# Administrative Changes to FDA's CLIA Categorization Program

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Clinical Laboratory Improvement Advisory Committee
Centers for Disease Control and Prevention
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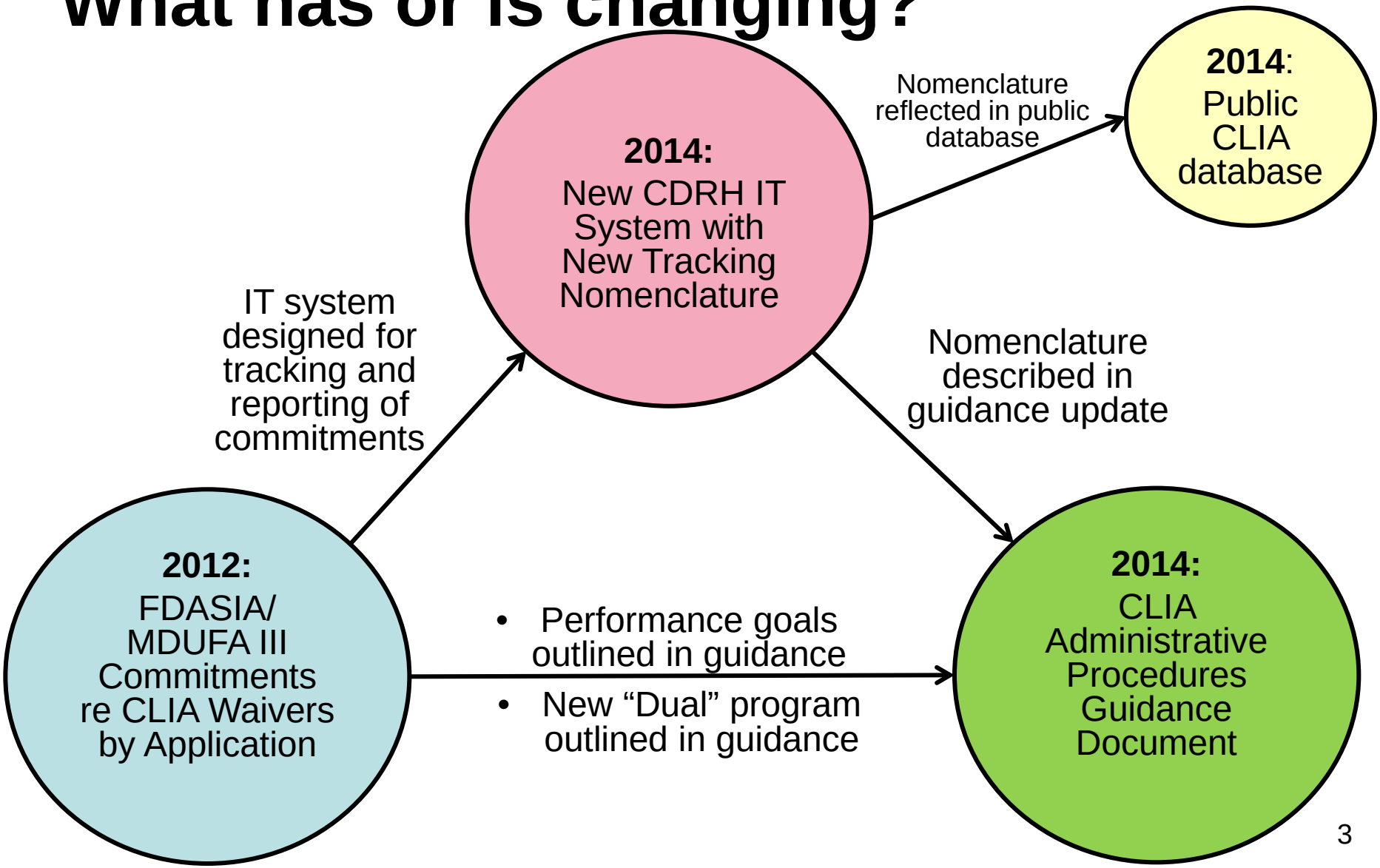
Atlanta, GA

