FDA Update

CLIAC

November 8, 2023

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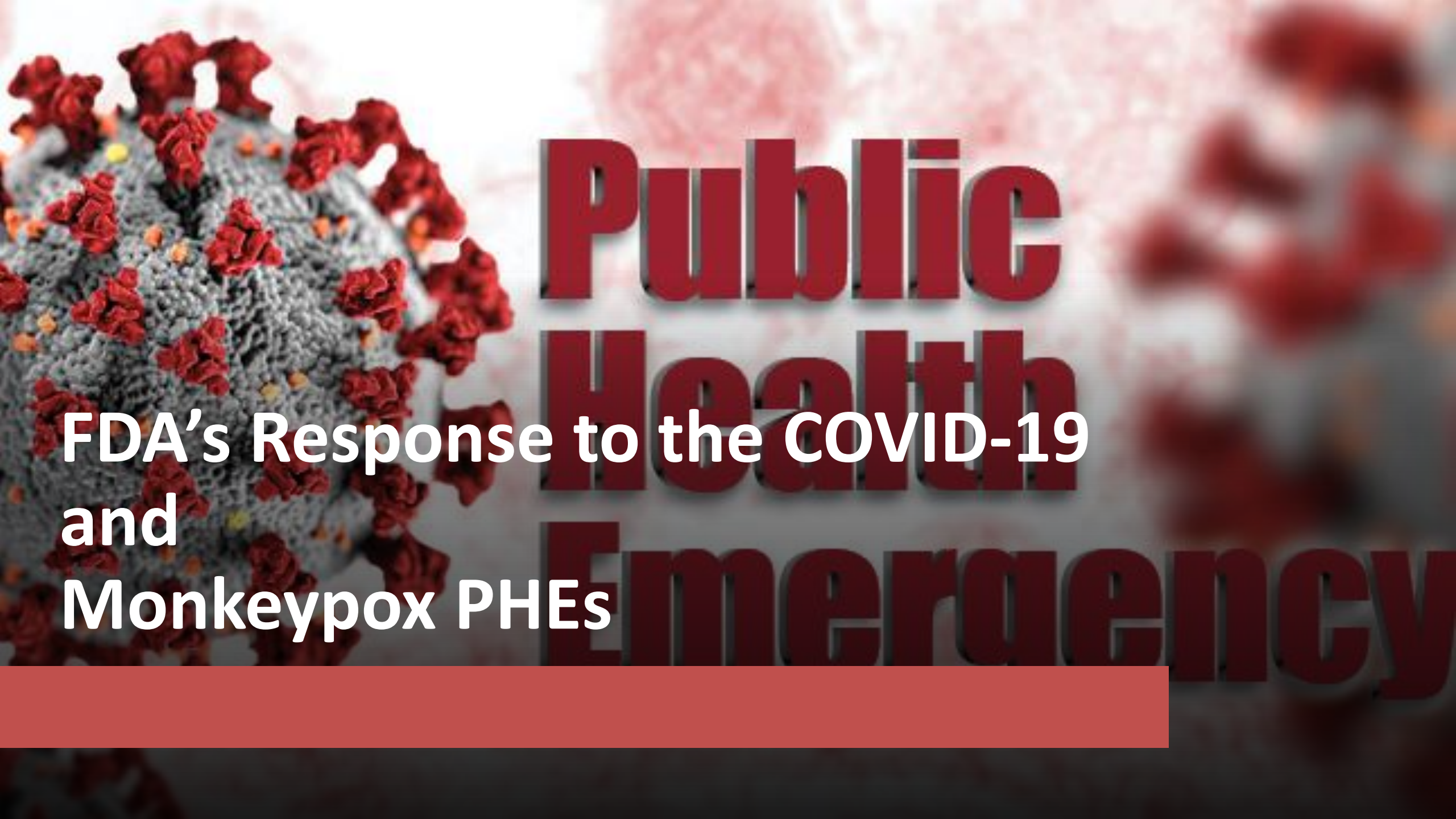
CDRH | Food and Drug Administration



