This content was published before guidance to change "monkeypox" to "mpox" was delivered to CDC programs in Dececmber 2022.

FDA Update

CLIAC

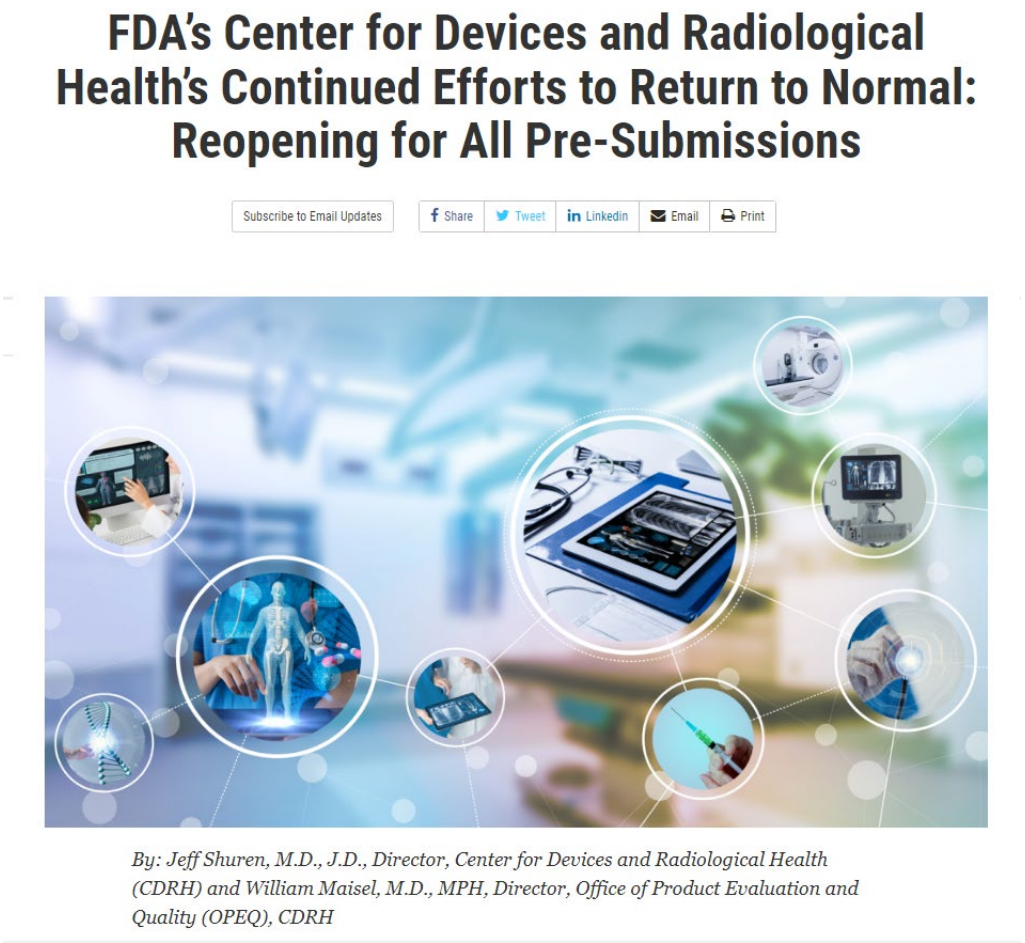
November 9, 2022

Timothy Stenzel, M.D., Ph.D.
Director, Office of In Vitro Diagnostics
(OHT7 – Office of Health Technology 7)
Office of Product Evaluation and Quality (OPEQ)
CDRH | Food and Drug Administration

Congress Passes MDUFA V Legislation

- Reauthorization of the Medical Device User Fee Amendments (MDUFA) authorizes FDA to collect user fees for the review of device applications for fiscal years 2023 through 2027
- The program and initiatives outlined in the MDUFA V Commitment Letter are predicated on significant interaction between the Agency and industry
- On 10/11/22, CDRH launched the Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot. The TAP Pilot is a new component of the MDUFA V Agreement intended to speed access to high quality, safe, effective and innovative medical devices