# Overview of
# What has or is changing

- Administrative Tracking Mechanisms
- MDUFA III Commitment Letter
- Guidance for CLIA Administrative Procedures
- Public CLIA database

# What has or is changing?

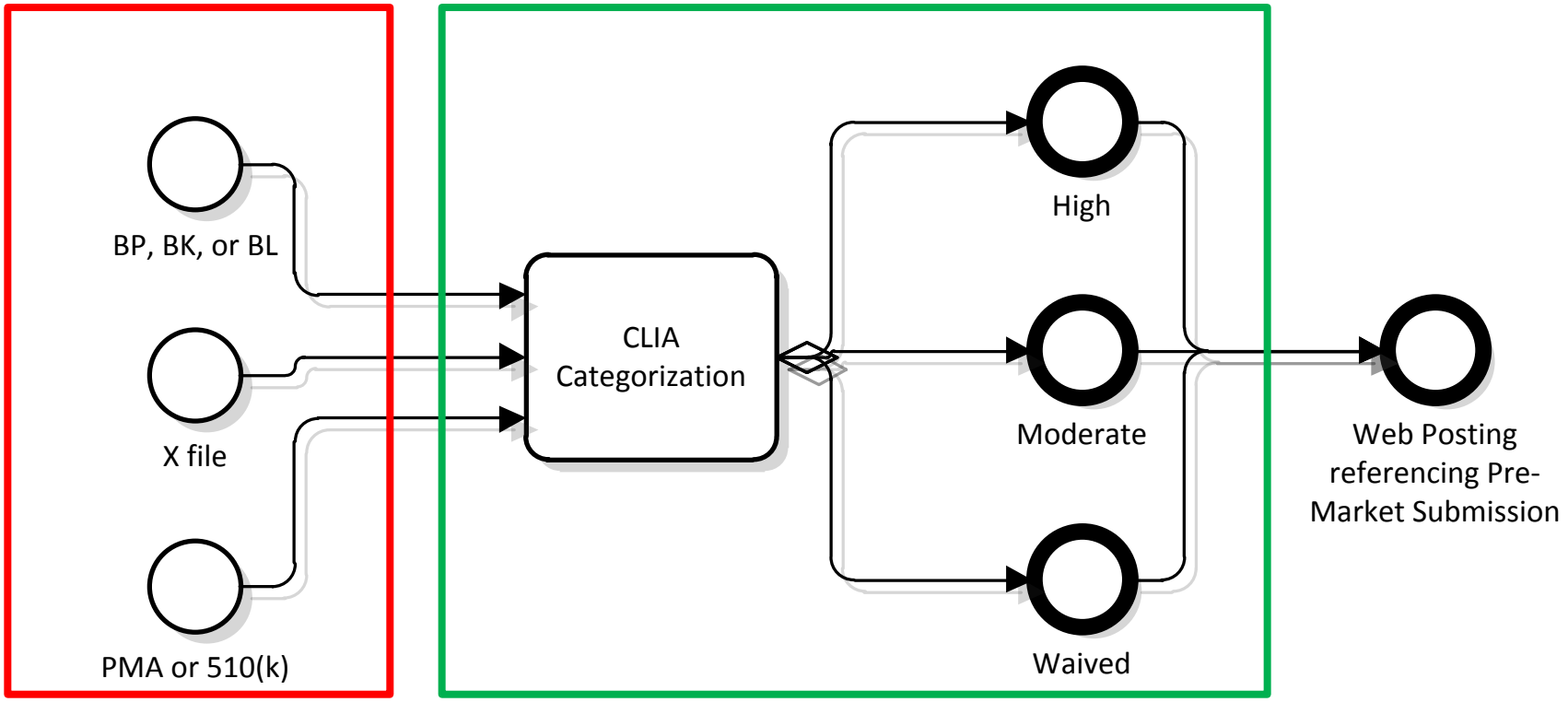


# CLIA CATEGORIZATION RECORDS (CR)

# What is Changing on March 21st 2014?

**Administrative processes for CLIA Categorizations are changing**

**Scientific Review Processes for CLIA Categorizations are NOT changing**



# CLIA Categorization Record Changes

| Type of CLIA Categorization | Today CLIA Categorizations tracked under: | On March 21th 2014 CLIA will be filed as: | Parent Document |