FDA's Response to the COVID-19 and Monkeypox PHEs

COVID-19 Tests Authorized as of October 30, 2023

297

Molecular diagnostic tests

- 33 Pooling
- 68 Asymptomatic single use screening
- 6 Serial screening
- 25 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 25 Point-of-care
- 73 Home collection
  - 16 Direct-to-consumer
  - 5 Multi-analyte
  - 14 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

65

Antigen diagnostic tests

- 59 Point-of-care
- 2 Prescription at-home tests
- 32 Over-the-counter (OTC) at-home tests
- 50 Serial Screening
- 3 Serial Testing
- 4 Multi-Analyte

83

Serology and other immune response tests

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

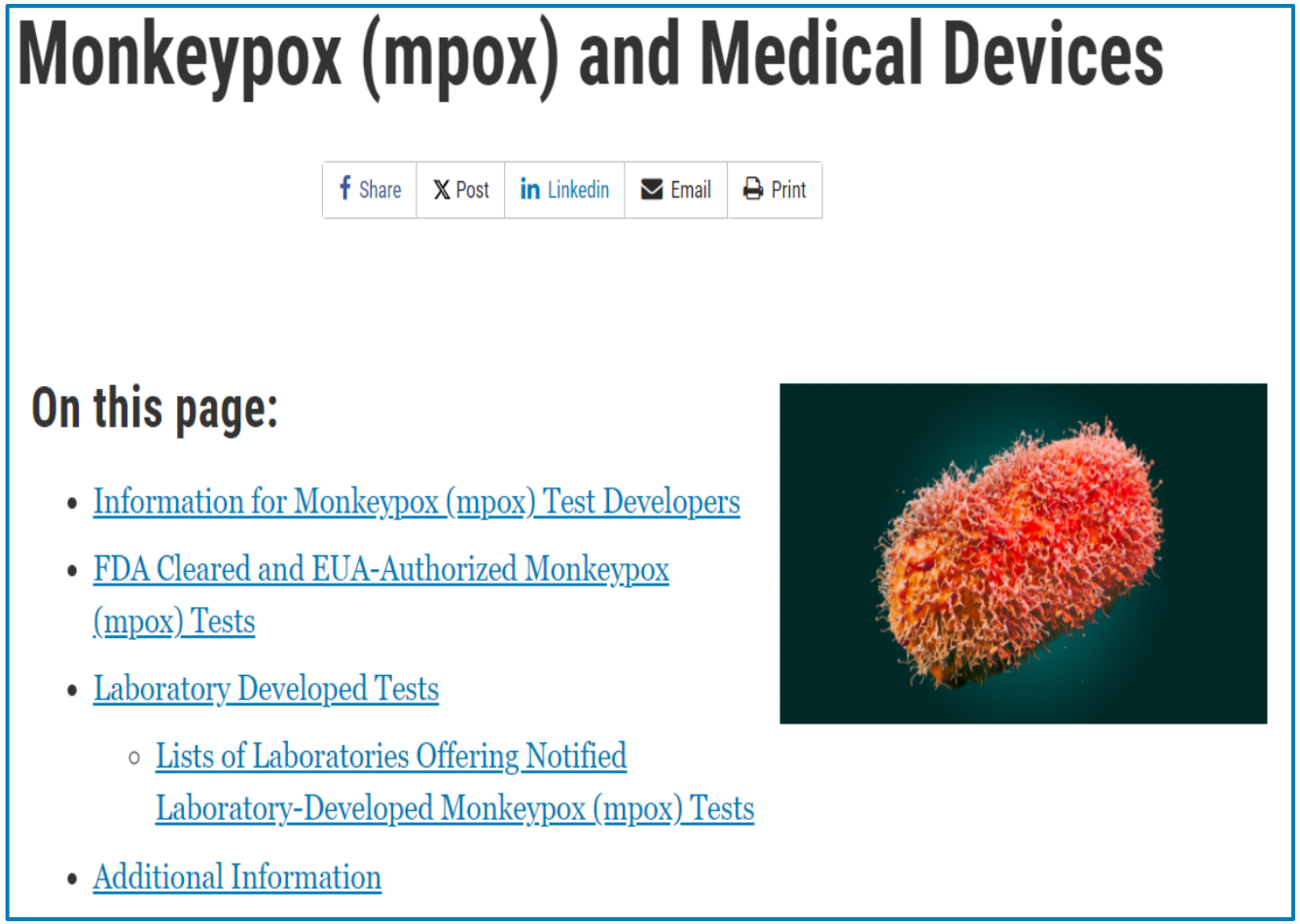
At-Home OTC COVID-19 Diagnostic Tests and Expiration Date Extensions

