

# CDC Update

Devery Howerton, PhD  
Director, Division of Laboratory Science and Standards

CLIAC Meeting  
August 29, 2012  
Atlanta, Georgia



# Outline

- ❑ Recognition of CLIAC's 20 years of service
- ❑ Cytology workload workgroup meeting
- ❑ Proficiency testing update
- ❑ Genetic testing guidance
- ❑ Quality improvement research agenda

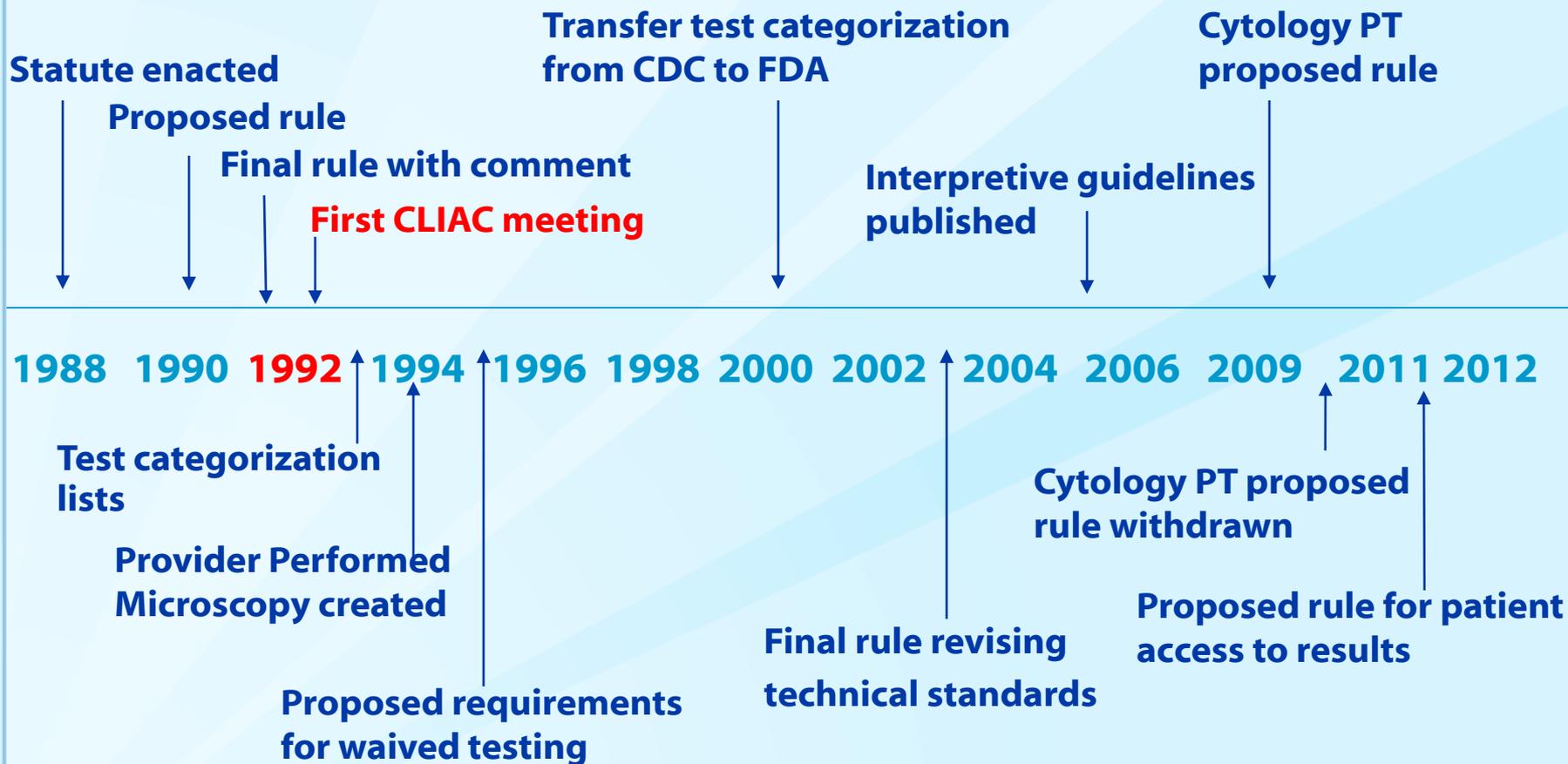
**In Recognition of the 20<sup>th</sup>  
Anniversary of the  
Clinical Laboratory Improvement  
Advisory Committee**

