Submitting a Request for CLIA Categorization: Challenges of an Uncategorized Test System

IVD Roundtable

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Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration

Real Case of an Uncategorized Test System

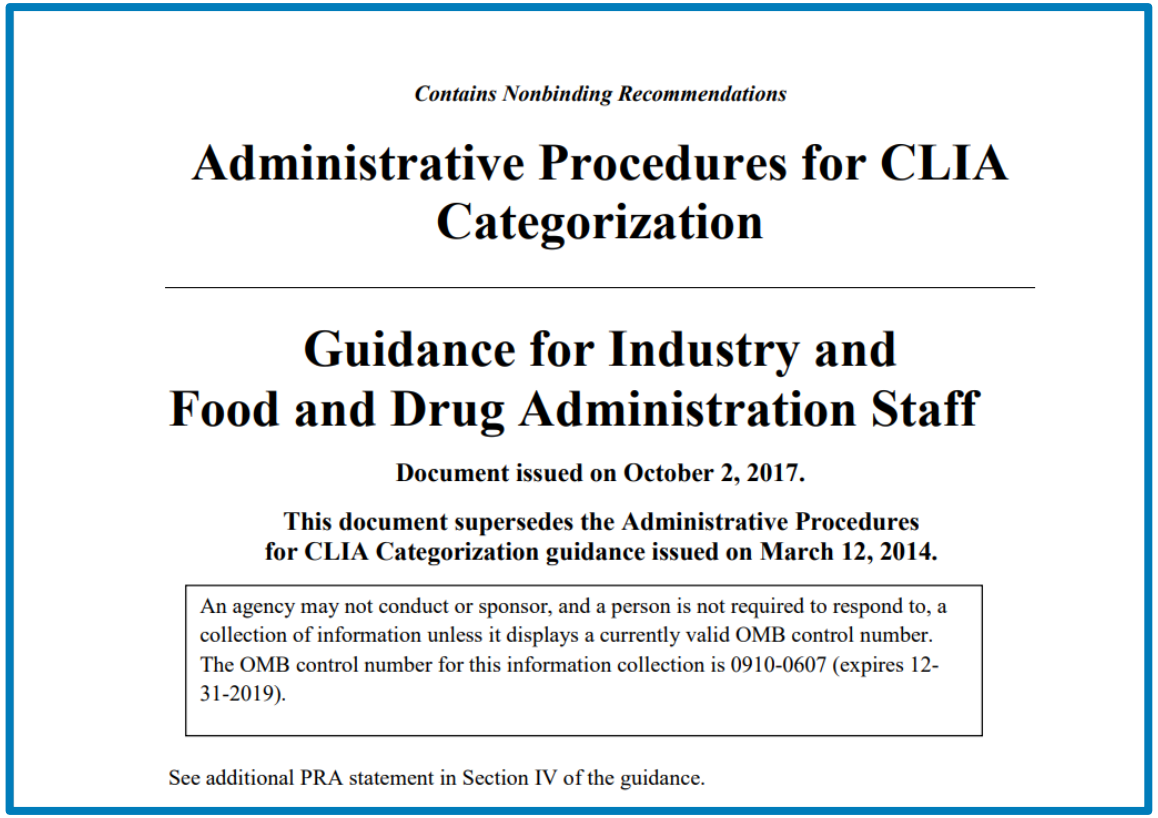
CMS Citation to lab: *"since the analytes we reviewed in your lab (X, X, X) performed on the X instrument are not on the FDA categorization database, they would default to high complexity since they are not FDA approved/cleared. Therefore establishment studies are required per 493.1253(b)(2). When a lab performs the establishment studies, they can use the information in the IFU as a guide, but not in place of performing these studies." This determination stands until the tests are cleared/approved by the FDA."*

- In response to the citation, the laboratory intended to remove the test system from their lab
- After discussing with FDA and confirming the assays were legally marketed, CMS contacted the lab informing them that they could continue using the test system (lab held a CLIA certificate to perform high complexity tests)

Challenges of an Uncategorized Test System

- **Challenge for CMS/CLIA Inspectors**: Can be misinterpreted to mean that the test is not FDA cleared/approved
- **Challenge for Laboratories**: Can be cited by CMS for performing a test that is not FDA cleared/approved and therefore, required to conduct establishment studies
  - Disruption of laboratory services
  - Impact patient care
- **Challenge for Manufacturers**: Can significantly impact business if labs stop using their test in response to the CMS citation

Manufacturers can help minimize problems related to uncategorized tests by submitting a request for CLIA categorization



Contains Nonbinding Recommendations

Administrative Procedures for CLIA Categorization

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 2, 2017.

This document supersedes the Administrative Procedures for CLIA Categorization guidance issued on March 12, 2014.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0607 (expires 12-31-2019).

See additional PRA statement in Section IV of the guidance.

Contains Nonbinding Recommendations

Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 17, 2022.

The draft of this document was issued on December 18, 2017.

This document supersedes "Replacement Reagent and Instrument Family Policy; Guidance for Industry and FDA Staff" issued on December 11, 2003.

For questions about this document, contact OHT7: Office of In Vitro Diagnostics at 301-796-7692 and CDRH-OIR-Policy@fda.hhs.gov.

- IVDs with name and/or distributor changes
- IVDs exempt from premarket review

Administrative Procedures for CLIA Categorization

- New test systems (instrument & assay combinations)

Replacement Reagent and Instrument Family Policy

FDA CLIA Database

CLIA Categorization Request Process

- Simple Submission
  - Cover letter, updated labeling, 510(k)-cleared package insert, and application sheet (if applicable)
- No User Fees
- eCopy recommended, but not required
- Interactive Review
- Notification of Decision: 30 FDA days
- Posting of Categorization(s) in CLIA Database

Direct Links

Final Guidances:

- Administrative Procedures for CLIA Categorization
- Replacement Reagent and Instrument Family Policy

Other Resources:

- FDA CLIA Database

Thank You!

Questions? Please contact:

CLIA@fda.hhs.gov