- 37 OTC COVID-19 diagnostic tests authorized under EUA
- FDA web page provides information about Authorized At-Home OTC COVID-19 Diagnostic Tests including links to home use instructions for each test and information about updated expiration dates
- On September 25, 2023, the Biden administration resumed offering free at-home Covid tests to American households at COVID.gov/test

OHT7 has Reviewed and Closed Nearly 200 mpox Submissions

Since September 7, 2022, approximately **200** mpox-related files have been closed, including:

- **160** Pre-EUAs/Intent to submit EUA submissions
- **22** original EUA requests and **8** supplemental EUA requests
  - 8 Authorized NAATs, including Automated, POC, ITAP collaboration
- **3** 510(k)s cleared, expanding access to CDC NVO test



Monkeypox (mpox) and Medical Devices

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On this page:

- Information for Monkeypox (mpox) Test Developers
- FDA Cleared and EUA-Authorized Monkeypox (mpox) Tests
- Laboratory Developed Tests
  - Lists of Laboratories Offering Notified Laboratory-Developed Monkeypox (mpox) Tests
- Additional Information

Emerging from the Pandemic: CDRH's Efforts to Return to Normal

- 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
- CDRH has been operating under normal review timelines for all new premarket submissions for just over a year, and we're accepting all submission types for review in accordance with the performance goals established in the MDUFA V Commitment Letter
- COVID-19 Tests
  - Hundreds remain authorized under EUA
  - >30 EUA devices have successfully transitioned to traditional authorization through the 510(k) Premarket Submission pathway or the De Novo pathway
  - Developers are encouraged to seek traditional premarket clearance for most COVID-19 tests

Final COVID-19 Transition Guidances

- On March 27, 2023, CDRH issued two guidance documents to assist with transition plans for medical devices that were issued EUAs or fall within certain enforcement policies issued to support the response to the COVID-19 pandemic
  - *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)*
    - Referred to as "EUA Transition Guidance"
  - *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
    - Referred to as "Enforcement Policies Transition Guidance"
    - FDA's Policy for Coronavirus Disease-2019 Tests (Revised) and Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (Revised) are outside scope

*This slide presents high level discussion points. Please refer to the guidance documents for the details and official policies.

COVID-19 Transition Highlights

PHE and EUA Declarations

- The Public Health Emergency declared under Section 319 of the Public Health Service Act ended on May 11, 2023.
- The determination and declarations under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) remain in effect.
  - For each EUA declaration, FDA will publish advance notice of termination in the Federal Register, **180 days** before termination of the EUA declaration and associated EUAs.

COVID-19 Transition Guidances

- Outline the FDA's general recommendations to transition from certain policies adopted and operations implemented during the COVID-19 pandemic to normal operations, including the FDA's recommendations for:
  - Developing a transition implementation plan for in vitro diagnostics (IVDs) with an EUA
  - Submitting an IVD marketing submission
  - Taking other actions with respect to these IVDs
  - Additional information related to test developers and COVID-19 tests.

Traditional Marketing Authorization for COVID-19 Tests

COVID-19 Tests Granted Traditional Marketing Authorization by the FDA

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The FDA has been working with COVID-19 test developers seeking to pursue marketing authorization through the traditional premarket review pathways, which will allow these tests to continue to be used beyond the time allowed by emergency use authorization. This page lists COVID-19 tests that have received traditional marketing authorization. See the Marketing Your Device page for more information about the traditional premarket review and authorization process.

Background

Initially, COVID-19 tests were only available under emergency use authorization (EUA). Since the Secretary's 564 declaration related to in vitro diagnostic tests for COVID-19, on February 4, 2020, the FDA has granted EUAs for many COVID-19 tests. Tests with an active EUA can continue to be used as long as they are available and not expired. The FDA has also issued a guidance document with a Transition Plan for Medical Devices Issued EUAs Related to COVID-19 and encourages EUA holders to pursue traditional marketing authorization. Visit the COVID-19 Test EUA page for more information about these EUAs.