## CLIAC Duties Listed in Current Charter

Provide scientific and technical advice to CDC, FDA, CMS on

- ❑ Specific questions related to possible revision of the CLIA standards including
  - Impact of proposed revisions to the standards on medical and laboratory practice
- ❑ General issues related to improvement in clinical laboratory quality and laboratory medicine
  - Studies designed to improve laboratory services
  - Provision of non-regulatory guidelines to accommodate technological advances such as
    - New test methods
    - Electronic submission of laboratory information

# CLIA Regulatory Timeline



**NOTE: Over 50 FR Notices/regulations published related to CLIA**

# Committee at First Meeting: October 28-29, 1992



# CLIAC 1992 - 2012

- ❑ 46 CLIAC Meetings through 2012
- ❑ 7 Subcommittee Meetings
- ❑ 15 Workgroup Meetings
- ❑ Examples of Topics Addressed

Assisted Reproductive Technology

Bioterrorism

Cytology (includes Cytology PT)

Direct Access Testing

FDA Clearance/Approval Process

Genetics

Personnel

Point of Care/Physicians Office

Laboratories

Proficiency Testing

Quality Control/Quality Assurance

Survey Data/Information

Test Categorization

Unregulated Test Systems

Waiver

Electronic Health Records

IQCP

# CLIAC Members and Chairs

## □ Chairs

- Dr. Morton K. Schwartz – Feb. 1993 to Feb. 1999
- Dr. Toby Merlin – May 1999 to March 2003
- Dr. David Sundwall – Sept. 2003 to Feb. 2005
- Dr. Lou Turner – Sept. 2005 to Feb. 2008
- Ms. Elissa Passiment – Sept. 2008 to Aug. 2011
- Dr. Paula Santrach – Current Chair since Feb. 2012

## □ Members

- 20 current
- 116 total as of August 2012
- 4 industry liaisons

# Dr. Regina Benjamin, U.S. Surgeon General

CLIAC Member

1994 to 1999



# Impact of CLIAC Recommendations

- ❑ Changes to CLIA regulations
  - Quality control
  - Personnel
  - Provider-performed microscopy
  - Test categorization
  - Proficiency testing
- ❑ Voluntary standards/guideline development
  - CLSI M50: Quality Control for Commercial Microbial Identification Systems
  - CDC MMWR Publications

# Impact of CLIAC Recommendations

- ❑ CDC MMWR Publications
  - MMWR - Good Laboratory Practices for Waived Testing Sites
  - MMWR - Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions
  - MMWR - Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders
- ❑ Development of educational material for good laboratory practices (posters, booklets, online training)

## Clinical Laboratory Improvement Advisory Committee February 2012



**First Row – Left to Right:** Dr. Linda Sandhaus, Dr. Devery Howerton (CDC Ex Officio Representative), Dr. Paula Santrach (Chair), Dr. May Chu (Designated Federal Official), Dr. Anand Dighe, Dr. Alberto Gutierrez (FDA Ex Officio Representative);  
**Second Row:** Dr. David Wilkinson, Dr. Anthony Okorodudu, Dr. Robert Sautter, Ms. Karen Lacy, Dr. Judy Daly, Dr. Christine Bean, Dr. Paul Kimsey, Ms. Julie Gayken, Rev. Eugene Augustine, Jr. (Consumer Consultant), Dr. John Fontanesi;  
**Third Row:** Ms. Andrea Murphy (Management and Program Analyst), Ms. Nancy Anderson (Executive Secretary), Dr. Linda Ward, Dr. Robert Baldor, Mr. Robert Di Tullio (AdvaMed Liaison Rep.), Dr. Martha Crenshaw, Dr. Rosemary Zuna, Dr. Edward Chan;  
**Not Present:** Dr. Jeffrey Kant, Dr. Gail Vance, Ms. Judy Yost (CMS Ex Officio Representative)