|---|---|---|---|
| Devices Approved / Cleared by CDRH/OIR | 510(K), PMA, HDE, De Novo | CRxxxxxx | Kxxxxxx, Pxxxxxx, Hxxxxxx |
| Devices Approved / Cleared / Licensed by CBER | BP, BL, BK | CRxxxxxx | BPxxxxxx, BLxxxxxx, BKxxxxxx |
| Pre-Market Review Exempt Devices | X-file (Xxxxxxx) | CRxxxxxx | CRxxxxxx |
| Name Changes (e.g., name, distributor) | 510(k) Add-to-File or PMA supplement | CRxxxxxx | Kxxxxxx, Pxxxxxx, Hxxxxxx, |

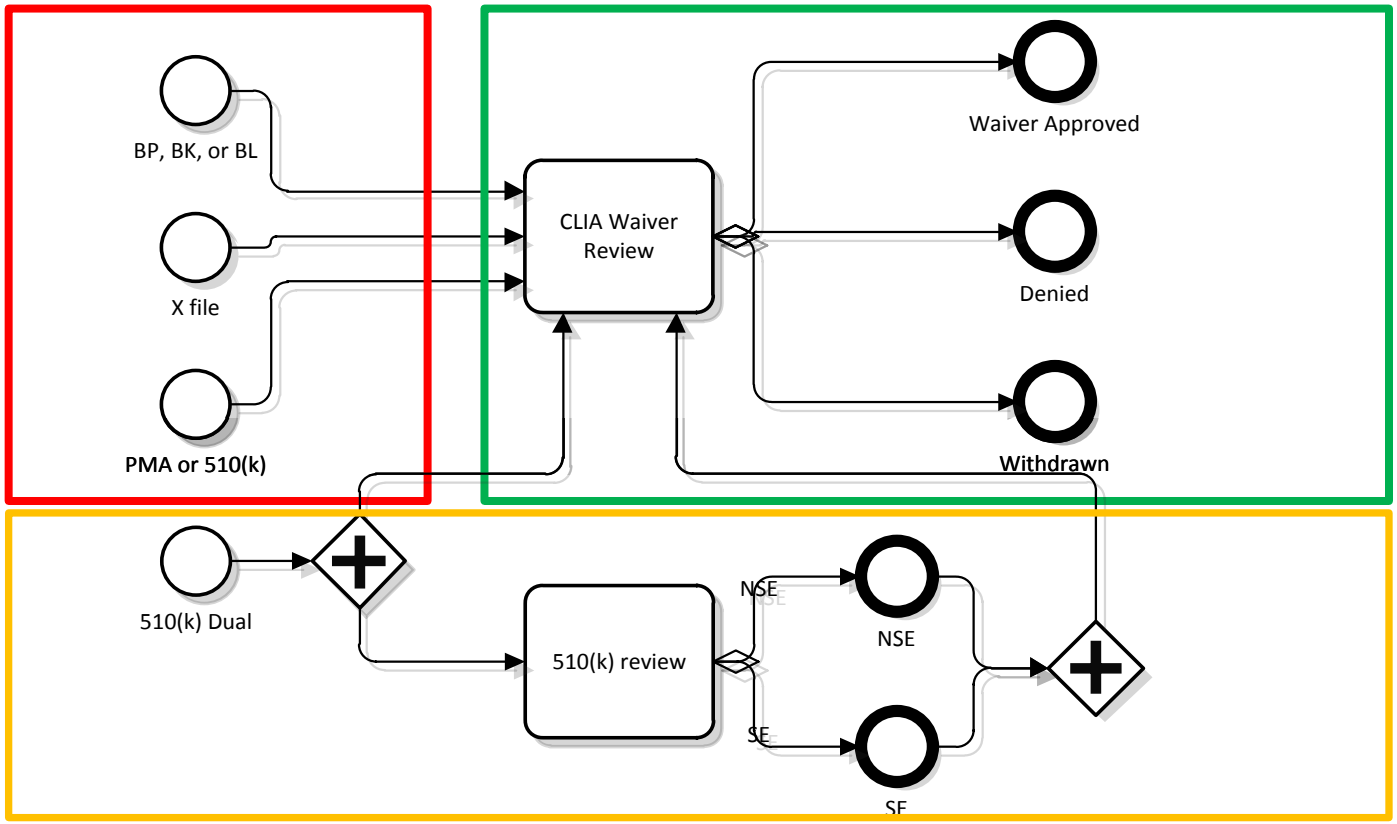
# CLIA WAIVER BY APPLICATION (CW)