CDRH's Efforts to Return to Normal



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

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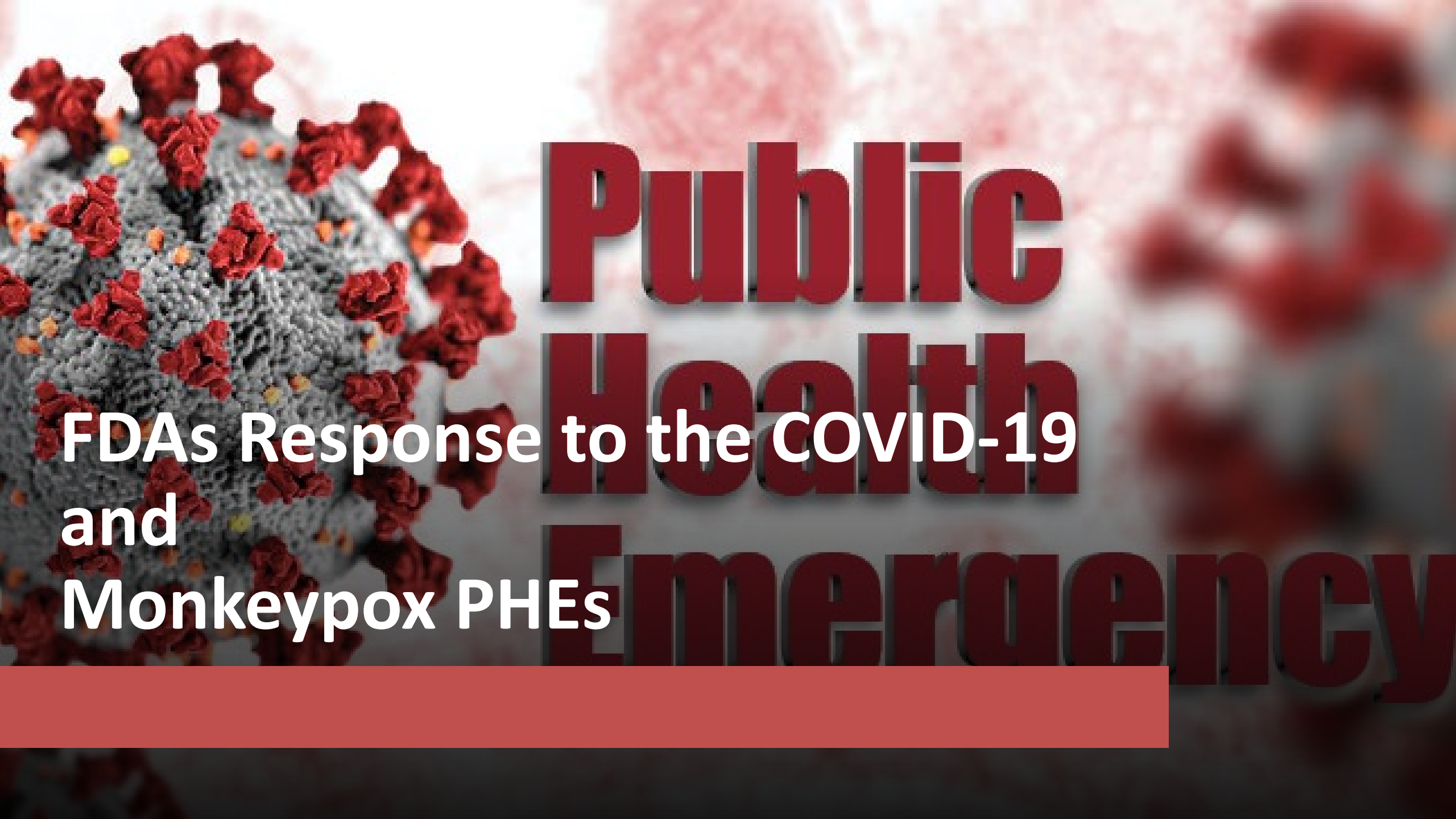
By: Jeff Shuren, M.D., J.D., Director, Center for Devices and Radiological Health (CDRH) and William Maisel, M.D., MPH, Director, Office of Product Evaluation and Quality (OPEQ), CDRH