# CLIAC Website Updates

- ❑ 2013 CLIAC Member Nominations
  - Submit potential candidates for consideration by October 1, 2012
    - Note that not all candidates may be selected at this time, but will be entered into a database for the future
    - Nomination slate depends on outgoing expertise and demographic balance required for Federal Advisory Committees
  - Provide candidate name(s), contact information, credentials and expertise
  - Send information or questions to [CLIAC@cdc.gov](mailto:CLIAC@cdc.gov)
- ❑ Sign-up for CLIAC email notices
- ❑ Download of meeting presentation PDFs now available for mobile devices

**<http://wwwn.cdc.gov/cliac/default.aspx>**

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- ❑ Proficiency testing update
- ❑ Genetic testing guidance
- ❑ Quality improvement research agenda

# Workload in Image-Assisted Gynecologic Screening Workgroup

- ❑ Consultative meeting held August 15-16, 2012
- ❑ Sponsored by CDC and hosted by the FDA
- ❑ Participants included
  - Cytopathologists
  - Cytotechnologists
  - Cytology Screening Device Manufacturers
  - CDC, CMS, and FDA staff

# Workgroup Roster

## □ **Workgroup Members**

- Tarik Elsheikh, MD – Chair
- William Crabtree, PhD, SCT (ASCP) – Co-chair
- George Birdsong, MD
- John Fontanesi, PhD
- Gary W. Gill, CT(ASCP)
- Ronald Luff, MD, MPH
- Fern Miller, MSM CT(ASCP)
- Janie Roberson, SCT(ASCP)
- Thomas H. Roberts, MD
- Brenda L. Schultz, SCT(ASCP)

## □ **Image-assisted Screening Device Manufacturers**

- Karen Atkison and Mark Sistare, PhD - BD Diagnostics
- Mark Kieras and Suzanne Werneke - Hologic, Inc

# Workgroup Charge

- Provide input to CDC, CMS, and FDA on the challenges associated with establishing a maximum workload limit for individuals that screen Pap smears utilizing semi-automated screening devices, and suggestions for how to obtain data to determine the maximum workload limit. Topics addressed will include:
  - Definition of slide “screening time” when performing semi-automated cytology screening
  - Operational study design for collecting data and information that can be used to determine the maximum workload limit when using semi-automated screening devices. (See next slide for details)
  - Guidance on the best methods for calculating and monitoring individual and general laboratory workload limits.

# Workgroup Charge – Operational Study Design

Input will be solicited from workgroup members regarding:

- ❑ Study questions
- ❑ Criteria for evaluating various workload limits, e.g., the accuracy of screening at various screening speeds and the laboratory's percentage of abnormal cases
- ❑ Criteria for screening time for a full 8 hour workday, portions thereof, and maximum hours of gynecologic screening per 24 hours.
- ❑ Guidelines for exclusion of non-screening time (data entry, QA responsibilities, preparation of slides, etc.) from 8 hour workday
- ❑ Practical approaches for data and information collection
- ❑ Potential study partners

# Meeting Outcome and Next Steps

- ❑ Workgroup participants provided input on items identified in Charge
- ❑ CDC, CMS, and FDA will assimilate workgroup suggestions and develop a feasible study plan
- ❑ CDC will solicit a proposal and fund a study
- ❑ Additional input may be solicited from workgroup experts
- ❑ CLIAC will be kept informed of progress and additional advice or recommendations may be sought at future meetings

