FIT'S Quantity, Quality and Oversight

Helen Landicho, RAC
Senior Vice President Regulatory Affairs
Polymedco, Inc./Polymedco Cancer Diagnostic Products

WEO CRC Meeting – May 15, 2015

AGENDA

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

CLIA

- Clinical Laboratory Improvement Amendments (CLIA), United States regulations passed in 1988.
- CLIA covers tests and test systems that meet risk, error, and complexity requirements are issued a CLIA certificate of waiver.
- Tests classified at Waived, Moderate and Highly complex.

Rapid FITs on the US market

- ~24 manufacturers of FIT (*FDA Database*[1])
- ~37 different labeled CLIA Waived FIT kits[2]
  - Fourteen Manufactures OEM multiple FITs
  - Two manufacturers linked to 13 different FITs
- Rapid FITs are CLIA Waived

1 FDA 510(k) database
2 FDA CLIA database

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.

Quality 1992-2007

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

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

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.