



# Introduction: CLIAC Genetics Workgroup Good Laboratory Practices for Molecular Genetic Testing

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# CLIAC and Genetic Testing: Key Events

- **NIH/DOE Task Force Report – 1997**
- **CLIAC Workgroup 1 – 1997**
- **CLIAC recommended changes to CLIA – 1998**
- **CDC Notice of Intent – 2000**
- **CLIAC Workgroup 2 – 2000**
- **CLIAC finalizes recommendations – 2001**



# CLIAAC 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 CLIA 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 CLIAAC 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 CLIAAC
  - 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**