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- ❑ Genetic testing guidance
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# Proficiency Testing (PT) Update

## CLIA rule revision accomplishments to date

Fall 2010	CLIAAC recommends 23 potential changes
Spring 2011	CDC developed a framework for inclusion of analytes/tests
Winter 2011	CDC compiled list of proposed analytes/tests to be added or removed, changes needed for microbiology
Spring 2012	CDC and CMS met with PT programs for consultation on proposed analyte changes, grading, and potential changes to microbiology PT <ul style="list-style-type: none"><li>- Narrowed the list of potential new analytes/tests based on feedback concerning cost, stability, scoring issues, etc.</li></ul>
Currently	CDC is developing proposed acceptance limits <ul style="list-style-type: none"><li>- Based on PT programs' data and/or biological variability</li><li>- Proposed limits will be tested and fine-tuned, in collaboration with PT programs</li></ul>

# PT Update: Laboratory Survey

- ❑ Internet-based survey targeting CLIA-certified laboratories that participate in PT
  - 20,500 Certificate of Compliance and 16,200 Certificate of Accreditation laboratories
- ❑ Purpose: systematic analysis to understand
  - How laboratories use PT for quality monitoring and improvement
  - PT practice variation by laboratory types
  - Need for educational materials to promote good PT practices
- ❑ Survey has been developed and pilot tested
- ❑ Proceeding with OMB clearance and anticipate a Spring 2013 launch

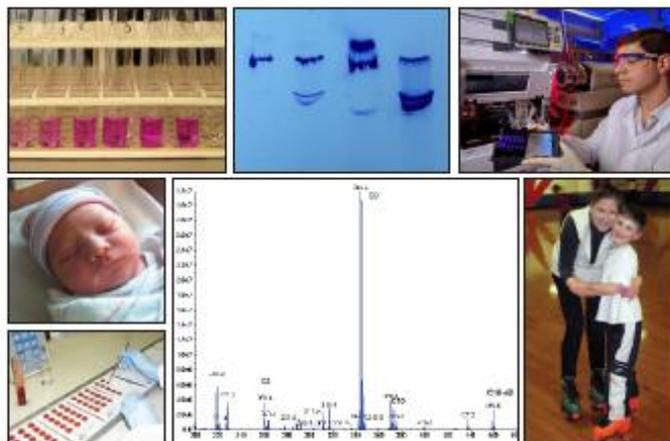
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# Genetic Testing Guidance

- ❑ MMWR publication April 6, 2012: “Good laboratory practices for biochemical genetic testing and newborn screening for inherited metabolic disorders”
- ❑ Web-based training course on good laboratory practices for molecular genetic testing for inherited disorders:
  - just released!
  - available at the following site: [www.nltn.org/321-12.htm](http://www.nltn.org/321-12.htm)
  - link is also available on CDC website: <http://wwwn.cdc.gov/clia/default.aspx>
- ❑ Guidance on technical aspects of quality management using next generation sequencing: publication in review

## Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders



### Clinical Laboratory Improvement Advisory Committee Biochemical Genetic Testing Good Laboratory Practices Workgroup (2009–2010)

**Chairperson:** Carol L. Greene, MD, University of Maryland School of Medicine, Baltimore, Maryland.  
**Members:** Bruce Barnhop, MD, PhD, University of California—San Diego, Rady Children's Hospital, San Diego, California; Michele Caggana, ScD, New York State Department of Health, Albany, New York; Joel Charrow, MD, Children's Memorial Hospital, Chicago, Illinois; Tina Cowan, PhD, Stanford University Medical Center, Stanford, California; Harry Hannon, PhD, Atlanta, Georgia; Julie Ann Neddich, MD, Quest Diagnostics—Nichols Institute, San Juan Capistrano, California; Stephen Raab, MD, University of Colorado Denver, Aurora, Colorado; David L. Smalley, PhD, Tennessee Department of Health, Nashville, Tennessee; Erin Strobel, PhD, University of Maryland School of Medicine, Baltimore, Maryland; V. Reid Sutton, MD, Baylor College of Medicine, Houston, Texas; Georgijne D. Vladuta, PhD, The Buffalo General Hospital, Buffalo, New York; Emily S. Wynn-Doen, PhD, RaDe Advisors, Livermore, California.