New webpage provides information on tests with de novo and 510(k):

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-tests-granted-traditional-marketing-authorization-fda

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

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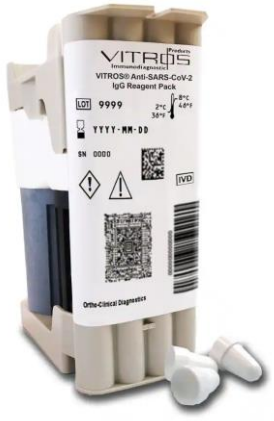


Multiple marketing authorizations have been granted using the De Novo review pathway, a regulatory pathway for low-to moderate-risk devices of a new type:

- **BioFire Respiratory Panel 2.1 (RP2.1):** First COVID-19 molecular diagnostic test. *Granted March 17, 2021*
- **Quidel Sofia 2 SARS Antigen+ FIA:** First COVID-19 antigen test. *Granted March 8, 2023*
- **VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Test and Anti-SARS-CoV-2 IgG Test:** First COVID-19 serology tests. *Granted May 5, 2023*
- **Cue COVID-19 Molecular Test:** First over-the-counter (OTC) test for COVID-19 to be granted marketing authorization using a traditional premarket review pathway and the first ever at-home test authorized using a traditional premarket review pathway for any respiratory illness. *Granted June 6, 2023*

OHT7 Key Activities

Premarket Activities

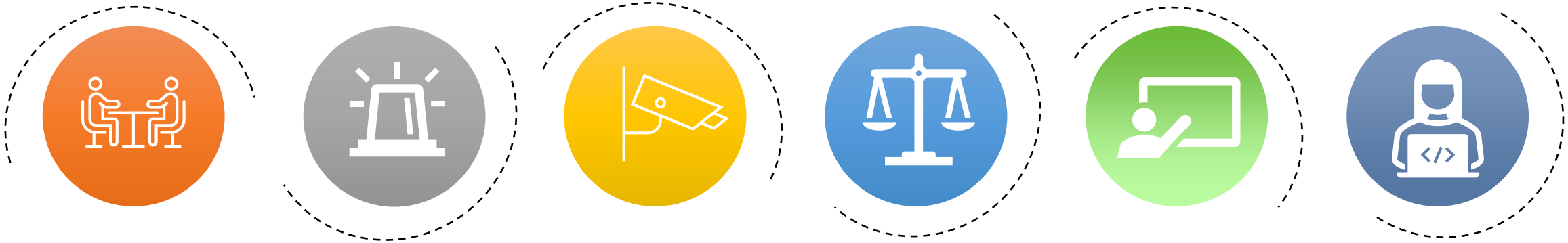
- PMA, 510(k), De novo request reviews
- Investigational Device Exemptions
- Humanitarian Device Exemptions
- Pre-submissions
- Breakthrough designation requests
- Premarket inspections
- CLIA waiver applications
- CLIA categorizations

Postmarket Activities

- Monitoring and Surveillance
- Postmarket Inspections
- Postmarket Studies
- Recalls
- Compliance and Enforcement Actions
- Safety communications

External Engagement & Outreach

- External training and engagement
- Public meetings
- Conferences
- Town Halls
- Inquiry responses



Emergency Use

- Emergency Use Authorizations
- Cross-agency collaborations
- Stakeholder engagement, including Town Halls

Guidance

- Issue new guidances
- Update existing guidances
- Training and webinars

Program Development & Operations

- Internal training
- Performance tracking
- Data reporting

FY 2023 OHT7 Premarket Review Progress

~ 1621 Submissions:

- ~90 PMAs and PMA Supplements
- ~300 510(k)s
- ~20 De Novos
- ~900 Pre-Submissions
- ~50 IDEs
- 1 CLIA Waiver by Application
- 15 Dual 510(k) and CLIA Waiver by Application
- ~80 EUAs

