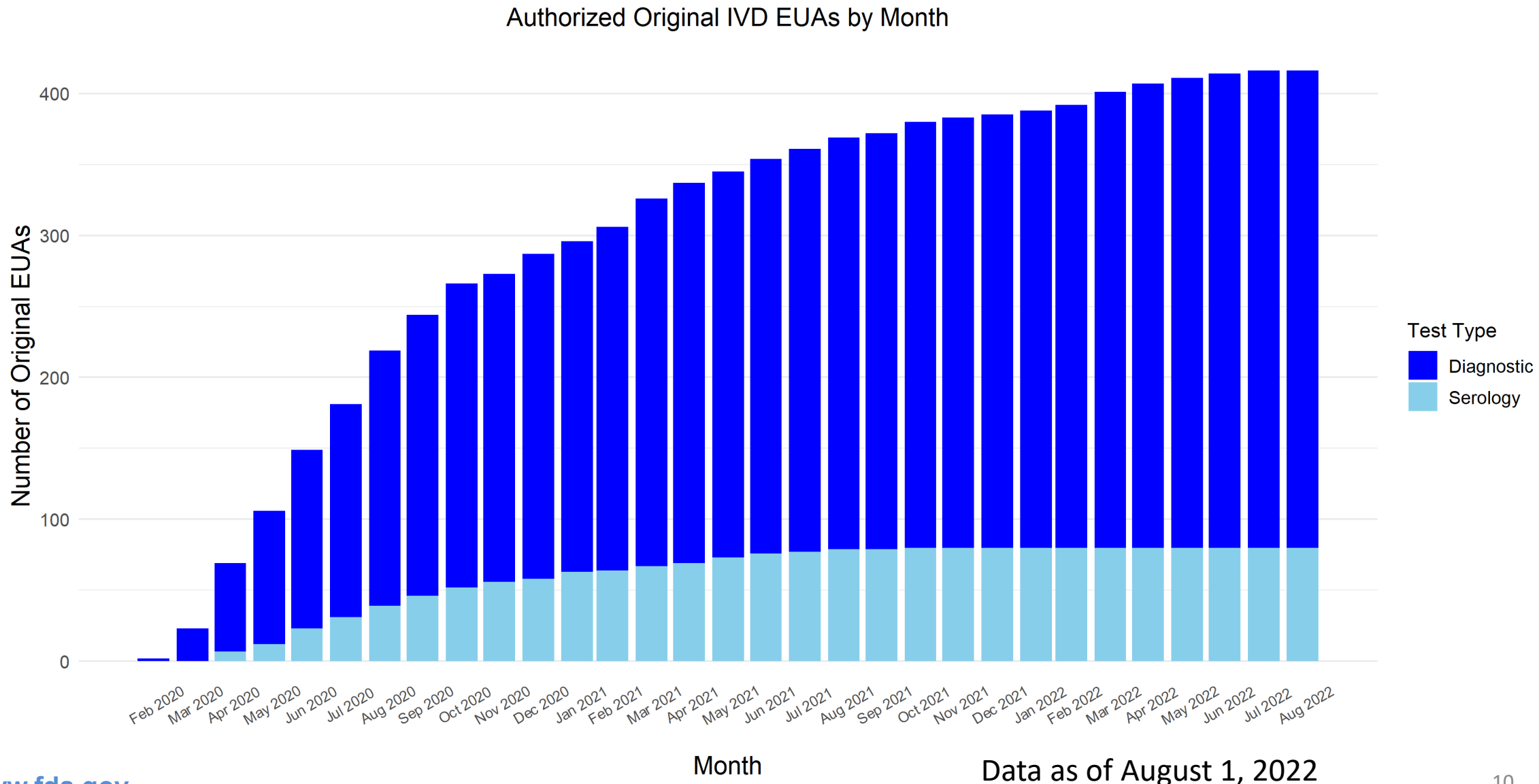
CDRH's Efforts to Return to Normal



- CDRH is accepting and immediately initiating the review process for all new IVD 510(k), De Novo and PMA premarket submissions. These conventional premarket submissions are currently being reviewed under extended timelines
- CDRH is now accepting all IVD pre-submissions, effective June 1, 2022
- Withdrawal of FDA guidance *Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices — Questions and Answers (Revised),* effective July 7, 2022

FDA's Center for Devices and Radiological Health's Continued Efforts to Return to Normal: Reopening for All Pre-Submissions | FDA