### Clinical Laboratory Improvement Advisory Committee (2010–2011)

**Chairperson:** Eliza Pastment, EdM, American Society for Clinical Laboratory Science, Bethesda, Maryland.  
**Members:** Ellen Baron, PhD, Stanford University Medical Center, Palo Alto, California; Christine Bean, PhD, New Hampshire Department of Health and Human Services, Concord, New Hampshire; Susan Cohen, Bethesda, Maryland; Judy Daly, PhD, Primary Children's Medical Center, Salt Lake City, Utah; Nancy Elder, MD, University of Cincinnati, Cincinnati, Ohio; Marilyn D. Francis, The MITRE Corporation, McLean, Virginia; John Fontana, PhD, University of California—San Diego, School of Medicine, San Diego, California; Julie Gaykin, HealthPartners and Regions Hospital, Bloomington, Minnesota; Geraldine Hall, PhD, Cleveland Clinic Foundation, Cleveland, Ohio; Carol L. Greene, MD, University of Maryland School of Medicine, Baltimore, Maryland; Norman Harbaugh, Jr., MD, Kids Health First Pediatric Alliance, Atlanta, Georgia; Lee H. Hiborne, MD, David Geffen School of Medicine at University of California—Los Angeles, Los Angeles, California; Paul Kinney, PhD, California Department of Public Health, Richmond, California; James Nichols, PhD, Baystate Medical Center, Springfield, Massachusetts; Gary Oversturf, MD, University of New Mexico School of Medicine, Albuquerque, New Mexico; Stephen Raab, MD, University of Colorado at Denver, Aurora, Colorado; Linda Sandhaus, MD, Case Western Reserve University Hospitals and Medical Center, Cleveland, Ohio; Paula Santrach, MD, Mayo Clinic, Rochester, Minnesota; Jared N. Schwartz, MD, Presbyterian Healthcare, Charlotte, North Carolina; David L. Smalley, PhD, Tennessee Department of Health, Nashville, Tennessee; Gail Vance, MD, Indiana University School of Medicine, Indianapolis, Indiana; Emily Wynn-Doen, PhD, RaDe Advisors, Livermore, California; Rosemary Zana, MD, The University of Oklahoma Health Science Center, Oklahoma City, Oklahoma.

**Designated Federal Officials:** Thomas L. Hearn, PhD, National Center for Emerging and Zoonotic Infectious Diseases, May Chu, PhD, Office of Surveillance, Epidemiology, and Laboratory Services, CDC, Atlanta, Georgia.

**Ex-Officio Members:** Alberto Gutierrez, PhD, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Maryland; Judith Yost, MA, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, Baltimore, Maryland; Devery Howerton, PhD, Office of Surveillance, Epidemiology, and Laboratory Services, CDC, Atlanta, Georgia.

**Liaison Representative:** Luann Ochs, MS, Advanced Medical Technology Association, Washington, DC.

# Feedback from MMWR Continuing Education Activity

- ❑ Participation to date:
  - Registered: 107
  - Completed: 69 (43% CEU, 33% CNE, 16% CME, 6% CHES)
- ❑ General comments and suggestions:
  - “The contents were very helpful”; “informative”; “excellent”; “great learning experience”; “keep up the great work”
  - “Would have liked to see more information on how to explain the lab practices for genetic testing/newborn screening in easier terms to patients/parents”
  - “a lot to absorb”; “hard to read”
  - “make it worth more CE hours”; “make the CE activity system more user-friendly”