# What is Changing on March 21st 2014?

**Administrative processes for CLIA Waiver by Applications are changing**

**Scientific Review Processes for CLIA Waiver Reviews are NOT changing**

## DUAL



# CLIA Waiver By Application Changes

| Type of CLIA Waiver by Application | Today CLIA Waiver By Application tracked under: | On March 21th 2014 CLIA will be filed as: | Parent Document |
|---|---|---|---|
| Devices Approved / Cleared by CDRH/OIR | 510(k) Add-to-File or PMA supplement | CWxxxxxx | Kxxxxxx, Pxxxxxx, Hxxxxxx |
| Devices Approved / Cleared / Licensed by CBER | BP, BL, BK | CWxxxxxx | BPxxxxxx, BLxxxxxx, BKxxxxxx |
| Pre-Market Review Exempt Devices | X-file (Xxxxxxx) | CWxxxxxx | CWxxxxxx |
| **Dual** 510(k) and CLIA Waiver by Application | Manually | CWxxxxxx | Kxxxxxx |

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# What has changed: MDUFA III Commitments

- Performance goals for CLIA Waivers by Applications (ie, IVDs that are legally marketed and for which the sponsor is seeking a waiver categorization)
  - FDA will engage in a substantive interaction within 90 days
  - FDA will issue a decision for 95% within 180* FDA days

**330 if advisory panel review is required*

# What has changed: MDUFA III Commitments

- New Dual 510(k) + Waiver by Application
  - Requires Pre-Submission
  - FDA will engage in a substantive interaction within 90 days
  - FDA will issue a decision for 90% within 210 FDA days

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# What is changing: Updates to Guidance

- Categorizations and Waiver by Applications
  - Explains when a “CR” or “CW” number will be assigned
  - Includes review and management expectations throughout the entire submission process
    - FDA will post waiver categorization in public CLIA database upon notification of Waiver Granted
    - Option for sponsors to submit Pre-Submissions to request FDA feedback on planned protocols or study designs to support CLIA waiver
    - Explanation of Duals
      - lack of experience with process
      - Most useful recommendations are device-specific and covered during the mandatory Pre-Submission phase

