



CDC Update for CLIAC Meeting February 4, 2009

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Topic Areas

- **CDC Staffing Changes**
- **Status Molecular Genetic Testing MMWR**
- **Timeline Biochemical Genetic Testing Recommendations**
- **Formation of CLIAC PT Regulation Workgroup**
- **New CDC Guidelines**
- **“Alliance for the Healthiest Nation”**



- **Richard Besser, M.D. named Acting Director CDC and ATSDR Administrator**
 - ❖ Former Director of Coordinating Office for Terrorism Preparedness and Emergency Response
- **Bill Nichols will serve as Acting CDC COO, replacing Bill Gimson**
 - ❖ Former Chief Management Officer COGH; Dir. Of Financial Management Office; Dir. of PGO
- **3 Interim Deputy Directors named**
 - ❖ Science and Program: Anne Schuchat, M.D.
 - ❖ Policy, Legislation, Communications: Donald Shriber
 - ❖ Management and Budget: Bill Nichols



MMWR Recommendations & Report on Molecular Genetic Testing

Document:

**Good Laboratory Practices for Ensuring the Quality of
Molecular Genetic Testing for Heritable Diseases and
Conditions**

Purpose:

**Highlight areas needing specific guidance for QA
Provide CLIA recommendations for complying with CLIA
and GLP
“Living” document that would evolve with the changing field**

Users:

**Laboratories performing MGT
Healthcare professionals and public who order MGT
Accrediting agencies, surveyors, third party payers who
evaluate practices and policies**



MMWR R&R Process: Good Laboratory Practices for Ensuring the Quality of Molecular Genetic Testing

- **9/10/08: Workgroup report presented at CLIAC**
- **CLIAC recommendations formulated**
- **CDC prepared initial draft**
- **Draft circulated for comments (CLIAC, CMS, FDA, NIH Office of Biotech Activities, CDC: NOPHG, NCBDDD, NCEH)**
- **Edits incorporated**
- **11/11/08: Submitted to MMWR editorial office**
- **12/19/08: CDC provided responses to initial editorial inquiries**
- **Spring 2009: Projected publication**



MMWR R&R Content:

Good Laboratory Practices for Ensuring the Quality of Molecular Genetic Testing

- **Executive Summary**
- **Introduction**
- **Background**
 - Growth and scope of MGT for heritable diseases and conditions
 - CLIA oversight for MGT
 - Concerns related to MGT
- **Methods**
 - Data collections and assessment
 - Development of CLIAC recommendations



MMWR R&R Content: Good Laboratory Practices for Ensuring the Quality of Molecular Genetic Testing

- **Recommended Good Laboratory Practices**
 - **Definition of Genetic Tests removed**
 - **Total Testing Process (preanalytic, analytic, postanalytic)**
 - **Personnel Qualifications and Responsibilities**
 - **Confidentiality of Patient Information**
 - **Laboratories Responsibility Regarding Persons Authorized to Order**
 - **Considerations Before Offering MGT**
 - **QMS Approach**



MMWR R&R Content

Good Laboratory Practices for Ensuring the Quality of Molecular Genetic Testing

- **Conclusions**
- **Acknowledgements**
- **References**
- **Terms and Abbreviations Used**
- **Continuing Education Activity**