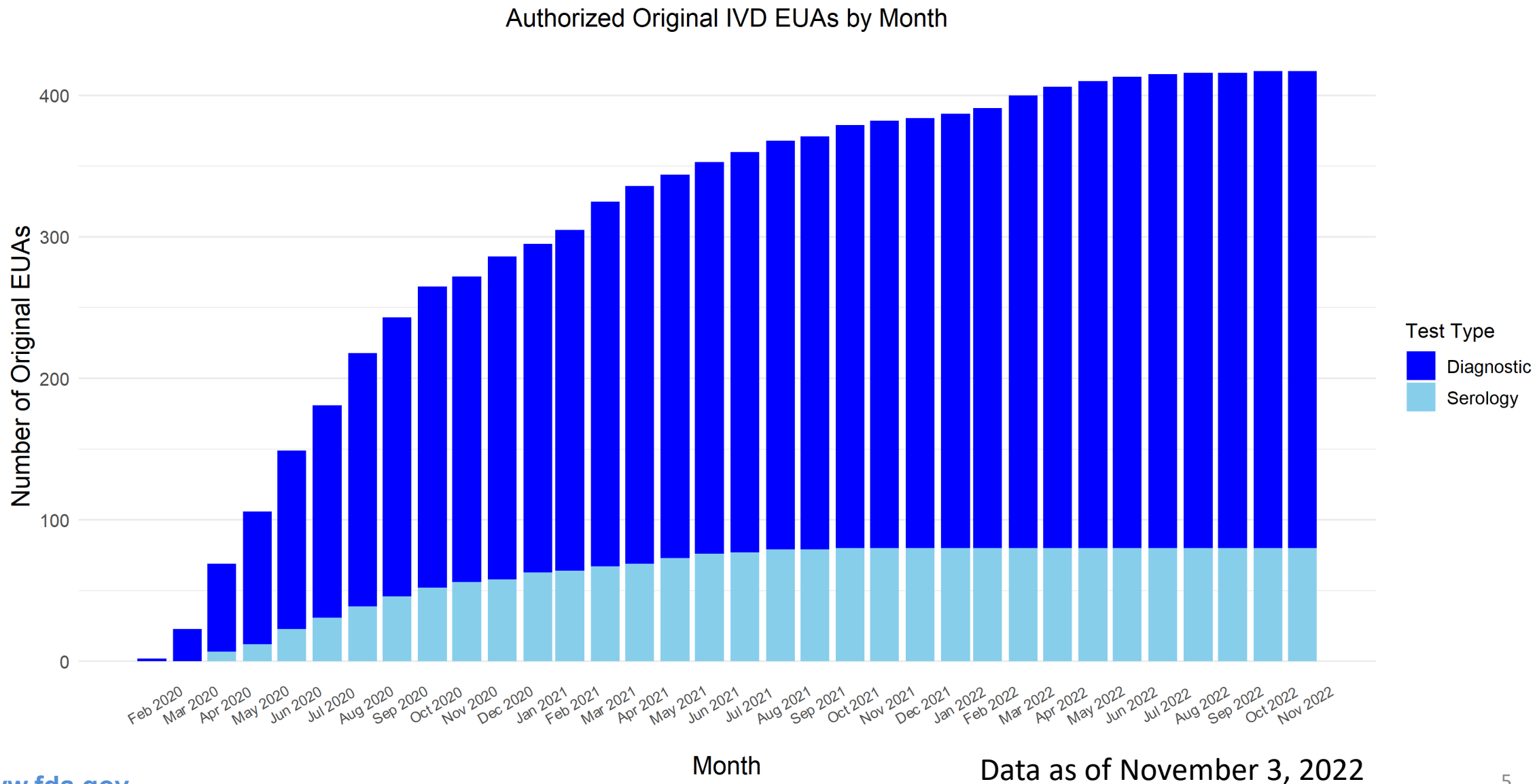
- CDRH is accepting and immediately initiating the review process for all new IVD 510(k), De Novo and PMA premarket submissions
- CDRH is now accepting all IVD pre-submissions, effective June 1, 2022
- Withdrawal of FDA guidance *Effects of the COVID-19 Public Health Emergency on Formal Meetings and 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



FDAs Response to the COVID-19 and Monkeypox PHEs

COVID-19 EUA Authorizations



Data as of November 3, 2022

COVID-19 Tests Authorized as of November 3, 2022

298

Molecular diagnostic tests

- 35 Pooling
- 65 Asymptomatic single use screening
- 8 Serial screening
- 23 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 22 Point-of-care
- 77 Home collection
  - 16 Direct-to-consumer
  - 6 Multi-analyte
  - 15 Saliva home collection
- 20 Standalone home collection kits
- 3 Standalone saliva collection devices
- 1 Prescription at-home test
- 4 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
- 35 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

