FDA Update

CLIAC

April 10, 2024

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(OHT7 – Office of Health Technology 7)
Office of Product Evaluation and Quality (OPEQ)
CDRH | Food and Drug Administration

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

CDRH Intends to Initiate the Reclassification Process for Most High Risk IVDs

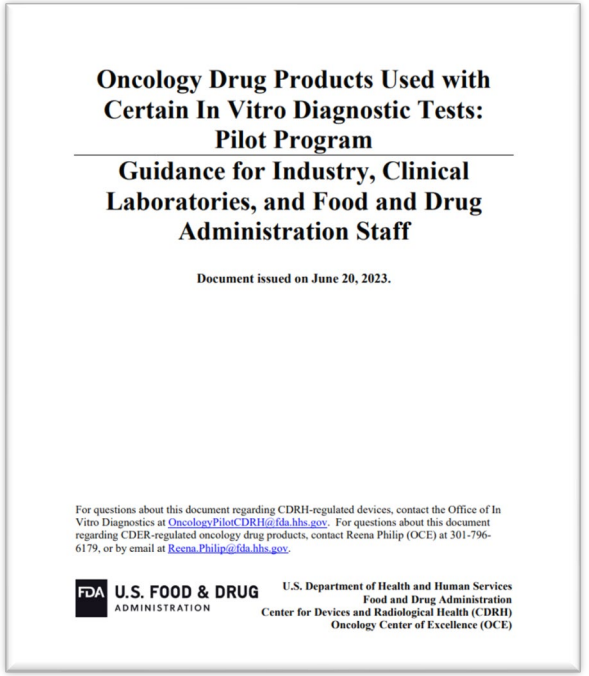
- Proposed reclassification for most IVDs that are currently class III (high risk) into class II (moderate risk)
  - Primarily infectious disease and companion diagnostic IVDs
- Premarket review of reclassified tests under the 510(k) pathway
  - High risk mitigated through special controls
- Microbiology Devices Panel meeting held on September 7, 2023. The Panel recommended FDA should reclassify from Class III to Class II the following types of devices:
  - Hepatitis B tests
  - Parvovirus antibody assays
  - M. tuberculosis assays
- Reclassifications may lead to increased access

Medical Devices News and Events

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

- Goal is to assure the availability of effective companion diagnostic tests for oncology drug treatment decisions.
- 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.

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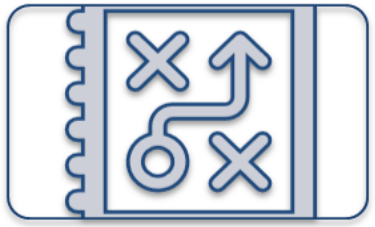
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Oncology Center of Excellence (OCE)