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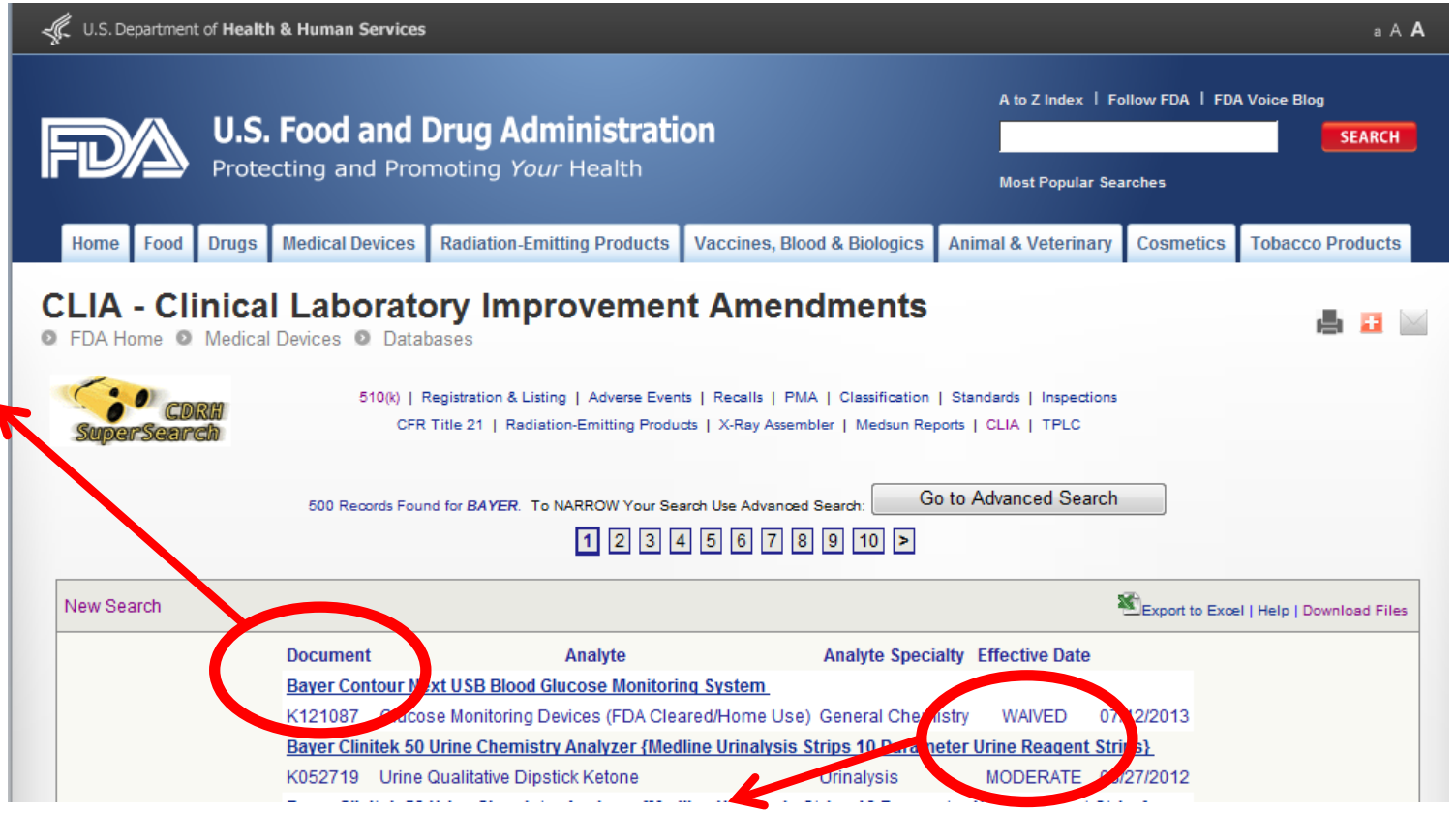
# Public CLIA database changes

