

CDC Update

Clinical Laboratory Improvement Advisory Committee Meeting

February 14, 2012

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Office of Surveillance, Epidemiology and Laboratory Services



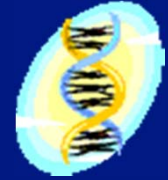
Topic Outline

- ❑ Standards, guidelines, reference materials
- ❑ Educational outreach
- ❑ Public health laboratory efficiency initiative

Standards, Guidelines and Reference Materials

- ❑ **Reference materials for genetic testing**
- ❑ **Next generation sequencing: guidelines for quality practices to transition into clinical testing**
- ❑ **Good laboratory practice recommendations for biochemical genetic testing & newborn screening**
- ❑ **CLIA requirements for proficiency testing**

Development of Reference Materials for Cytogenetic Microarray Analysis



Progress so far:

- ❑ Selected DNA from 95 Coriell cell lines containing common cytogenetic abnormalities
- ❑ **First 45 Samples:**
 - DNA was characterized using 4 commercial CMA platforms
 - Raw data was analyzed by 8 clinical cytogeneticists
 - A consensus genotype is being developed for each sample.
- ❑ **DNA from the remaining 50 samples is currently being characterized using the 4 commercial CMA platforms**

Next-generation Sequencing: Standardization of Clinical Testing (Nex- StoCT) Working Group

- ❑ **Next-generation sequencing for the clinical laboratory = cost-effective large scale sequencing (gene panels, whole genome, etc.)**
- ❑ **Applied to selection/evaluation of cancer modalities, rare disease diagnosis, and potential for other clinical applications**
- ❑ **Complex technology - How are regulations and professional standards to be applied?**
- ❑ **Nex-StoCT Working group established**



Next-generation Sequencing: Standardization of Clinical Testing (Nex- StoCT) Working Group

- ❑ **Face-to-face meeting (April 2011) + continued consultation**
 - 41 experts; focus on heritable conditions
 - Considered test validation, quality control, and proficiency testing/alternate assessment

- ❑ **Outcomes: Principles and Guidance**
 - Manuscript in preparation
 - Sharing outcomes with other national efforts (that include FDA, CLSI, CAP, ACMG, AMP)

- ❑ **Next steps:**
 - GeT-RM project to develop a clinically useful consensus human genomic sequence derived from characterized cell lines
 - Nex-StoCT 2 (planning in progress)

Good Laboratory Practice Recommendations for Biochemical Genetic Testing & Newborn Screening



- ❑ **2008-2009: Initial information review and assessment by CDC**
 - Gaps/concerns affecting quality of biochemical genetic testing (BGT) and newborn screening (NBS) for **inherited** disorders
- ❑ **2009-2010: Development of CLIAC Recommendations**
 - 2009: CLIAC BGT workgroup & Feb. 2010: CLIAC meeting
 - CLIAC recommendations(<http://wwwn.cdc.gov/cliac/default.aspx>)
- ❑ **2010-2011: Additional input to complement CLIAC recommendations** (SACGHS, SACHDNC, APHL)
- ❑ **2011-2012: Preparation & publication of CDC MMWR recommendation** - In press, expected April 2012

Proficiency Testing (PT) Status of Regulatory Revisions

- ❑ Developed draft list of analytes for which PT will be required and proposed changes to microbiology
- ❑ Determination of proposed criteria for acceptable performance (scoring schemes) in development
- ❑ Meeting planned with PT programs for March 13-14
 - Feasibility issues
 - Scoring schemes
- ❑ Regulatory impact analysis: survey of laboratories in collaboration with APHL to evaluate how PT is used

Educational Outreach

- ❑ Good laboratory practices for waived testing
- ❑ Evidence-based practice methods
- ❑ State training grants

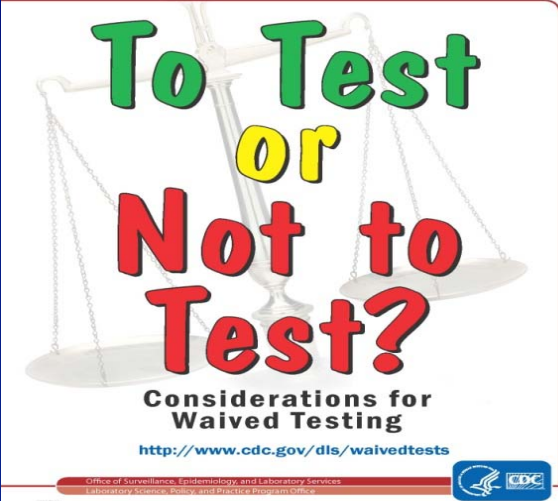
Ready? Set? Test! online training

- ❑ An online training module provides scenario based training and offers continuing education credit for physicians, nurses, pharmacists, and others
- ❑ October 14, 2011 training CDC Train link went "live" on www.cdc.gov/dls/waivedtests
- ❑ November 10, 2011 began email promotions
- ❑ Kentucky PH Dept requiring all laboratory testing personnel who perform waived testing to complete the training



Ready? Set? Test! Online Course			
Total Registered	1457	Credit Type	Total Hours Awarded
Completed	589	CEU/CE	35.8
In Progress	847	CME	5
Withdrawn	21	CNE Contact Hours	137

To Test or Not to Test? Considerations for Waived Testing booklet



Introduction

BACKGROUND
Health care providers use laboratory test results to diagnose disease, determine prognosis, and monitor a patient's treatment or health status. Current practice shows an increased trend for medical decisions based on simple tests performed at the point of care. Many of these test systems are waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and can be performed without routine regulatory oversight under a Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS).

