



# Publication and Promotion of MMWR R&R – Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions

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**CDC**

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# MMWR™

Morbidity and Mortality Weekly Report

[www.cdc.gov/mmwr](http://www.cdc.gov/mmwr)

Recommendations and Reports

June 12, 2009 / Vol. 58 / No. RR-6

## Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions

**INSIDE: Continuing Education Examination**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION

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## Purposes

- ❖ Highlight areas needing specific guidance for ensuring quality testing
- ❖ Provide recommendations for good laboratory practices to:
  - Clarify applicable CLIA requirements
  - Address need for specific quality assurance measures not included in CLIA

## Intended Users

- ❖ Laboratories performing MGT
- ❖ Users of laboratory services: Healthcare professionals and others who order MGT, referring laboratories
- ❖ Surveyors, health professionals evaluating laboratory practices and policies (third party payers, accrediting organizations, inspectors)

## Pre-publication information dissemination

- ❖ Invited commentary in April 2009 *ASCP Critical Values*
- ❖ Planned publication announced by Judy Yost at June 3, 2009 AACC Teleconference
- ❖ June 11:
  - CDC Media Advisory Press Release
  - DLS email announcement to federal agencies, professional organizations, accrediting organizations, exempt state programs, CLIAC, CLIAC workgroup, others
  - CDC Office of Public Health Genomics, Spotlight on Genomics & Health Weekly Update
  - Announcement at Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) meeting on June 11-12
  - Forwarded via email listservs of genetics groups and professional organizations to respective members and subscribers

## Immediate responses after publication:

- ❖ 5 interviews with the media
- ❖ Cited in 19 news articles
- ❖ Listserv broadcasts
- ❖ Link to MMWR on websites
- ❖ Information dissemination within organizations, institutions
- ❖ Local TV
- ❖ Blogs on Twitter and Yahoo groups

**\*See handout for more details**



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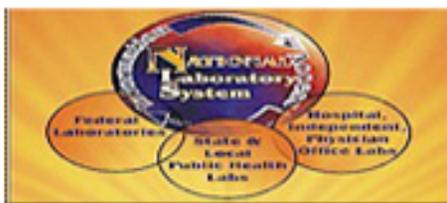
## Division of Laboratory Systems



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A nationwide laboratory system is crucial to the future health and safety of our communities...

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### International Laboratory

Related Resource and Activity Directory...

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- [MMWR - Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions](#) [\[HTML\]](#) | [\[PDF\]](#)
- [MMWR - Good Laboratory Practices for Waived Testing Sites](#)
- [Coagulation Laboratory Testing Practices](#)

## Quick Links

- [Biosafety](#)
- [DPDX](#)
- [Upcoming Events](#)
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## Presentations

- ❖ EuroGentest Laboratory Quality and Management Symposium, Leuven, Belgium. June 18-19, 2009
- ❖ Next Generation Molecular Diagnostics Summit, Washington, DC. Aug. 11-12, 2009
- ❖ Meeting of Japanese Committee on Clinical Laboratory Standards, Tokyo, Japan. August 22, 2009 (Keynote speech by Dr. Joe Boone)
- ❖ Association for Molecular Pathology 15<sup>th</sup> Annual Meeting, Nov. 19-22, 2009 (Early-bird session)

## Print Copies

- ❖ CMS: 525
- ❖ SACGHS: 50
- ❖ New York State Clinical Laboratory Evaluation Program: 12
- ❖ 2009 AACCC Annual Meeting: 70+
- ❖ Other meetings
- ❖ CLIAC Molecular Genetic Testing Workgroup members
- ❖ CLIAC members: in binder
- ❖ Additional copies available for public



# Continuing Education Activity

## As of August 24, 2009

❖ Total Participants	623
Nurses (CNE)	222
CEU	201
Physicians (CME)	137
Non physicians (CME)	41
Health Educators (CECH)	22

- ❖ Mostly compliments applauding importance, timeliness, value, usefulness, guidance
- ❖ Media questions
  - What prompted the decision to issue these guidelines now?
  - What consumer impact are these recommendations expected to have?
  - What role does CDC expect to play in the offering of new genetic tests?
  - Why is there the emphasis on laboratory responsibility for providing test information to users?
- ❖ Questions and requests
  - How would the MMWR recommendations affect existing specimen collection procedures?
  - How should laboratories use the MMWR? There are already too many standards and guidelines
  - How would the MMWR impact direct-to-consumer genetic testing?
  - Request for Spanish translation

- ❖ Post Q&As on DLS website
  - Responses targeted to different reader groups
  - Currently in clearance
- ❖ Create and distribute supporting documents
  - Invited commentaries
  - Fact sheets, brochures
- ❖ Presentations at professional conferences
  - Topics submitted for 2010 ACMG annual meeting
  - Upcoming 2010 meetings and conferences with DLS presence
- ❖ Training courses and workshops
  - Proposed for 2010 National Society of Genetic Counselors training course
  - Exploring training modules through NLTN

## Planned Next Steps (cont.)

- ❖ Promote awareness in collaboration with:
  - Other federal agencies
  - Professional organizations
  - Patient groups
  - Standard-setting organizations
  - CLIAC and other advisory committees
- ❖ Develop informational and educational materials for specific user groups
- ❖ Work with CMS to provide MMWR information to surveyors
- ❖ Monitor comments and feedback in order to:
  - Evaluate effectiveness and utility of the recommendations
  - Monitor need for future update

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  - CLIAC

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# Questions for the Committee

- ❖ Have we reached the intended audience?
- ❖ What future efforts should be taken to promote awareness in the laboratory and healthcare community?
- ❖ What steps should be taken to encourage implementation of the MMWR recommendations?
- ❖ What additional informational materials should be developed?
- ❖ How should we monitor and evaluate the impact of the MMWR?
- ❖ Who could serve as partners or collaborators to help with these efforts?