**<u>Current</u> FDA website view:**

Have document column with Marketing Application #




Complexity

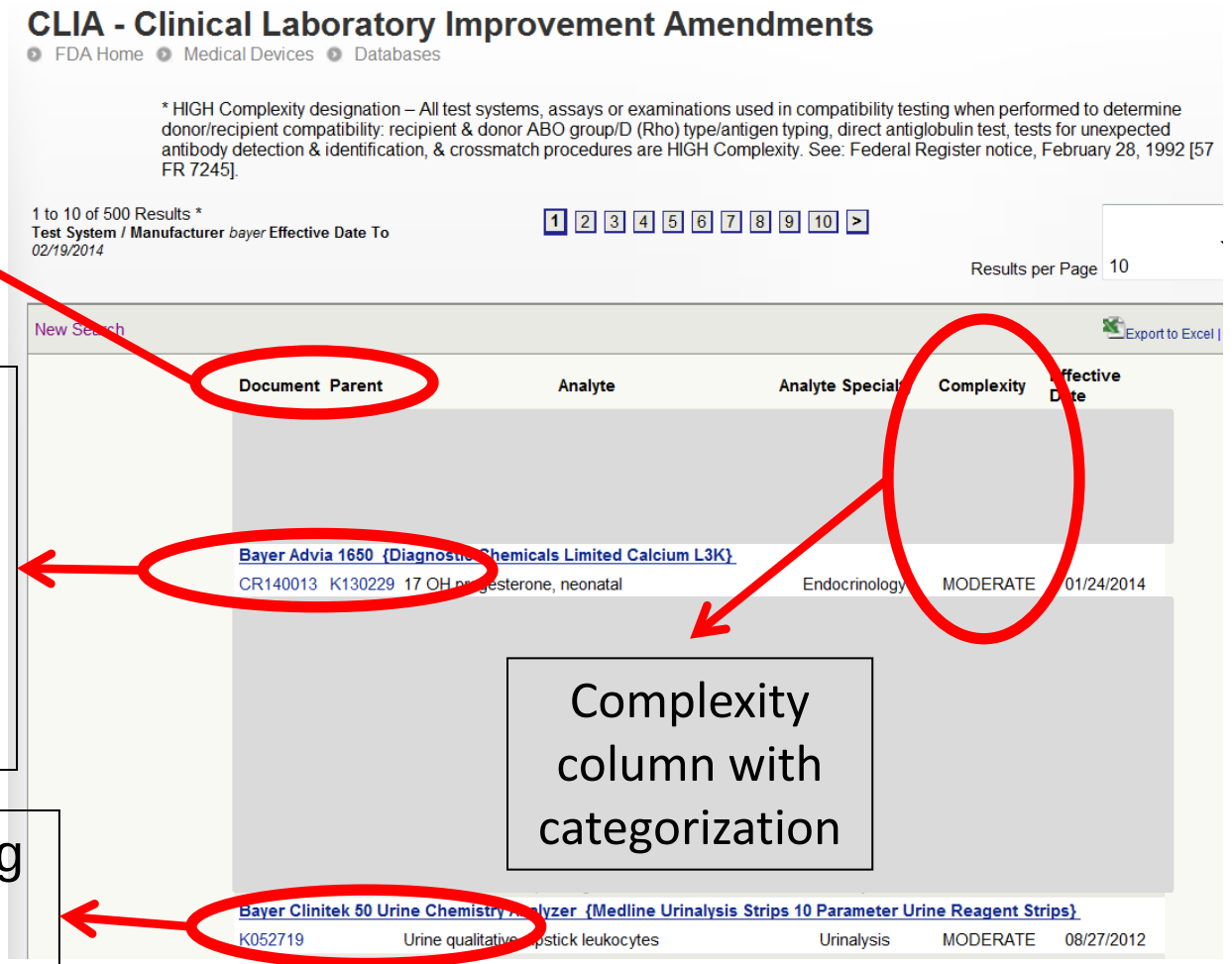
# Public CLIA database changes

**<u>Updated</u> FDA website view:**

Includes Document <u>and</u> Parent column

Newly entered IVD includes **CR** info in <u>Document Column</u> and <u>Marketing Application info in Parent column</u>