PURPOSE
This booklet describes considerations and preparations needed prior to performing waived testing and may assist those who want to implement and oversee waived testing or offer a new test under a CLIA Certificate of Waiver.

Additional materials that may be useful:

- The **Ready? Set? Test!** booklet describes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver.
- The **Ready? Set? Test!** poster lists ten good practices for testing.
- The **Ready? Set? Test!** online training provides scenario based training on recommended practices for waived testing and offers continuing education credit.

These materials can be found here: <http://www.cdc.gov/dls/waivedtests/>

Although some of the recommendations in this booklet exceed CLIA requirements for waived testing, following these good testing practices will likely lead to reliable, high-quality test results, and will enhance patient safety.

Table of Contents

Introduction	9	Testing personnel	15
Background	3	Overview	15
Purpose	3	Choose the Right Employee	15
Overall considerations	7	Employee Training	15
Overview	7	Employee Performance	16
Benefits	7	Starting to test	17
Issues to Consider	7	Overview	17
 Oversight of testing	8	Manufacturer's Instructions	17
Overview	8	Procedures	17
Responsibility for Management	8	Quality assurance	19
Personnel Support	8	Overview	19
Regulatory requirements	9	Assessments	19
Overview	9	Tips	20
Waived Tests	9	Resources	21
CLIA Certificate of Waiver	9	Appendix A	23
State and Local Requirements	10	Appendix A1	28
Safety	10	Appendix A2	31
Requirements for Confidentiality and Patient Privacy	11	Appendix B	35
Location for testing	12	Appendix C	39
Overview	12	Appendix D	43
Environment	12	Appendix E	47
Waste Disposal	12	Appendix F	51
Selecting tests	13	Appendix G	53
Overview	13		
Test Characteristics	13		
Types of Samples	13		
Cost	14		

- ❑ **To Test or Not to Test?** booklet describes
 - considerations and preparations needed prior to performing waived testing
 - may assist those who want to implement and oversee waived testing or offer a new test under a CLIA Certificate of Waiver
- ❑ Now available for distribution
- ❑ Presentation topic at COLA Symposia April 2012
- ❑ You can request copies of the products and register for the training at WaivedTesting@cdc.gov or by calling 404-498-2290.

On-Line Training for Evidence-Based Laboratory Practice

- ❑ Module 1: An Overview of A-6 Methods- *in use by the laboratory community*
- ❑ Module 2: Key Steps in Planning Quality Improvement Projects – near completion
- ❑ Additional modules under consideration

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Laboratory Medicine Best Practices Initiative

Welcome to Module 1 The A-6 Cycle: Review and Evaluation Methods for Quality Improvement

This module is one of a multi-part tutorial intended to:

- Increase the awareness of the LMBP A-6 systematic evidence review methods
- Increase knowledge in the application of evidence-based principles to quality improvement projects

Target Audience

An important goal of this training is to reach those who provide approval or support for quality improvement (QI) projects, those who are active in the design and implementation of projects and those who contribute to QI projects.



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Information and Activities:

- Tutorials, technical reports, review findings
- Calls for evidence, calls for review topics
- Announcements of publications and meeting participation

The screenshot displays the website's header and navigation menu. The header includes the logo "LABORATORY MEDICINE Best Practices" and a login section with fields for "User Name" and "Password", and a "Log In" button. Below the header is a navigation bar with six orange buttons: "ABOUT US", "GET INVOLVED", "OUR METHODS", "OUR FINDINGS", "LEARNING", and "CONTACT US". The "GET INVOLVED" button is highlighted, showing a dropdown menu with five options: "Register", "Data Submission", "Suggest Topics", "Network", and "Public Comments". The main content area features a large image of a scientist in a white lab coat and purple gloves working in a laboratory. To the right of the image is a blue banner with the text "The Laboratory Medicine Best Practice Network" and a "REGISTER" button with a right-pointing arrow. Below the banner is an orange bar with the text "News and Announcements" and a right-pointing arrow. At the bottom of the page, there are three small colored circles: orange, yellow, and blue.