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

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

*Two EUAs for one test with and without telehealth proctors

List of Authorized At-Home OTC COVID-19 Diagnostic Tests

COVID-19 Test Policy Update Encourages Developers to Seek Traditional Premarket Review for Most Test Types

September 28, 2022 – Policy Update

- FDA generally expects EUAs (or marketing authorization) for all COVID-19 tests
- Encouraging traditional review pathways; reducing types of tests prioritized for review under EUA
- Continuing prior enforcement policy for tests already being offered during ongoing FDA review
- FDA does not expect EUA requests for certain validated modifications made by a high-complexity CLIA-certified laboratory to an authorized COVID-19 diagnostic test

*Enforcement policies regarding LDTs **do not apply** to tests with home specimen collection or at-home tests*

*These slides present high level discussion points. Please refer to the guidance document for the details and official policies.

COVID-19 EUA Review Priorities

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

The FDA generally intends to focus its review on EUA requests and supplemental EUA requests from experienced developers for:

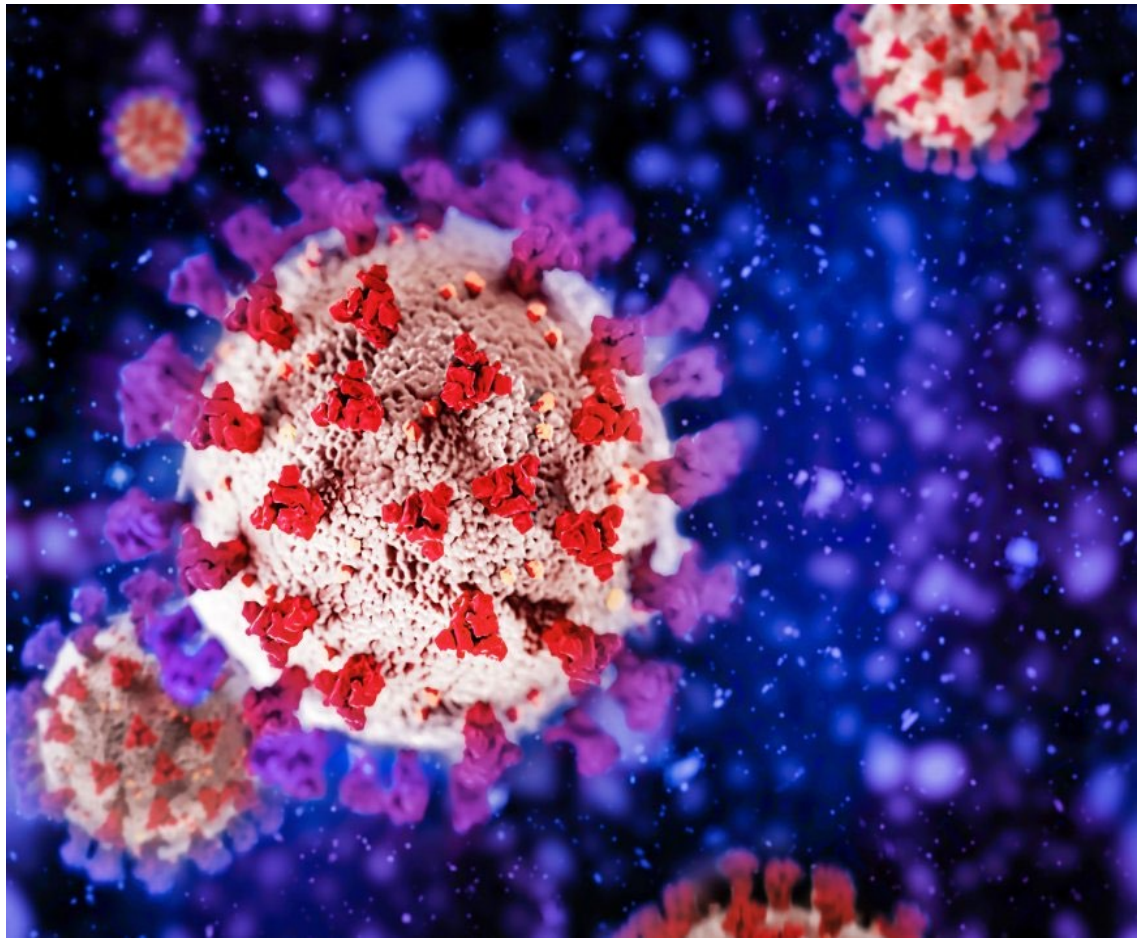
- Diagnostic tests that are likely to have a significant benefit to public health (such as those that employ new technologies)
- Diagnostic tests that are likely to fulfill an unmet need (such as diagnosing infection with a new variant or subvariant)
- Supplemental EUA requests for previously authorized tests when the request is intended to fulfill a condition of authorization or includes a modification that will significantly benefit public health or fulfill an unmet need
- Tests for which the EUA request is from (or supported by) a U.S. government stakeholder, such as tests funded by the Biomedical Advanced Research and Development Authority (BARDA) or the National Institutes of Health's Rapid Acceleration of Diagnostics (RADx)