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

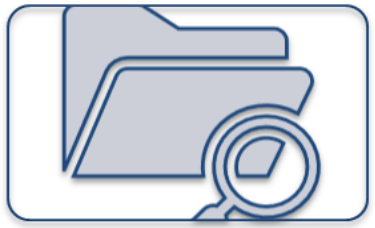
Oncology Diagnostics Pilot Program

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

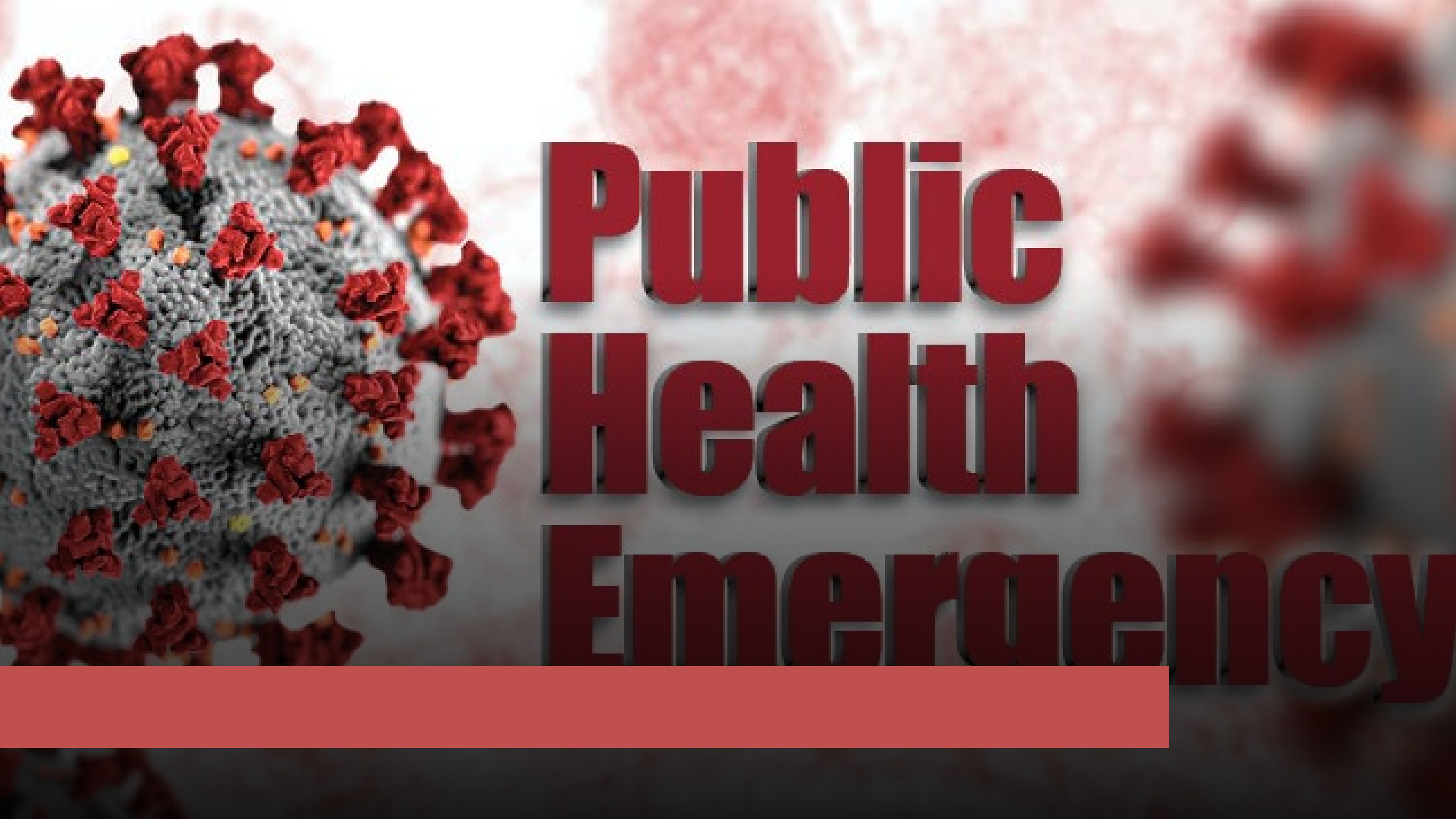
FDA will post to its website the minimum performance characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug



Healthcare professionals may use this information to guide their choice of companion diagnostic test



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


Public
Health
Emergency

PHE Tests Authorized as of April 1, 2024

299

COVID Molecular diagnostic tests

Including:

- 26 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 24 Point-of-care
- 72 Home collection
  - 16 Direct-to-consumer
  - 5 Multi-analyte
  - 14 Saliva home collection
- 5 Over-the-counter (OTC) at-home tests

78

COVID-19 Serology and other immune response tests

69

COVID-19 Antigen diagnostic tests

Including:

- 63 Point-of-care
- 33 Over-the-counter (OTC) at-home tests
- 8 Multi-Analyte

8

mpox NAAT diagnostic tests

Including:

- Automated
- Point-of-care
- Tests developed in collaboration with ITAP

Highly Pathogenic Avian Influenza (HPAI) A(H5N1)

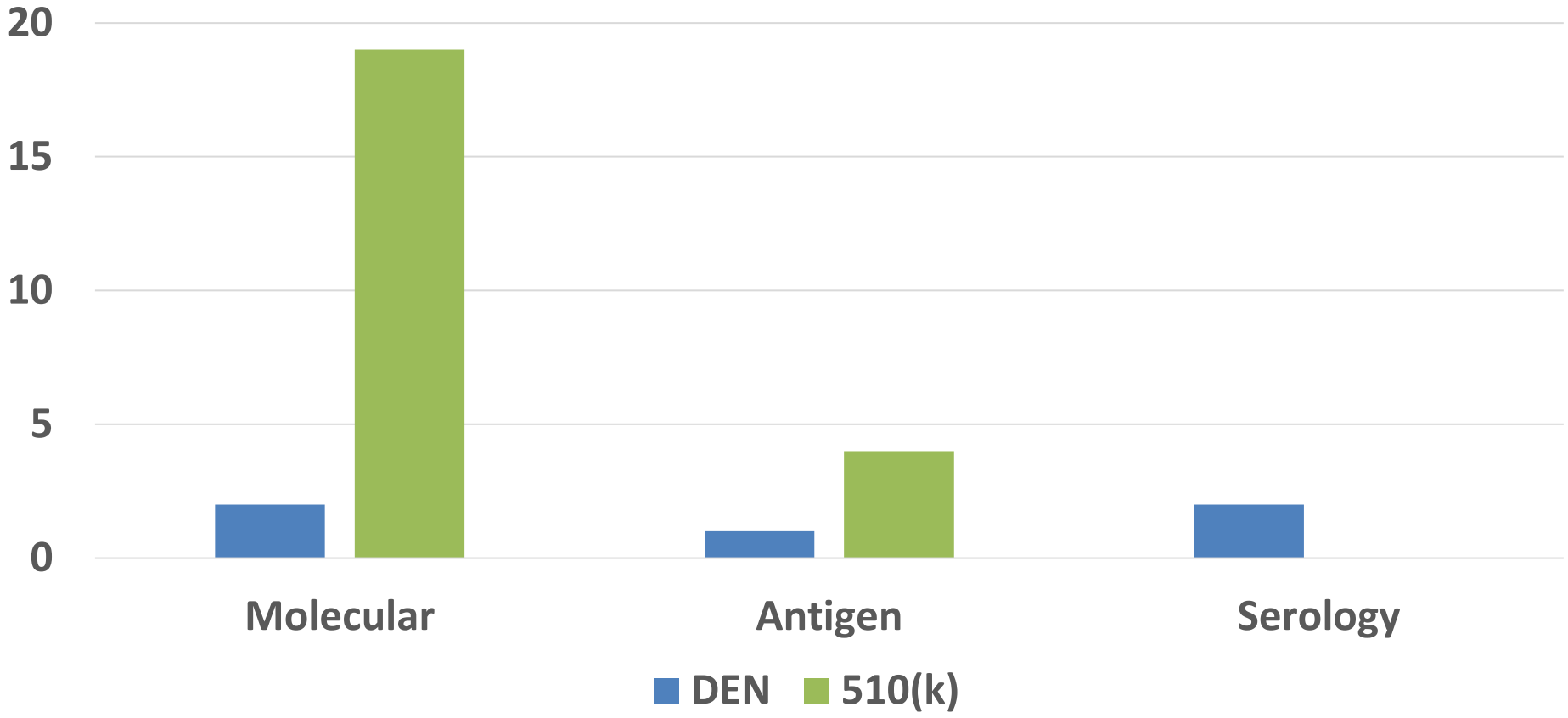
- Current assessment of test detection capability
- Working closely with Federal Partners to monitor the situation

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 Tests Granted Traditional Marketing Authorization



