FDA Update

CLIAC

November 6, 2024

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CDRH | Food and Drug Administration

OHT7 Key Activities

Premarket Activities

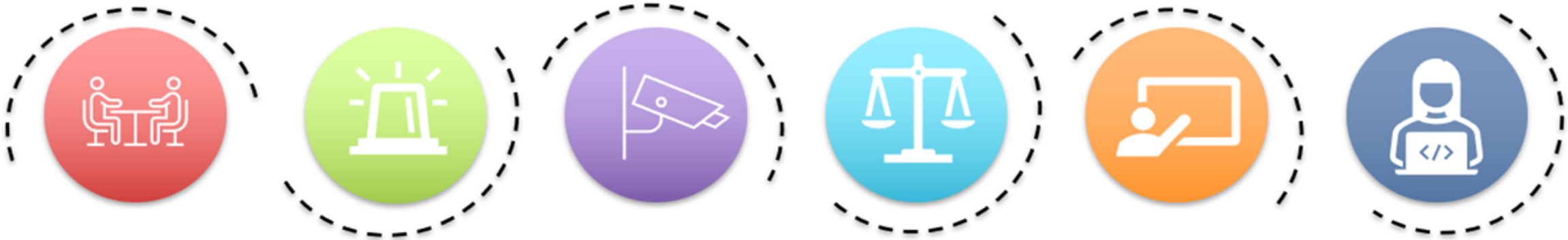
- PMA, 510(k), De novo request reviews
- Investigational Device Exemptions
- Humanitarian Device Exemptions
- Pre-submissions
- Breakthrough designation requests
- Premarket inspections
- CLIA waiver applications
- CLIA categorizations

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

Home Use/Home Access Tests

- Instrumental to enabling transition of care from the hospital to home
- Give patients health information from the privacy of home
- Some may detect possible health conditions when patients have no symptoms, enabling early treatment
- Some may monitor conditions to allow frequent changes in treatment

ALLTEST FENTANYL URINE TEST CASETTE

OTC at-home test for the preliminary detection of fentanyl in urine

ACON FLOWFLEX COVID-19 TEST

OTC home use visually-read antigen test for COVID-19

Home Use/Home Access Tests

Considerations for Home Use Testing

- Type of specimen
- Method of specimen collection
- Complexity of testing (e.g., pre-analytical incubations)
- Toxicity of reagents
- Risks of misinterpretation, non-specific results
- Need for HCP input

Home Use/Home Access Tests

- FDA has long encouraged development of at-home tests - >400 OTC tests authorized in the last 10 years alone.
- OTC tests like pregnancy tests and blood glucose tests benefit millions of Americans each year.
- FDA continues working closely with developers of OTC tests – and has authorized many types of OTC tests, including these examples:

- OTC COVID-19 tests
- OTC blood glucose meters
- OTC pregnancy tests
- OTC drugs of abuse tests
- OTC PT-INR tests to monitor safety in patients on warfarin
- OTC cholesterol tests
- OTC HbA1c tests to monitor blood glucose control in people with diabetes
- OTC genetic risk tests

CDRH Initiates 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
- **September 25, 2024**: FDA proposed reclassification of antigen, antibody, and nucleic acid-based Hepatitis B Virus assay devices **(comment period ends 11/25/2024)**
- **October 23, 2024:** FDA issued a final order to reclassify cytomegalovirus (CMV) deoxyribonucleic acid (DNA) quantitative assay devices intended for transplant patient management
- Reclassifications may lead to increased access

Federal Register: Proposed Rule
Federal Register: Final Rule

Highly Pathogenic Avian Influenza (HPAI) A(H5N1)

- Current assessment of test detection capability
  - Conducting updated reactivity risk assessments for flu IVDs
  - The results of these analyses are important to ensure that tests are available which are expected to detect H5N1
- Working closely with Federal Partners to monitor the situation
- Update to the Influenza Diagnostic Tests web page

PHE Tests Authorized as of October 29, 2024

290

COVID Molecular diagnostic tests

Including:

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

78

COVID-19 Serology and other immune response tests

77

COVID-19 Antigen diagnostic tests

Including:

- 72 Point-of-care
- 38 Over-the-counter (OTC) at-home tests
- 19 Multi-Analyte

8

mpox NAAT diagnostic tests

Including:

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

Do Not Use Cue Health's COVID-19 Tests Due to Risk of False Results

May 13, 2024: FDA issued a safety communication warning home test users, caregivers, and health care providers not to use Cue Health's COVID-19 Tests due to increased risk of false results