YTD Office Highlights for 2023

- First de novo authorization for a preeclampsia risk assessment test, which had been designated as a breakthrough device (and helps address one of the unmet public health needs highlighted in the breakthrough device designation guidance)
- First de novo authorization of an in vitro diagnostic intended to aid in the assessment of risk of progressive kidney function decline in adult patients with Type 2 diabetes and existing chronic kidney disease
- Cleared two “mega submissions” which allow for the simultaneous antimicrobial susceptibility testing of a larger number of drugs and drug concentrations than previously cleared systems
- First De Novo authorization for a COVID-19 molecular testing at-home over-the-counter (OTC) use test
- First two SARS-CoV-2 serology tests for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum or plasma samples
- First adeno-associated virus (AAV) companion diagnostic IVD test to detect pre-existing antibodies to help health care providers identify patients who may benefit from receiving gene therapy to treat severe hemophilia A
- First commercially available rapid TBI biomarker laboratory-based blood test to evaluate concussions
- Clearance of four completely new insulin pumps – more than doubling the number of options patients have had for the last decade
- Clearance of an automated insulin dosing (AID) system that introduces a new paradigm in simplified user experience, expanding access to users who want a more hands-off approach to managing their insulin pump therapy
- Clearance of improved versions of iCGM sensors, which drops a prior restriction against use in AID systems.
- First de novo for a digital behavioral therapeutic to aid in the management of type 2 diabetes

FDA Clears First Over-the-Counter Test to Detect Fentanyl

- **Alltest Fentanyl Urine Test Cassette**: First over-the-counter (OTC) test for the preliminary detection of fentanyl in urine. Cleared October 26, 2023
- Rapid test provides results from urine samples in 5 minutes
- CLIA Waived by regulation: 42 CFR 493.15(b)(1)
- OHT7 expedited review of this test, making a decision on the submission in only 16 days from the date it was received
- This clearance is an example of the FDA's continued efforts to reduce morbidity and mortality associated with opioid overdoses

FDA Grants First Marketing Authorization for a DNA Test to Assess Predisposition for Dozens of Cancer Types

- **Invitae Common Hereditary Cancers Panel:** First test of its kind to be granted FDA marketing authorization evaluates DNA extracted from a blood sample to identify variants in 47 genes known to be associated with an elevated risk of developing certain types of cancer
- Sequencing based in vitro diagnostic test helps detect hundreds of genetic variants associated with an elevated risk of developing certain cancers
- Helps to identify potential cancer-associated hereditary variants in individuals with already-diagnosed cancer
- De Novo Granted September 29, 2023

FDA News Release

Potential Future Reclassification of Certain Microbiology Devices

On September 7, 2023, the Microbiology Devices Panel ("the Panel") of the Medical Devices Advisory Committee met to discuss and make recommendations on the potential future reclassification of certain infectious disease in vitro diagnostic devices.

The Panel believed that based on the available information, the FDA should reclassify from Class III to Class II the following types of devices:

- Qualitative HBV Antigen tests, Qualitative HBV Antibody tests, Quantitative Anti-HBs tests, and/or Quantitative HBV Molecular tests
- Parvovirus antibody assays
- M. tuberculosis assays

FDA Proposes Rule Aimed at Helping to Ensure Safety and Effectiveness of Laboratory Developed Tests

- The proposed rule seeks to amend the FDA's regulations to make explicit that IVDs are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory.
- Along with this amendment, the FDA is proposing a policy under which the agency intends to provide greater oversight of LDTs, through a phaseout of its general enforcement discretion approach to LDTs.
- Submit comments to the docket: FDA-2023-N-2177

[FDA News Release]


NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Proposed Rule

Medical Devices; Laboratory Developed Tests

A Proposed Rule by the Food and Drug Administration on 10/03/2023

This document has a comment period that ends in 55 days. (12/04/2023)

SUBMIT A FORMAL COMMENT

5 comments received. View posted comments

PUBLISHED DOCUMENT

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Proposed rule.

SUMMARY:

The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, FDA is proposing a policy under which FDA intends to phase out its general enforcement discretion approach for laboratory developed tests

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
10/03/2023

Agencies:
Food and Drug Administration

Dates:
Either electronic or written comments on the proposed rule must be submitted by December 4, 2023.