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News and Announcements

CLIA State Training Grants

- ❑ **Through the Association for Public Health Laboratories (APHL) Cooperative Agreement**
- ❑ **12 states awarded training grants in December 2011**
 - Purpose: develop and deliver training on CLIA-related topics and/or quality management systems
 - Target audience: clinical and/or physician office laboratories
- ❑ **Topics include:**
 - Good laboratory practices for waived testing
 - Proficiency testing participation for quality improvement
 - How to avoid the most common CLIA deficiencies
 - Competency assessment
 - Quality management systems
 - Use of CLSI guidelines for antimicrobial susceptibility testing

Public Health Laboratory Efficiency Initiative

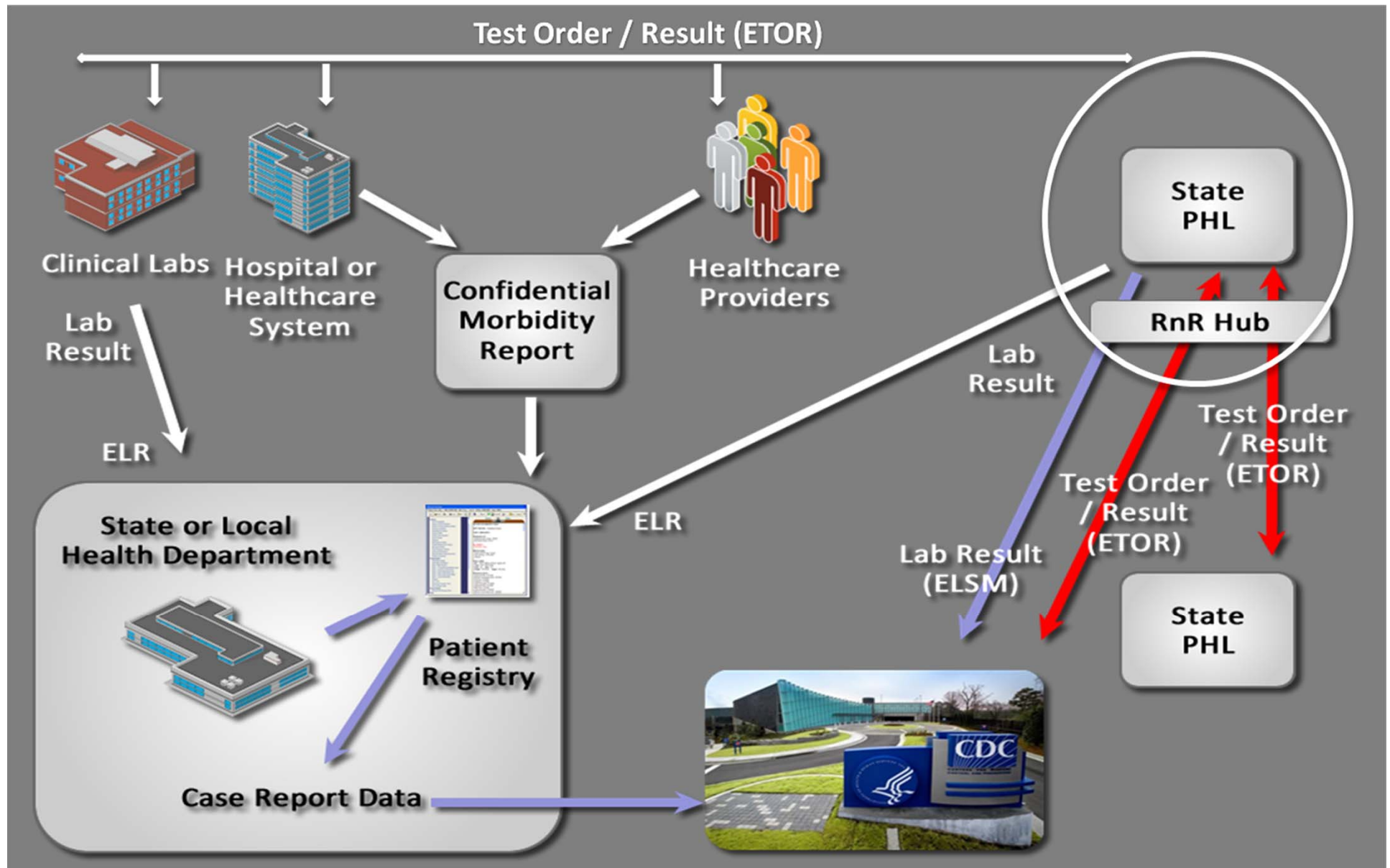
Laboratory Efficiencies Initiative (LEI): Addressing Today's Realities

- ❑ State public health (PH) laboratory budget cuts
- ❑ PH laboratories have lost staff
- ❑ Eliminated or reduced some testing services
- ❑ Ability to maintain services might impair
 - outbreak investigation,
 - emergency response,
 - surveillance, and
 - public health prevention programs

Laboratory Efficiencies Initiative (LEI) Operating Principles

- ❑ Collaborative effort among states, localities, APHL and CDC in sustaining PH testing services
- ❑ State-driven strategies to enable solutions within and between states and public health programs
- ❑ Assessment of alternative management practices to
 - identify other revenue sources
 - share/consolidate some services
 - increase efficiency, e.g., standardize platforms, streamline workflow, enhance informatics interoperability

The PHL e-health domain



Questions?

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.

Laboratory Science, Policy and Practice Program Office
Office of Surveillance, Epidemiology and Laboratory Services