Legacy IVD Marketing App info remains in Document column

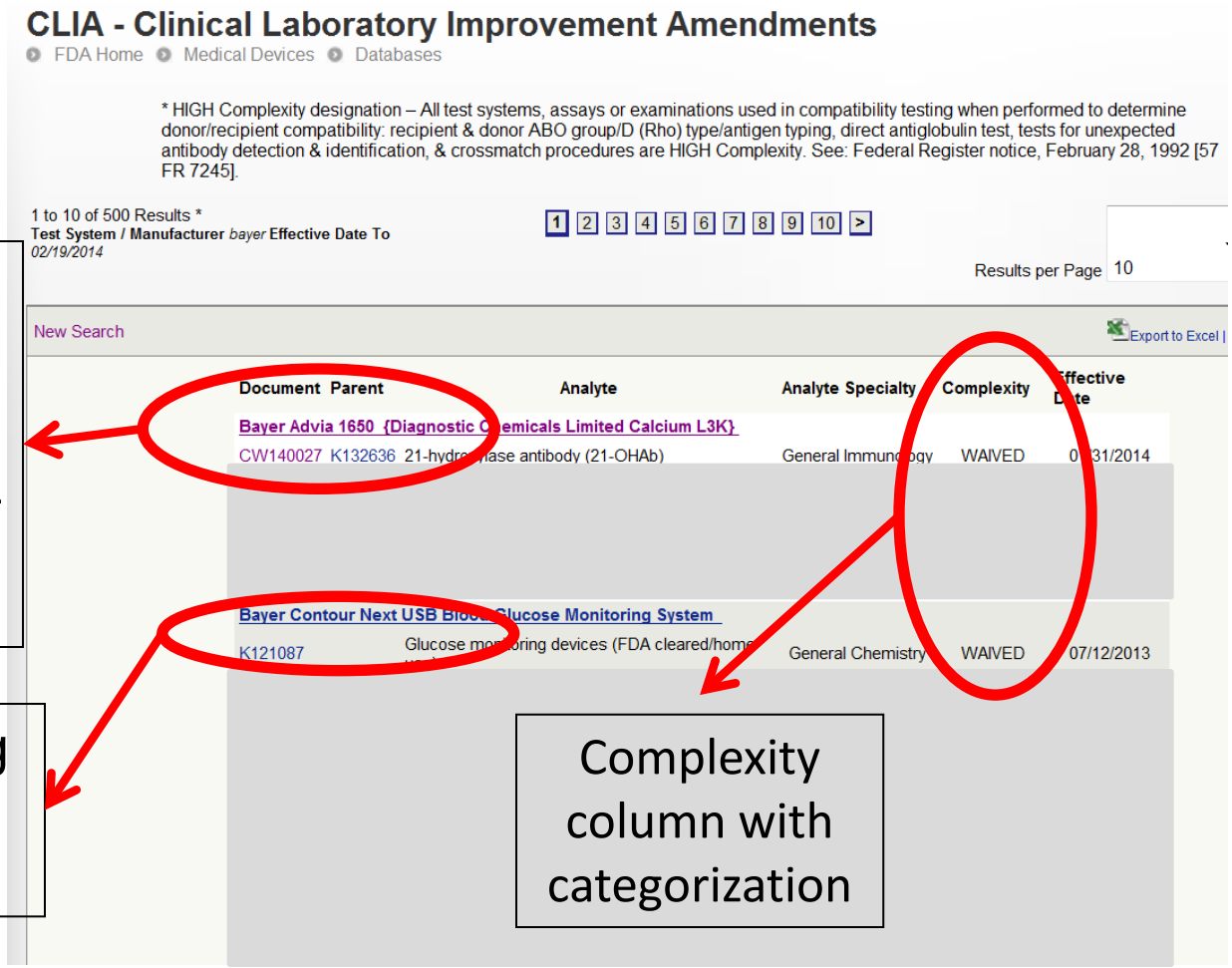


# Public CLIA database changes

**<u>Updated</u> FDA website view:**

Newly entered IVD includes **<u>CW</u>** <u>info in Document Column</u> and <u>Marketing Application info in Parent column</u>

Legacy IVD Marketing App info remains in Document column



# CLIA IT Rollout Plan

- Updated guidance document: “Administrative Procedures for CLIA Categorization”
  - Will publish in the next few weeks
- Public Webinar Program Update
  - Online webinar shortly after guidance is published
- FDA IT internal systems and public website
  - Will go live March 21st 2014

# References

- CLIA Administrative Procedures Guidance

Please search at **fda.gov** in a few weeks when it's published

- CLIA Waiver by Application Guidance

**http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079632.htm**

- CLIA Public Database

**http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm**

# Thank you!

- Please contact Ann Chappie or Prakash Rath with CLIA related questions at:

**CDRHCLIACoordinator@fda.hhs.gov**