The FDA and the CLIA Test Categorization Process

FDA Round Table
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Ann Chappie, MT HHS
Scientific Reviewer – Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Overview

- What – When – Why – Where
- Waived categorizations
- FDA CLIA Waiver Guidance
- Future categorizations

What is categorization?

Process to assign marketed test systems into 3 categories of complexity:

→Waived

→Moderate

→High

Transferred to FDA in early 2000 from CDC

Why do categorization?

- CMS regulation 42 CFR 493.17 - categorization of specific laboratory tests by level of complexity
- Majority of the categorizations are moderate
- Default is high complexity

What is not categorized for CLIA?

- Sample not taken from the body - non-invasive test
- QC materials
- Calibration materials
- Breath tests

What are the criteria for mod and high?

7 criteria per CMS 42 CFR 493.17

- →Knowledge
- →Training and experience
- →Reagents and materials preparation
- →Characteristics of operational steps
- →Calibration, QC, PT materials
- →Troubleshooting and maintenance
- →Interpretation and judgment

7 criteria scored as 1, 2, or 3

- → Score of 1 = minimum
- → Score of 3 = specialized
- → Total scores of 12 or < = moderate complexity
- → 13 or > = high complexity

What is categorized for CLIA?

Test systems on materials derived from the human body

→FDA cleared or approved test systems - reagent and instrument

→Stand alone cassette type test no instrument

→510(k) exempt devices such as lipase, LDH, estradiol –given X numbers

When is a new categorization needed?

- Name of device changes
- Name of distributor changes
- *Apply cleared reagents to another marketed instrument or new family member instrument introduced
- Device modification – raise/lower complex

*FDA guidance for replacement reagents
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079185.htm

Pilot Program

Spreadsheet

- When you should use
- What information is included
- Where you obtain the information

Where to find categorizations?

- FDA website – search CLIA database

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm

Moderate Complexity

- General chemistries
- DOA
- Urinalysis analyzers + dipsticks (when first cleared)

… also have waived categorizations

- Definition of waived test
- 3 paths to waiver
- FDA guidance on CLIA waiver

42 U.S.C. Section 263a(d)(3)

"simple laboratory examinations and procedures that have been approved by the FDA for home use or that…are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result"

42 U.S.C. Section 263a(d)(3)

"including those that – (A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or (B) …pose no unreasonable risk of harm to the patient if performed incorrectly"

How do test systems qualify for CLIA waiver?

- By Regulation – 42 CFR 493.15(c) for 9 generic tests (FOB, u. preg., u. dipstick (visual read), OTC glucose, spun hematocrit, ovulation, hemoglobin single analyte instrument, hemoglobin copper sulfate, and ESR)
- By FDA Clearance or Approval for home use
- **By Meeting the statutory criteria**

FDA CLIA Waiver Guidance Jan 2008

- Emphasis on intended users testing patient specimens over time

- Emphasis on traceable comparative method
- Scientifically based flex studies

- LINK - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070890.pdf

Guidance and Law - Differences

- Law is binding
- Guidance recommends how to meet the law– guidance is not binding
- Other scientific approaches to meet the law – communicate with FDA through pre-ide process

Most common CLIA waived tests

- Drugs of abuse
- Visual urine dipsticks
- Glucose monitoring systems
- Visual urine hCG

How most common are CLIA waived?

- By OTC use
  →DOA

- By regulation
  →urine dipsticks
  →visual hCG
  →glucose monitoring – (OTC)

Future CLIA categorizations

- Technology changes
- New analytes
- QC needs? – external vs. internal
- Continue FDA open communications – pre-ide process – workshops
- Continue collaborations (FDA, CMS, CDC)

Thank you!

Ann.chappie@fda.hhs.gov

301-796-6139