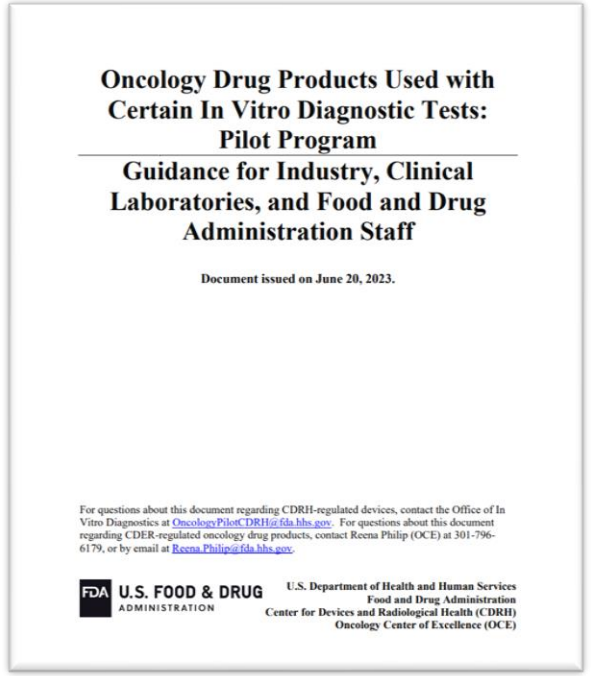
Comments Close:
12/04/2023

Document Type:
Proposed Rule

Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program

FDA is piloting a new approach to provide greater transparency regarding minimum performance characteristics that certain tests for certain oncology drugs should meet

- One step that may be helpful in reducing the risk of using LDTs for oncology drug treatment decisions while we continue to work on a broader approach for LDTs, including **moving forward with rulemaking**.
- This pilot **does not alter the standards** for approval of the oncology drug products or for marketing authorization of the corresponding companion in vitro diagnostics.
- At this time, the scope of this voluntary pilot program is **limited** to 9 drug sponsors and where:
  - A test is needed to identify the intended patient population of an oncology drug product for which no satisfactory alternative exists;
  - such a test uses the same technology as a previously FDA-authorized companion diagnostic;
  - the accuracy of such a test can be supported by a well-validated reference method, comparator, or materials; and
  - the anticipated benefits of the drug are so pronounced as to outweigh the risks of approval without contemporaneous approval of a companion diagnostic.



Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program

Guidance for Industry, Clinical Laboratories, and Food and Drug Administration Staff

Document issued on June 20, 2023.

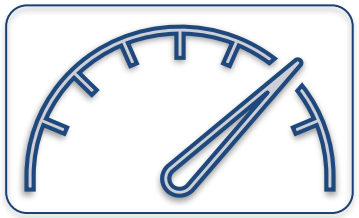
For questions about this document regarding CDRH-regulated devices, contact the Office of In Vitro Diagnostics at OncologyPilotCDRH@fda.hhs.gov. For questions about this document regarding CDER-regulated oncology drug products, contact Reena Philip (OCE) at 301-796-6179, or by email at Reena.Philip@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

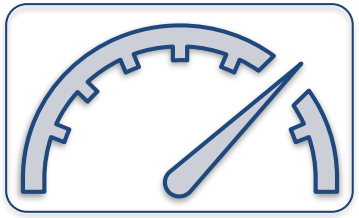
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Oncology Center of Excellence (OCE)

https://www.fda.gov/media/169616/download

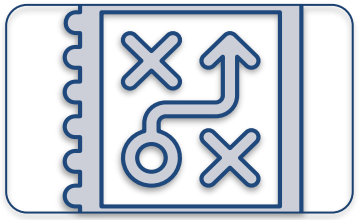
Oncology Diagnostics Pilot Program



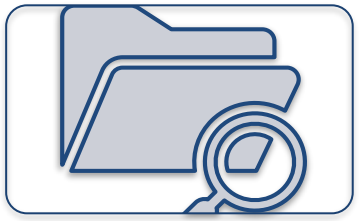
FDA will request performance information for the tests used to enroll patients into the clinical trials that support drug approval



FDA will post to its website the minimum performance characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug



Laboratories may use this information to guide their development of LDTs to identify specific biomarkers used for selecting cancer treatment



This transparency aims to help facilitate better and more consistent performance of these tests, resulting in better drug selection and improved care for patients with cancer

U.S. FOOD & DRUG ADMINISTRATION

Thank You