EUA Authorizations



Data as of August 1, 2022

Tests Authorized as of August 1, 2022

302

Molecular diagnostic tests

- 35 Pooling
- 59 Asymptomatic single use screening
- 8 Serial screening
- 24 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 22 Point-of-care
- 78 Home collection
  - 16 Direct-to-consumer
  - 6 Multi-analyte
  - 14 Saliva home collection
- 20 Standalone home collection kits
- 3 Standalone saliva collection devices
- 1 Prescription at-home test
- 3 Over-the-counter (OTC) at-home tests

51

Antigen diagnostic tests

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

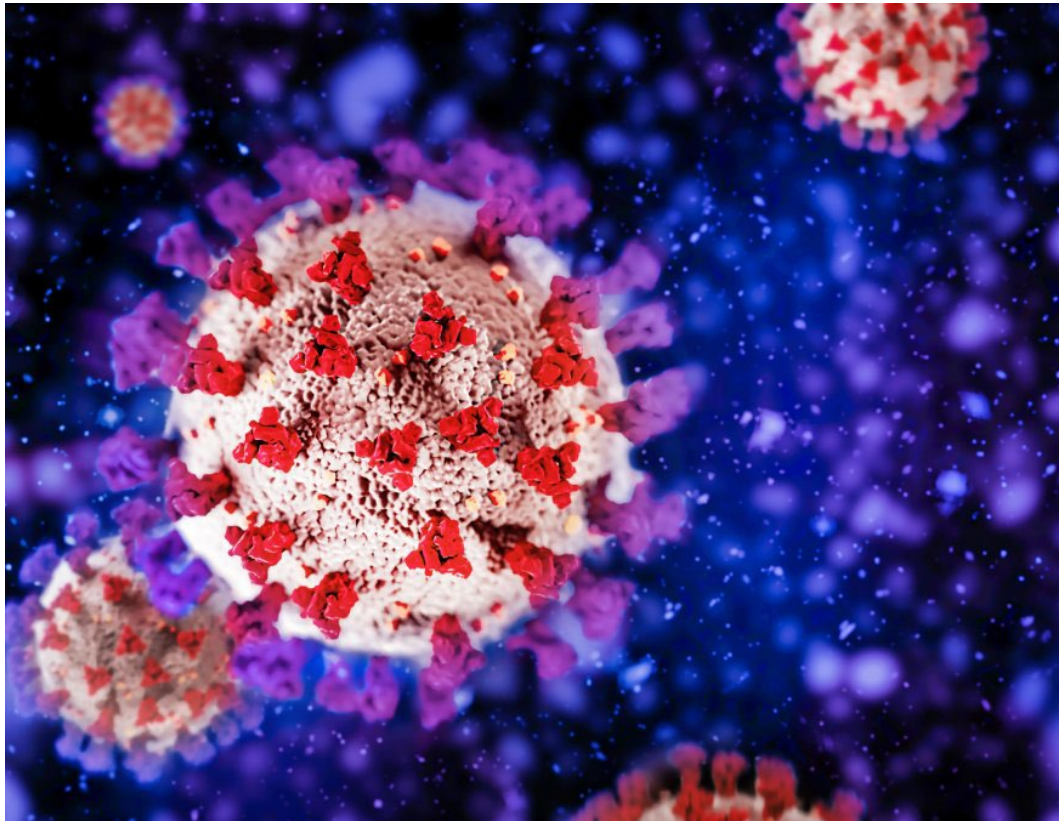
85

Serology and other immune response tests

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

In Vitro Diagnostics EUAs: Novel Tests for SARS-CoV-2

- **InspectIR COVID-19 Breathalyzer**: First COVID-19 diagnostic test using breath samples. Authorized April 14, 2022
- **Labcorp VirSeq SARS-CoV-2 NGS Test**: First genotyping test for SARS-CoV-2. Authorized June 10, 2022
- **SARS-CoV-2 NGS Assay:** Test for genotyping and identifying specific mutations of SARS-CoV-2. Authorized July 28, 2022



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

- Collaboration between the FDA and the NIH RADx program

- **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
  - Watmind USA

- These tests contribute significant manufacturing volume for OTC tests on the US market

OTC EUA Requests and Authorizations

22 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
Genabio Diagnostics, Inc.
Watmind USA

*Two EUAs for one test with and without telehealth proctors

- 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 and updated expiration dating