[COVID-19 Tests Granted Traditional Marketing Authorization by the FDA | FDA]

Data as of 4/1/2024

Independent Test Assessment Program (ITAP) provides support for FDA authorization of rapid IVD tests

- Collaboration between the FDA and the NIH RADx program
- To date, FDA has authorized 13 COVID-19 tests, four COVID-19/Flu combo tests, and one mpox test after being evaluated through ITAP
- **Sekisui OSOM Flu SARS-CoV-2 Combo Home Test**: Authorized February 29, 2024
  - Intended for qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens
  - First OTC antigen test that detects both flu and COVID-19 viruses to receive an EUA following collaboration with the NIH ITAP

ITAP for Hepatitis C Virus (HCV) RNA Point-of Care POC Diagnostics

In collaboration with FDA, the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) Tech program solicited proposals to accelerate the validation, regulatory authorization, and commercialization of innovative point-of-care (POC) tests (CLIA Waived) for hepatitis C virus RNA (HCV RNA) detection and quantitation.

Independent Test Assessment Program (ITAP) | National Institute of Biomedical Imaging and Bioengineering (nih.gov)

ITAP for HCV POC Diagnostics - POCTRN - GAITS

HCV RNA Tests: End Goal

- Support Viral Hepatitis Elimination in the US by making an HCV RNA first line diagnostic test available in the US market→ Test and Treat

Goal

Advantages

- Diagnose individuals who may not normally go to doctor
- Treat individuals same visit and minimize loss to follow up

VISION

The United States will be a place where new viral hepatitis infections are prevented, every person knows their status, and every person with viral hepatitis has high-quality health care and treatment and lives free from stigma and discrimination.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.

https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf

FDA Grants Marketing Authorization for Cytology Test Based on Artificial Intelligence (AI) Technology

Hologic Genius Digital Diagnostics System with the Genius Cervical AI algorithm:
Granted January 31, 2024

- Intended for the creation and viewing of digital images of scanned ThinPrep Pap Test glass slides
- Aid in cervical cancer screening for the presence of atypical cells, cervical neoplasia, including its precursor lesions, carcinoma, as well as all other cytological categories, as defined by The Bethesda System for Reporting Cervical Cytology
- Includes the Genius™ Digital Imager, Genius™ Image Management Server (IMS), the Genius™ Review Station, and the Genius™ Cervical AI algorithm

FDA Roundup

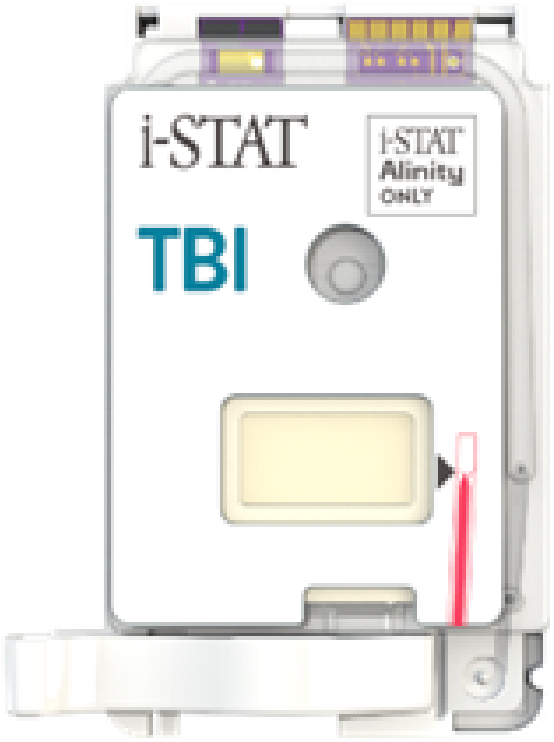
FDA Grants Marketing Authorization for First-of-a-Kind IVD Test for ADAMTS13 Activity