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

- **Twist Bioscience SARS-CoV-2 NGS Assay:** Test for genotyping and identifying specific mutations of SARS-CoV-2. Authorized July 28, 2022



FDA Issues Safety Communications for Monkeypox Testing and At-Home COVID-19 Antigen Tests

For Monkeypox Testing, Use Lesion Swab Samples to Avoid False Results

Use swab samples taken directly from a lesion (rash or growth) when testing for the monkeypox virus. The FDA is not aware of clinical data supporting the use of other sample types, such as blood or saliva, for monkeypox virus testing. Testing samples not taken from a lesion may lead to false test results.

July 15, 2022

At-Home COVID-19 Antigen Tests: Take Steps to Reduce Your Risk of False Negative

Perform repeat, or serial, testing following a negative result on any at-home COVID-19 antigen test, to reduce the risk an infection may be missed (false negative result) and to help prevent people from unknowingly spreading the SARS-CoV-2 virus to others.

August 11, 2022

Antigen EUA Revisions for Serial (Repeat) Testing

- On November 1, 2022, the FDA revised the authorized uses and required updates to product labeling regarding repeat, or serial, testing, for all currently authorized SARS-CoV-2 antigen tests.

- The revision requires test developers in the scope of the revision to take certain actions, including submitting a supplemental EUA request to the FDA with updated labeling to reflect the revised authorized uses, as follows:

  - Where a test was previously authorized for testing of symptomatic individuals (for example, within the first [number specific to each test] days of symptom onset), the test is now authorized for use at least twice over three days with at least 48 hours between tests

  - Where a test was previously authorized for testing of asymptomatic individuals (for example, individuals without symptoms or other epidemiological reasons to suspect COVID-19), the test is now authorized for use at least three times over five days with at least 48 hours between tests

Repeat Testing Revision Letter - November 1, 2022

FDA Takes Significant Action to Help Expand Access to Monkeypox Testing

Since the first case of monkeypox was detected in the U.S., the FDA has been:

- working with the CDC to increase production and distribution of the FDA-cleared CDC non-variola orthopoxvirus test
- clearing the use of additional reagents and automation to increase the testing capacity of laboratories using the CDC test
- proactively engaging with commercial manufacturers on the development and validation of both lab-based molecular diagnostic tests and rapid molecular or antigen tests for use at the point-of-care (such as clinics) or at home
- facilitating the development and availability of test components to help high-complexity CLIA-certified laboratories develop tests for monkeypox

