



# **CDC Update**

## **February 21, 2008**

**D. Joe Boone, Ph.D.**  
**Division of Laboratory Systems**  
**CDC**

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# Topic Areas

- Genetic Testing
  - ❖ MMWR
  - ❖ Workgroup
- Follow-up 2007 Institute - "Managing for Better Health"
- 2007 - 2008 Laboratory Medicine Reports
  - ❖ PT – Updates to Current US PT
  - ❖ Developing an Evidence-based Best Practices in Laboratory Medicine Process
  - ❖ Status of Laboratory Medicine in US
- CLSI M50 – QC for Microbial Identification Systems



# Genetic Testing MMWR

**Purpose:** Describe current “good practices” in genetic testing

**MMWR Draft Circulated:** Draft based on prior CLIAC recommendations

**Revised MMWR Plan:**

- Establish a workgroup to review and define consistent good practices
  - ❖ Determine which CLIAC recommendations are still relevant
  - ❖ Determine which are consistent with current professional guidance
  - ❖ Develop guidance where professional guidance is inconsistent or not available
- Prepare MMWR for November 2008 publication

**CLIAC Input:**

- Does this plan accomplish the goal of providing needed guidance?
- Workgroup nominations and MMWR content  
Suggestions by March 1



# Proposed MMWR R&R Document Good Laboratory Practices for Ensuring the Quality of Genetic Testing

## Outline - 1

### A. Executive Summary

### B. Introduction

### C. Background

- ❖ Rapid Growth of Genetic Testing
- ❖ Scope of Genetic Testing Nationwide
- ❖ CLIA Oversight for Laboratory Genetic Testing
- ❖ Concerns Related to Genetic Testing
  - Issues related to the pre-analytic phase of genetic testing
  - Analytic errors
  - Proficiency testing
  - Issues related to the post-analytic phase of genetic
  - Concerns related to genetic testing personnel
  - Concerns related to clinical validity, benefits, and risks of genetic tests
  - Personnel qualifications and training



# Proposed MMWR R&R Document Good Laboratory Practices for Ensuring the Quality of Genetic Testing

## Outline -2

### **D. Data Collection and Development of CLIA Recommendations**

### **E. Recommended Good Laboratory Practices**

- ❖ **Definition of Genetic Tests**
- ❖ **Facility Requirements**
- ❖ **Pre-analytic Phase of Testing**
  - **Individuals authorized to order tests**
  - **Informed consent**
  - **Test request**
- ❖ **Analytic Phase of Testing**
  - **Method validation**
  - **Control procedures**
  - **PT and alternatives**
- ❖ **Post-analytic Phase of Testing**
  - **Test report**
  - **Retention of records and specimens**
- ❖ **Personnel Qualifications and Responsibilities**



## Outline - 3

**F. Conclusions**

**G. References**

**H. Acknowledgements**

**I. Terms and Abbreviations**

**J. Continuing Education Questions**



# Follow-up to 2007 Institute: Managing for Better Health



## Workgroup 1:

- Develop white paper on performance measures for laboratory medicine
- Co-Chairs – Drs. Lee Hilborne and Elizabeth Wagar

## Workgroup 2:

- Develop a white paper on ways to better integrate laboratory tests and services into healthcare
- Co- Chairs – Drs. John Hickner and Mike Laposata

## Find a Home For Activities:

Exploring several options



# Laboratory Medicine Reports

- 2007 Reports – by Battelle are being edited
  - ❖ PT – Workgroup report posted on Battelle site
  - ❖ Best Practices – Workgroup report posted by CDC
  - ❖ Status of Laboratory Medicine – posted by Lewin Group
- 2008 Status Report - developed by Lewin Group
  - ❖ Three chapters planned
    - **Framing of Laboratory Medicine issues**
    - **Innovative Testing Technology**
    - **Patient-centered care and the future of Laboratory Medicine**



## Table of Contents

1. The Value of Laboratory Medicine in Health Care
2. Market Profile of the Laboratory Medicine Sector
3. Laboratory Medicine Workforce
4. Quality and the Total Testing Process
5. Quality Systems and Performance Measurement
6. Laboratory Information Systems
7. Federal Regulatory Oversight of Laboratory Medicine
8. Reimbursement for Laboratory Medicine



## Update on Status of CLSI M50: Quality Control for Commercial Microbial ID Systems

- CLIA requires testing each substrate or reagent in microbial ID systems for positive and negative reactivity with each batch, lot number, and shipment
- In 2005, ASM collects data on frequency of QC failures
- In 2006, ASM presents data to CLIAC
  - ❖ **CLIAC recommends that CLSI help determine appropriate QC**
- CLSI - Subcommittee develops QC guideline for microbial ID systems
- M50 - Proposed guideline published January 2008
  - ❖ **60 day comment period ending 3/10/08**
- CMS could allow laboratories to use approved guideline in lieu of current CLIA QC requirements



**Thank you  
Questions/Comments**



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