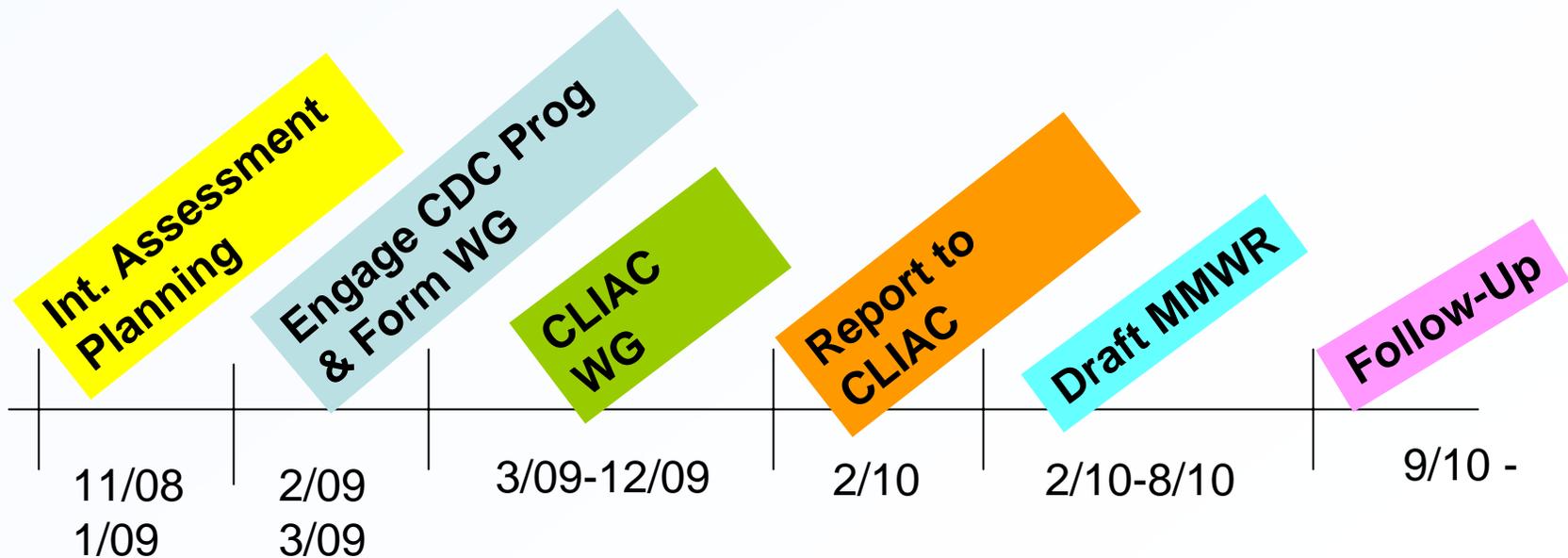
Future MGT Activities

- **Development of European guideline based on MMWR by CEN TC140**
- **Development of CLSI guideline for global usage**
 - **Areas of change include personnel training and credentials, confidentiality, retention requirements**
- **Alert key partners and users before and after publication of MMWR**
- **Training of surveyors, laboratories, users of MGT**
- **Evaluate CE activity**



Biochemical Genetic Testing

- September '08 CLIAC meeting recommendation made to form WG to address similar guidance needed for biochemical genetic testing

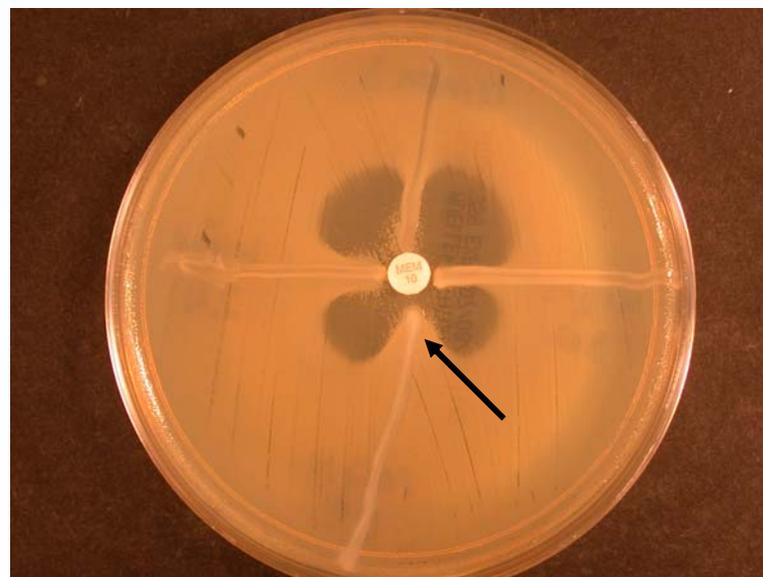
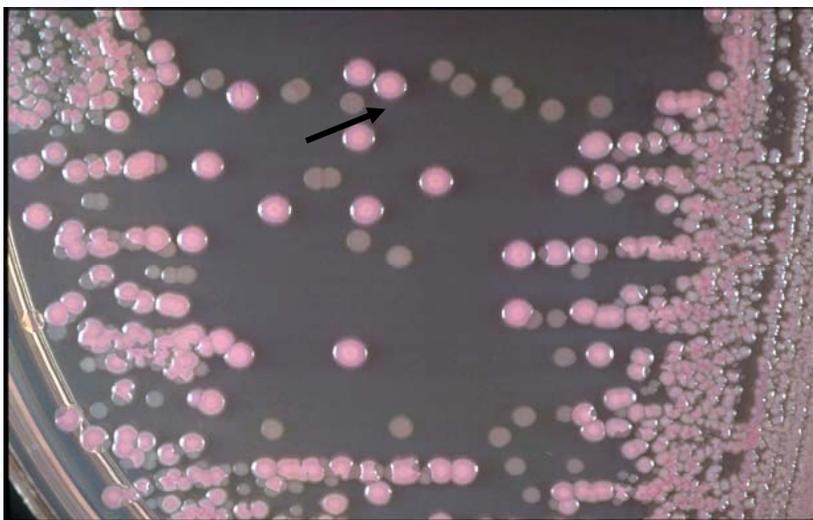




