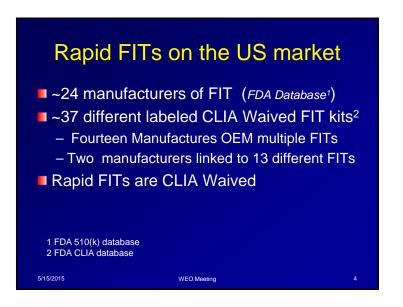




# AGENDA Quality Requirements 1992-2007 - 1992 FDA Guidance Document Quality Requirements 2007-2014 - 2007 FDA Guidance Document Quality after 2014 - Better Oversight



# Quality 1992-2007

- Guidance document issued by the FDA for Fecal Occult Blood (Guaiac test ) in 1992.
- Reviewed by the hematology division at the FDA.
- CLIA 88 enacted and list Fecal Occult Blood as a test that may be waived.

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# Quality 2007-2014

- Guidance document updated and issued by the FDA for Fecal Occult Blood (Guaiac test) in 2007.
- Further outlined analytical performance criteria
- Clinical data requirements
- CAP and API Survey specimens

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### Quality 1992-2007

- Challenges
  - Minimal expectations regarding analytical performance.
  - No clinical data confirmation
  - Hematology verses Chemistry review
  - POL studies used to determine cutoff

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## Quality 2014 and Beyond

- Adoption of CLSI standards for analytical performance measures.
- Updated FDA guidance document requested.
- Maybe a certification program for FIT should be in place similar to the NGSP for HbA1C.

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