Technoclone Technozym ADAMTS13 Activity: Granted February 28, 2024

- First-of-a-kind enzyme-linked immunosorbent assay (ELISA) intended for the qualitative determination of ADAMTS13 activity in platelet poor human citrated plasma
- Used in conjunction with other clinical and laboratory findings, the test is intended as an aid in the diagnosis of thrombotic thrombocytopenic purpura (TTP) in patients with thrombotic microangiopathy (TMA)
- The assay is measured on microplate readers capable of detecting a wavelength of 450 nm

[FDA Roundup]

FDA Clears POC IVD for the Evaluation of Suspected Mild Traumatic Brain Injury (mTBI)



Abbott Point of Care i-STAT TBI Cartridge:
Cleared March 27, 2024

- For the quantitative measurements of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in whole blood using the **i-STAT Alinity** instrument
- The interpretation of test results is used, in conjunction with other clinical information, to aid in the evaluation of patients, 18 years of age or older, presenting with suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15) within 24 hours of injury, to assist in determining the need for a CT scan of the head

FDA Roundup

FDA Clears First Over-the-Counter Continuous Glucose Monitor

FDA News Release

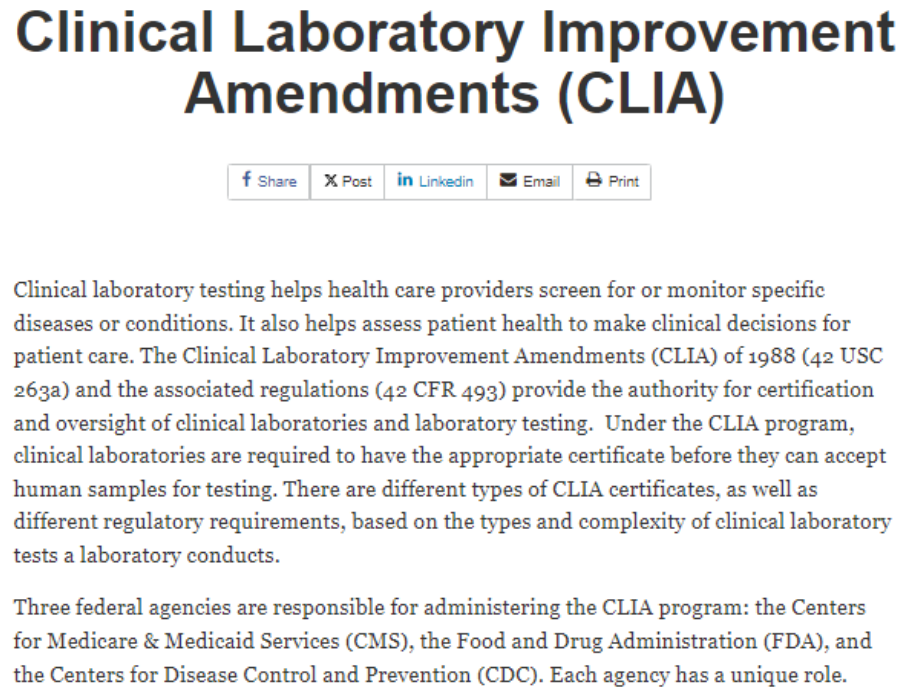
Dexcom Stelo Glucose Biosensor System: Cleared March 5, 2024

- First over-the-counter (OTC) integrated Continuous Glucose Monitor (iCGM) intended for anyone 18 years and older who does not use insulin
- System uses a wearable sensor, paired with an application installed on a user's smartphone or other smart device, to continuously measure, record, analyze and display glucose values
- Helps the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursion

Summary

Ways to interact with us:

- FDA CLIA Webpage
- Office of In Vitro Diagnostics Webpage
- Medical Device Safety Communications
- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program
- For CLIA-related questions: CLIA@fda.hhs.gov
- For COVID-19 Diagnostics questions: Covid19DX@fda.hhs.gov
- For mpox Diagnostics questions: MPXdx@fda.hhs.gov



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Thank You