Revision of CLIA PT Regulations

- **Subpart H: Laboratory Requirements**
- **Subpart I: PT Program Requirements**
- **Workgroup to be formed**
 - ❖ **Chair: James Nichols, Ph.D.**
 - ❖ **Composition: Balanced among stakeholders**
- **Meeting date: TBD**

- **Diagnosis of Shiga-Toxin Producing *Escherichia coli* by Clinical Diagnostic Laboratories**
- **Infection Prevention Control Guidance for Carbapenem-Resistant and Carbapenemase-Producing *Enterobacteriaceae* in Acute Care Facilities (HICPAC)**





CDC's Health Protection Goals for the 21st Century



Healthy People in Every Stage of Life



Healthy People in Healthy Places



Healthy People in a Healthy World

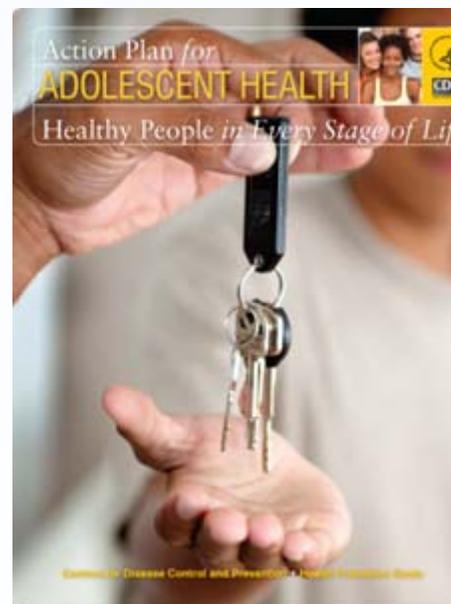
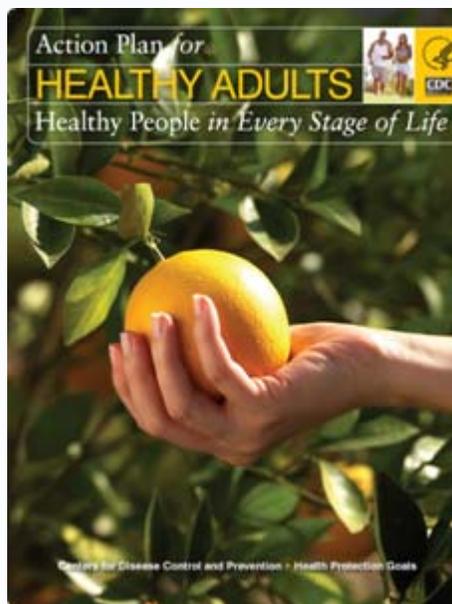


People Prepared for Emerging Health Threats

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CDC's Research Agenda

- ✓ Gap Analysis in what we know and what we need to know to improve people's health
- ✓ What do we need to know to help us accelerate our ability to achieve Health Protection Goals and become the Healthiest Nation?



A Health System for A Healthiest Nation: Health Protection for Life!



A Health System for A Healthiest Nation:
Health Protection for Life!

Public Health Network

Healthcare Delivery System

*Health Protection: Health Promotion,
Prevention, and Preparedness*

Disease Care

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Our Country Has a Critical Shortage of Health



The U.S. spends over \$2 trillion every year on healthcare, spending more than any other country.

- **Among industrialized countries, we rank no higher than 15th in health status (disability-adjusted life expectancy)**
- **Among all countries of the world, the U.S. ranks:**
 - 35th in infant mortality prevention
 - 30th in life expectancy at birth





Why Aren't We The Healthiest Nation?



- We are not getting the best value for what we are spending
- Health doesn't happen in the doctor's office or hospital
- Health happens in our homes, schools, workplaces and communities
- We do not invest enough in:
 - Promoting good health
 - Preventing disease, injury, and disability
 - Preparing for new health threats