FDA-Cleared and EUA-Authorized Monkeypox Tests

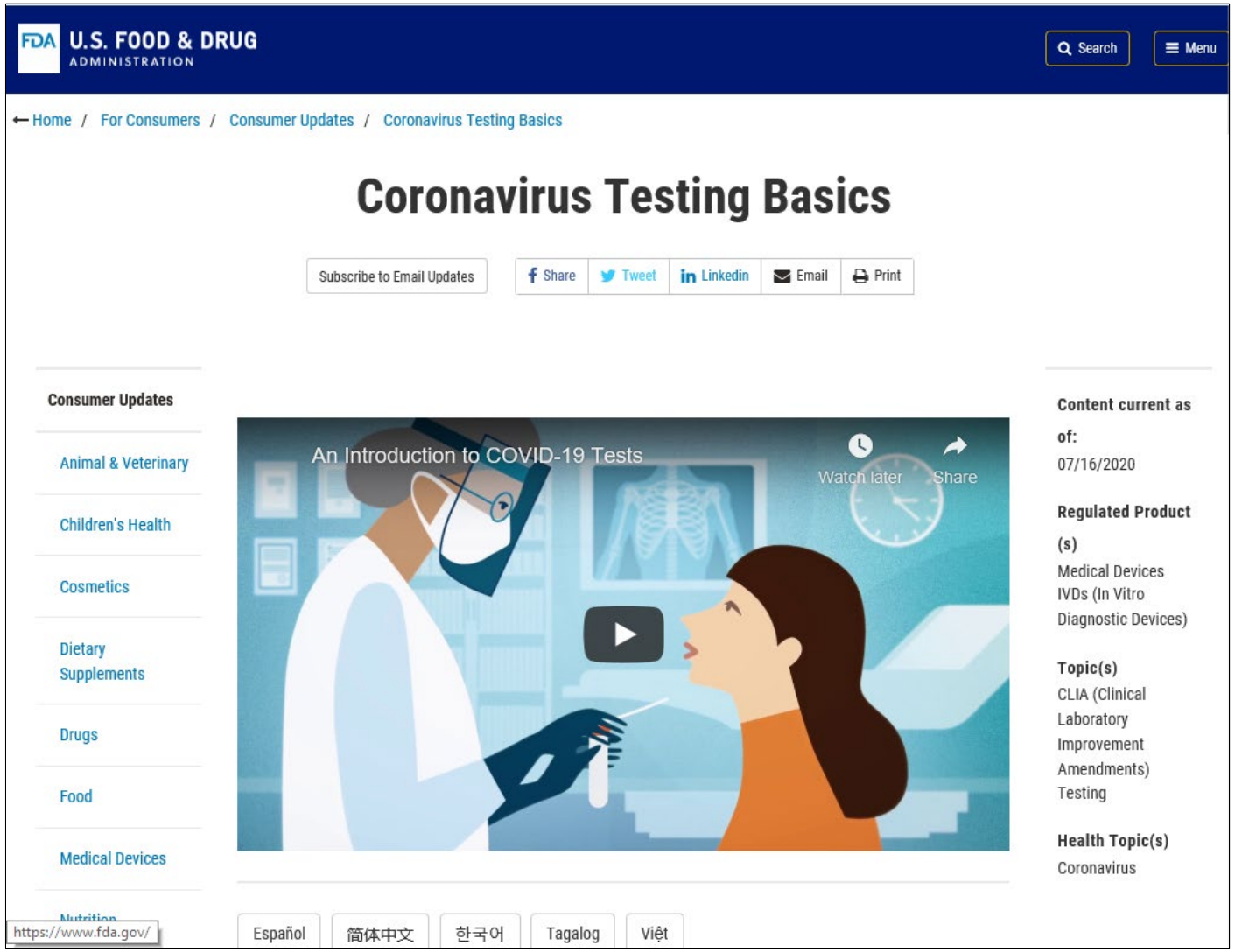
- **CDC Non-variola Orthopoxvirus Real-time PCR Primer and Probe Set:** Currently, the only 510(k) cleared test for monkeypox. Cleared September 20, 2018
- **Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR:** First EUA for a monkeypox in vitro diagnostic. Authorized September 15, 2022
- **Abbott Molecular Alinity m MPXV:** First commercial test kit to be authorized for detection of monkeypox. Authorized October 7, 2022

New Guidance to Facilitate Development of Additional Monkeypox Tests

On September 7, 2022, the FDA issued a guidance, *Policy for Monkeypox Tests to Address the Public Health Emergency*, that describes:

- Review priorities of emergency use authorization (EUA) requests for monkeypox diagnostic tests
- Enforcement policies for certain diagnostic tests that are developed by and performed in a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) that meets the requirements to perform tests of high complexity
- Enforcement policies for FDA-cleared or authorized monkeypox diagnostic tests that are modified
- Enforcement policies for certain serology tests
- Recommendations for diagnostic test validation

Outreach



- 99 Virtual Town Halls (approx. 58,000 participants) **includes both MPX and COVID-19 related town halls*
- FAQs on Testing for SARS-CoV-2 and Monkeypox
- Safety Communications
- Resources for Patients, Healthcare Providers, and Developers
- COVID-19 and Monkeypox Diagnostics Mailboxes

U.S. FOOD & DRUG ADMINISTRATION

Thank You