October 9, 2024: FDA revoked the Emergency Use Authorizations for both of Cue Health's COVID-19 test kits, the Cue COVID-19 Test, previously authorized for point-of-care use, and the Cue COVID-19 Test for Home and Over The Counter (OTC) Use, previously authorized for home use

October 15, 2024: FDA classified Cue Health's voluntary recall of their two COVID-19 tests as a class II recall

Safety Communication

ITAP for RNA Point-of Care (POC) Diagnostics: "Test to Treat"

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FDA NEWS RELEASE

FDA Permits Marketing of First Point-of-Care Hepatitis C RNA Test

Test Enables Single-Visit Testing and Treatment for Hepatitis C

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More Press Announcements

mediate Release: June 27, 2024

Español

Content current as of: 06/27/2024

Regulated Product(s) Medical Devices

Today, the U.S. Food and Drug Administration granted marketing authorization to Cepheid for the Xpert HCV test and GeneXpert Xpress System, the first hepatitis C virus (HCV) test that can be used to bring diagnosis to appropriately certified point-of-care settings for individuals at risk for hepatitis C. The test may be performed in

Cepheid Xpert HCV test and GeneXpert Xpress System: Granted June 27, 2024

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

ITAP for HCV POC Diagnostics - POCTRN - GAITS

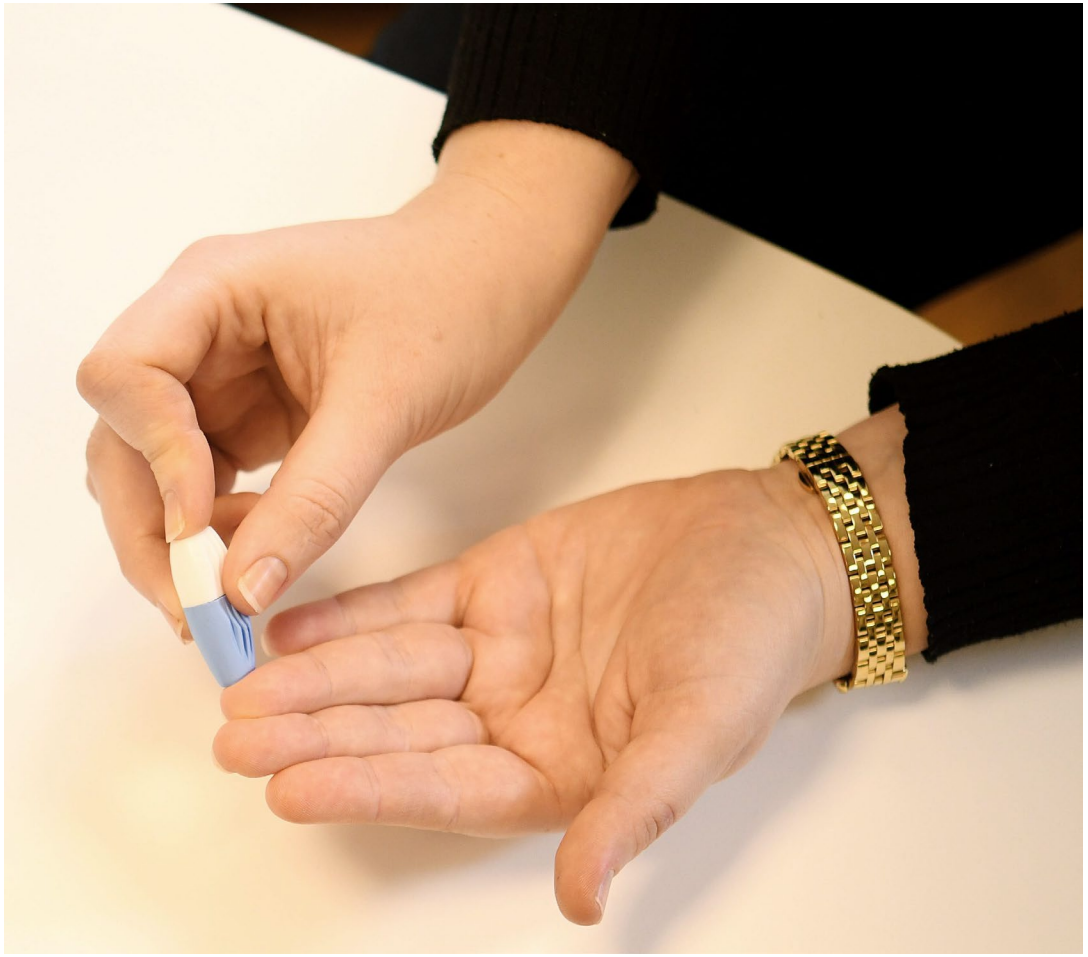
Press Release

FDA Marketing Authorization Enables Increased Access to First Step of Syphilis Diagnosis