# Feedback from MMWR Continuing Education Activity (continued)

## □ Changes to competence, skills, practice:

- “The document helped me improve my understanding of quality management of newborn screening testing”
- “After reading the materials I will start to collect newborn screenings on time”
- “better understanding of lab practice”
- “Enhanced my knowledge of newborn screening and how it relates to CLIA”
- “I am more aware of biochemical genetic testing and screening for newborns”
- “It reaffirmed my understanding of the quality practices required by NB Screening and assisted me with designing a performance validation protocol”
- “I have more knowledge of inherited metabolic diseases”

# Good Laboratory Practices for Molecular Genetics Testing

[fact sheets](#)   [course folders](#)   [exit](#)

HOME

INTRODUCTION 1

NEEDS AND  
REQUIREMENTS 2

PERSONNEL AND  
TEST METHODS 3

TEST PERFORMANCE  
VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY,  
REQUEST & REPORT 6

RETENTION AND  
ASSESSMENT 7

SUMMARY 8

# Good Laboratory Practices for Molecular Genetics Testing

[Start the course](#)



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fact sheets course folders exit

HOME

INTRODUCTION 1

NEEDS AND REQUIREMENTS 2

PERSONNEL AND TEST METHODS 3

TEST PERFORMANCE VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY, REQUEST & REPORT 6

RETENTION AND ASSESSMENT 7

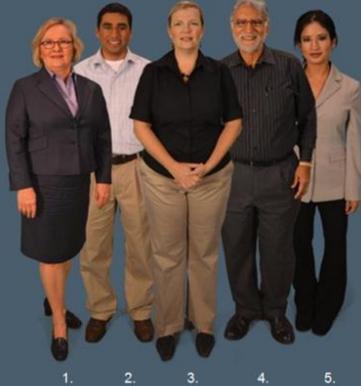
SUMMARY 8

Meet the team:

- Michelle Jones, MD is our laboratory director.
- Nicholas Greene, MD, PhD is fresh off a fellowship in medical genetics where he completed laboratory specialty training in molecular genetics and has just come to work for the hospital network.
- Julle Johnson, MT (ASCP) is your direct supervisor.

Also in your section are:

- Raja Parekh, MLT
- And
- Brianna Rossi, MT (ASCP)



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PREV PAGE NEXT PAGE

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fact sheets course folders exit

HOME

INTRODUCTION 1

NEEDS AND REQUIREMENTS 2

PERSONNEL AND TEST METHODS 3

TEST PERFORMANCE VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY, REQUEST & REPORT 6

RETENTION AND ASSESSMENT 7

SUMMARY 8

This is your workspace.

The folder below at your right contains resources referred to in this section. You will be able to save or download the information to your own computer.

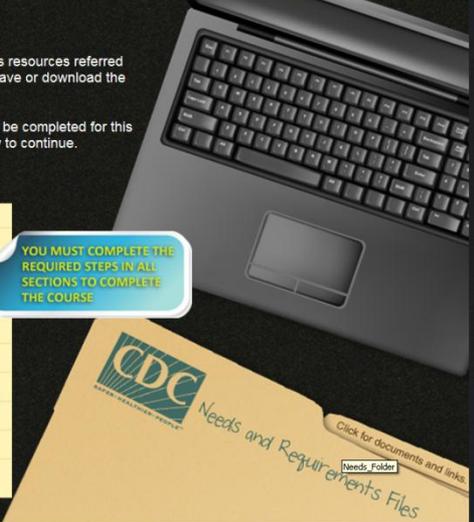
Below are required steps that need to be completed for this section. Select one of the steps below to continue.