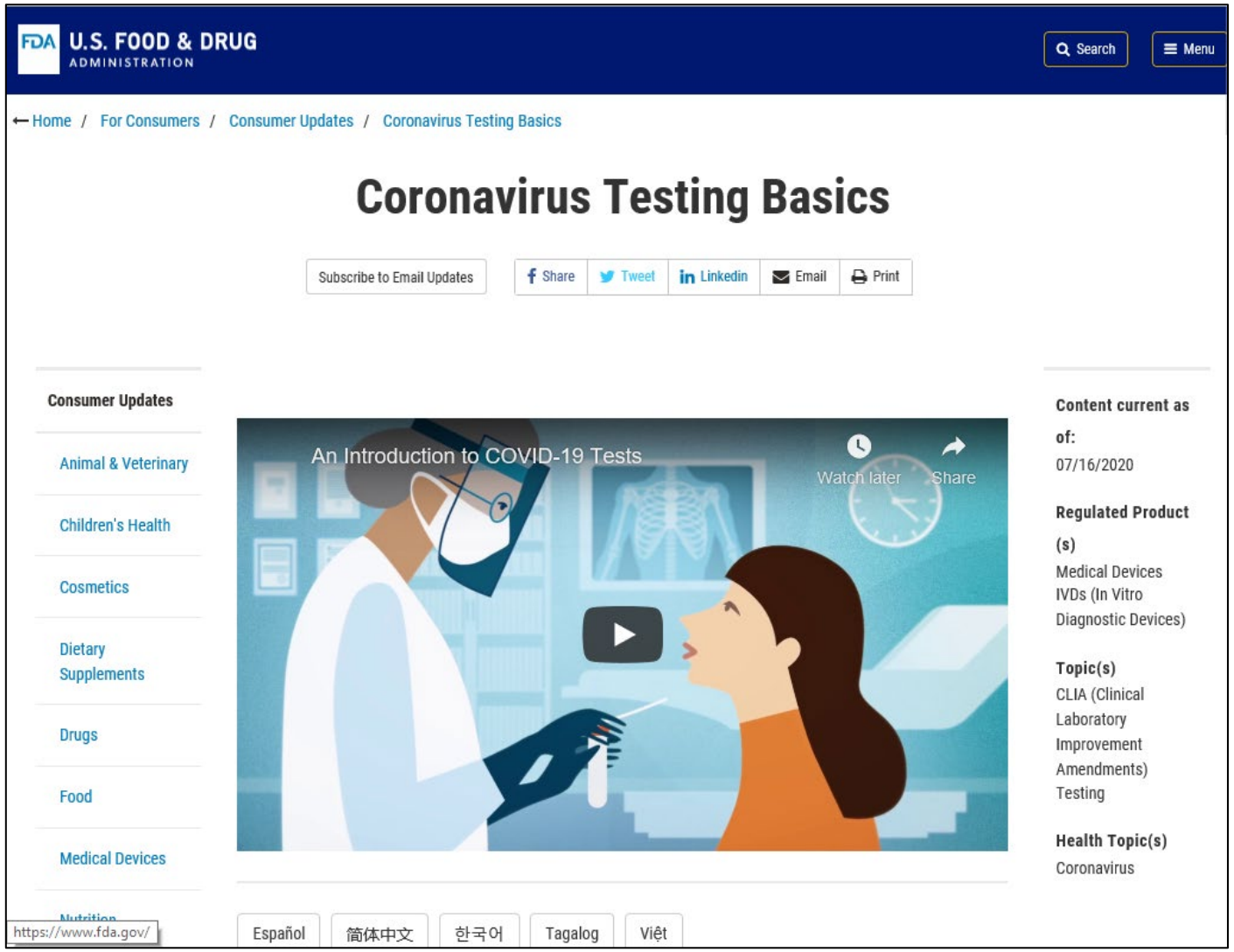
SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests

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



- 89 Virtual Town Halls (>55,500 participants)
- FAQs on Testing for SARS-CoV-2
- Safety Communications
- Resources for Patients, Healthcare Providers, and Developers
- COVID-19 Diagnostics Mailbox (200,000+ 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

FDA is Working to Ensure Monkeypox Test Accuracy and Availability

FDA has taken the following steps to support the response to the Monkeypox outbreak:

- Engaged with CDC and other agencies to support the response efforts at the CDC and in the CDC Laboratory Response Network (LRN) labs where 67 LRN labs are using CDC's FDA cleared Non-Variola Orthopox screening assay, which can detect Monkeypox from a lesion sample
- Working with CDC to increase production of its FDA-cleared test and the FDA has cleared the use of additional reagents and instruments to increase the throughput of the CDC test
- Engaged major reference laboratories and manufacturers to make Monkeypox tests and components more readily available as needed
- Exercising enforcement discretion for laboratory developed tests (LDTs) available for orthopoxvirus, or specifically for the monkeypox virus
- Issued FDA Safety Communication: For Monkeypox testing, use lesion swab samples to avoid false results

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

MDUFA V Commitment Letter

FDA Webpage for MDUFA V

U.S. FOOD & DRUG ADMINISTRATION

Thank You