NOWDiagnostics First To Know Syphilis Test: Granted August 16, 2024

- First at-home, over-the-counter test to detect Treponema pallidum (syphilis) antibodies in capillary whole blood
- The test provides an at-home result without a prescription, in approximately 15 minutes, which individuals can use to better inform next steps with a health care provider

Press Release



FDA Clears First Device to Enable Automated Insulin Dosing for Individuals with Type 2 Diabetes

Insulet SmartAdjust Technology:
Cleared August 26, 2024

- First automated insulin delivery (AID) system indicated for both type 1 and type 2 diabetes
- Automated insulin dosing technology previously available only for people with type 1 diabetes. This clearance helps expand access to this important diabetes management tool to millions of adults living in the U.S. with type 2 diabetes

Press Release

FDA Authorizes Marketing of First Home Flu and COVID-19 Combination Test Outside of Emergency Use Authorities

Healgen Rapid Check COVID-19/Flu A&B Antigen Test: Granted October 7, 2024

- Intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples

- First over-the-counter (OTC) test that can detect influenza to be granted marketing authorization using a traditional premarket review pathway

Press Release

Colorectal Cancer Screening Tests

Geneoscopy ColoSense: Approved May 3, 2024

- An RNA-FIT test for the qualitative detection of colorectal neoplasia associated RNA markers and for the presence of occult hemoglobin in human stool

Guardant Health Shield: Approved July 26, 2024

- A qualitative in vitro diagnostic test intended to detect colorectal cancer derived alterations in cell-free DNA from blood collected in the Guardant Blood Collection Kit

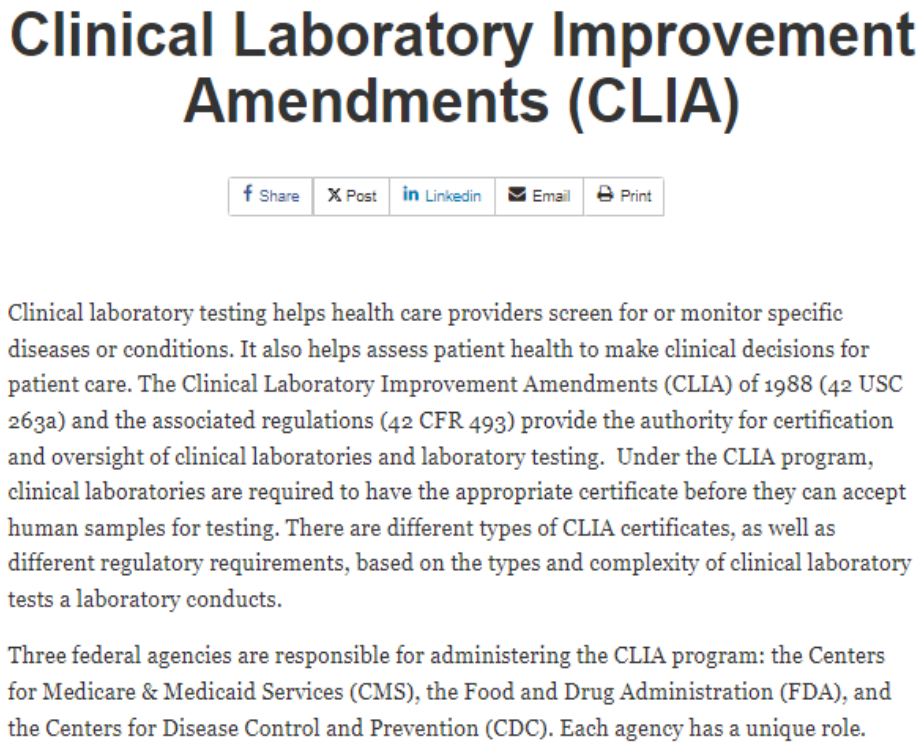
Exact Sciences Cologuard Plus: Approved October 3, 2024

- A qualitative in vitro diagnostic test intended for the detection of colorectal neoplasia-associated DNA markers and for the presence of occult hemoglobin in human stool, performed on samples collected using the Cologuard Plus Collection Kit

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