*Required Steps*

- Check regulatory requirements
- Check your e-mail
- Check FDA list of approved tests
- Evaluate the laboratory space

**CONTINUE TO NEXT SECTION**

**YOU MUST COMPLETE THE REQUIRED STEPS IN ALL SECTIONS TO COMPLETE THE COURSE**



Click for documents and links

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fact sheets course folders exit

HOME

INTRODUCTION 1

NEEDS AND REQUIREMENTS 2

PERSONNEL AND TEST METHODS 3

TEST PERFORMANCE VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY, REQUEST & REPORT 6

RETENTION AND ASSESSMENT 7

SUMMARY 8

*Review Question*

True or False

The CLIA general QC requirements apply to molecular genetic testing for heritable diseases.

True

False

PREV PAGE NEXT PAGE

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fact sheets course folders exit

HOME

INTRODUCTION 1

NEEDS AND REQUIREMENTS 2

PERSONNEL AND TEST METHODS 3

TEST PERFORMANCE VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY, REQUEST & REPORT 6

RETENTION AND ASSESSMENT 7

SUMMARY 8

Needs and Requirements Files

The following resources pertain to this section of the course. You can save or download them to your own computer.

- Test information to Provide Users of Laboratory Services Link to CMS web site
- Unidirectional workflow for molecular amplification procedures Link to FDA web site
- CLIA Oversight for Molecular Genetic Testing
- E-mail from Dr. Greene

PREV PAGE

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# Good Laboratory Practices for Molecular Genetics Testing

fact sheets course folders exit

HOME

INTRODUCTION 1

NEEDS AND REQUIREMENTS 2

PERSONNEL AND TEST METHODS 3

TEST PERFORMANCE VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY, REQUEST & REPORT 6

RETENTION AND ASSESSMENT 7

SUMMARY 8

Dr. Jones: Dr. Greene, thank you for that summary. This checklist will be a great tool for any future projects too.

This has definitely been a team effort. Thank you all for your hard work.

**You have completed the course!**

Take the final exam



PREV PAGE

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# Good Laboratory Practices for Molecular Genetic Testing: Online Course

## □ Audience

- Laboratory professionals directing, supervising, or performing molecular genetic testing
- Laboratory professionals interested in molecular genetic testing for heritable diseases
- Healthcare professionals providing laboratory services for molecular genetic testing
- Clinical molecular genetic testing training programs

## □ Continuing Education Credits

- ASCLS P.A.C.E.® Program: 2.0 contact hours through APHL
- Florida Laboratory Licensees: 2.0 contact hours in Supervision Administration, Quality Control/Quality Assurance and Safety
- CME: 2.0 AMA PRA Category 1 Credits™ through CDC

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- ❑ Recognition of CLIAC's 20 years of service
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- ❑ Proficiency testing update
- ❑ Genetic testing guidance
- ❑ **Quality improvement research agenda**

# Quality Improvement Research Agenda

- ❑ Presentations/discussion tomorrow on two ongoing initiatives:
  - Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)
  - Laboratory Medicine Best Practices Program (LMBP)
- ❑ Developing plans for new projects to:
  - Evaluate uptake and impact of laboratory practice guidelines and best practice recommendations
  - Investigate novel pre- and post-analytic challenges for transitioning next generation sequencing into the clinical laboratory
  - Assess needs for patient education about laboratory testing
  - Evaluate cytology workload limits using semi-automated screening devices

# Questions for CLIAC Concerning Investigational Initiatives

- ❑ Provide feedback tomorrow on the CLIHC and LMBP initiatives
- ❑ What other research initiatives do you think could be conducted to improve the quality of laboratory services within the framework of the IOM improvement aims:
  - Safety
  - Patient-centeredness
  - Efficiency
  - Effectiveness
  - Timeliness
  - Equity

# QUESTIONS?

**For more information please contact Centers for Disease Control and Prevention**

1600 Clifton Road NE, Mailstop F-11, Atlanta, GA 30333

CLIA Information Line: 1-404-498-2290 TTY: 1-888-232-6348

E-mail: [CLIAC@cdc.gov](mailto:CLIAC@cdc.gov) Web: <http://wwwn.cdc.gov/cliac/default.aspx>

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.