Introduction:

CLIAC Genetics Workgroup
Good Laboratory Practices for Molecular Genetic Testing

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CLIAC and Genetic Testing: Key Events

- CLIAC Workgroup 1 – 1997
- CLIAC recommended changes to CLIA – 1998
- CDC Notice of Intent – 2000
- CLIAC Workgroup 2 – 2000
- CLIAC finalizes recommendations – 2001
CLIAC and Genetic Testing: Key Events

• NPRM drafted – 2001 to 2006

• HHS: current CLIA is OK for Genetics – 2006

• CMS enhance oversight w current CLIA – 2007

• SACGHS Oversight Task Force Report – 2007

• Genetics Workgroup 3 – 2008

• MMWR R&R - 2009
The Long Genetics Road

- 19 CLIAC Meetings (1997-2008)
- Challenges:
  - Testing is testing vs genetic testing is unique
  - Oversight is adequate vs inadequate
- MMWR on MGT to be followed with biochemical and molecular cytogenetics and somatic genetic testing?
- New Issues raised?
Workgroup Focus and Tasks

• Workgroup Focus
  – Provide framework to assist CLIAC in developing recommendations for molecular genetic testing (MGT) good laboratory practices (GLP) for CDC to publish in MMWR
  – Practices are voluntary and may go beyond regulatory requirements

• Workgroup Tasks
  – Consider issues previously recognized by CLIAC
  – Evaluate GLP in MGT including:
    • current practice guidelines
    • accreditation standards
  – Suggest strategies where current standards and practices are lacking or inconsistent
  – Identify sources of data and information
  – Suggest additional quality measures
Work Group Members

- Carol L. Greene, MD - Chair
- Michele Caggana, ScD
- Tina Cowan, PhD
- Andrea Ferreira-Gonzalez, PhD
- Timothy J. O’Leary, MD, PhD
- Victoria M. Pratt, PhD
- Carolyn Sue Richards, PhD
- Lawrence Silverman, PhD
- Gail H. Vance, MD
- Thomas Williams, MD
- Jean Amos Wilson, PhD
- Emily S. Winn-Deen, PhD
Ex-Officio Members

- CMS
  - Penny Keller
  - Ronalda Leneau
  - Judith Yost
- FDA
  - Elizabeth Mansfield
  - Steven I. Gutman
- CDC
  - Nancy Anderson
  - Joe Boone
  - Bin Chen
  - MariBeth Gagnon
  - Sharon Granade
  - Devery Howerton
The Power of Words

- Lords prayer – 66 words
- Ten Commandments – 179 words
- Gettysburg address – 286 words
- Declaration of Independence – 1300 words
- Regulation on cabbage sale – 26,911 words
- Genetic Workgroup – 12,346 words
- Thank you – 2 words