CDC Update

Devery Howerton, PhD
Deputy Director, Division of Laboratory Programs,
Standards and Services (proposed)

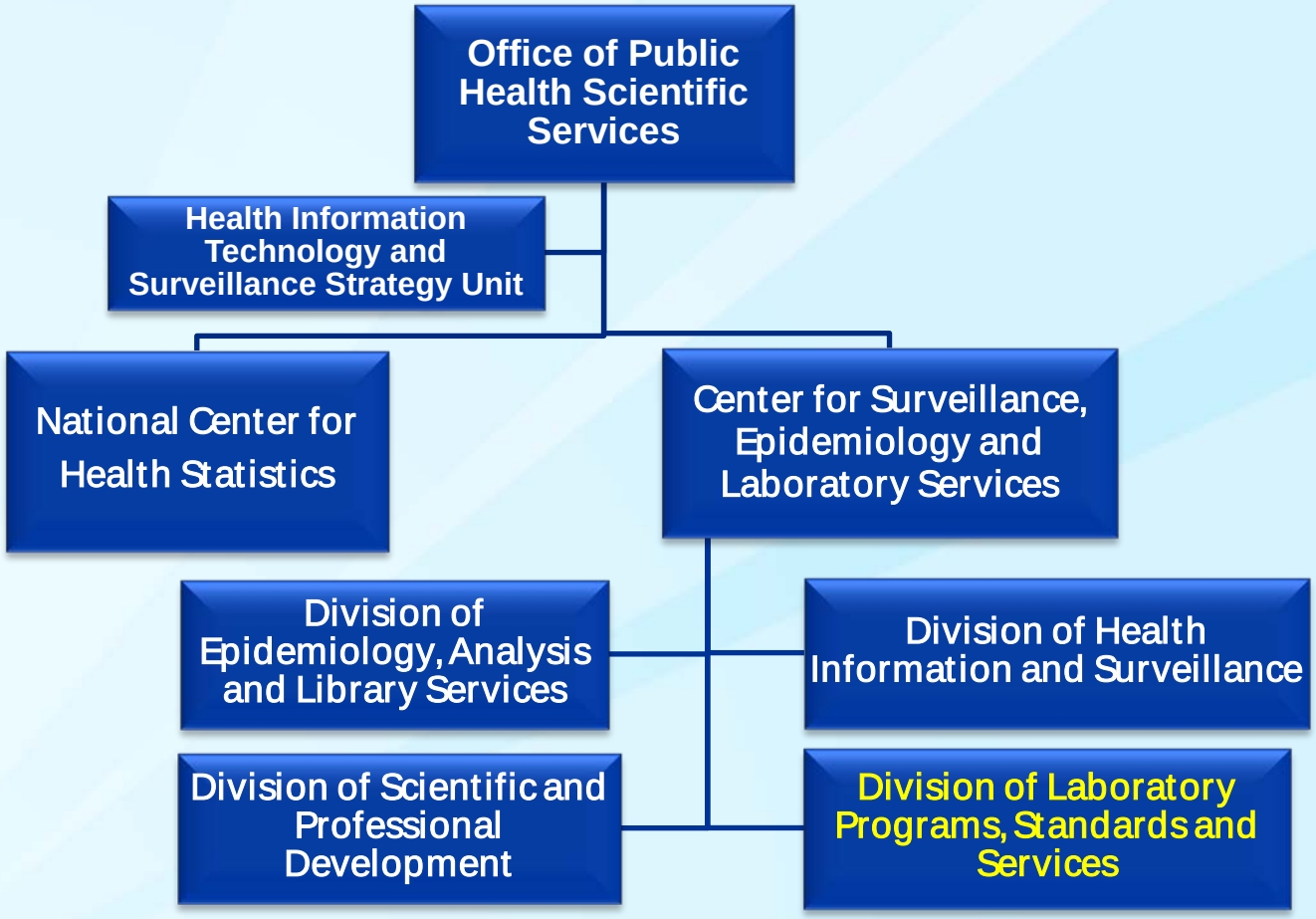
CLIAC Meeting
August 21, 2013
Atlanta, Georgia

Topic Outline

- Organizational structure
- Updated CDC CLIA website
- National proficiency testing survey
- Cytology workload assessment and measure
- Online courses/tutorials
- Evidence-based laboratory medicine
- Evaluating laboratory practice guidelines and recommendations
- Informatics self-assessment tool

Office of Surveillance, Epidemiology and Laboratory Services (OSELS)

Proposed Restructuring



Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
Proposed Restructuring

Updated CDC CLIA Website

CDC Home

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

Clinical Laboratory Improvement Amendments (CLIA)

- **CLIA Home**
- CLIA Law & Regulations
- CLIA History
- CLIAC
- Laboratory Search
- Test Complexities
- Links

CDC Home > LSPPPO Home

Email page link
Print page

Overview

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. CDC, in partnership with CMS and FDA, supports the CLIA program and clinical laboratory quality.

Contact Us:

Centers for Disease Control and Prevention, Division of Laboratory Science and Standards
1600 Clifton Road
Mailstop F-11
Atlanta, GA 30333, USA

800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348
CLIA Direct Line:
404-498-2290

Regulatory

CLIA Law & Regulations
View Clinical Laboratory Improvement Amendments of 1988 and the regulations applicable to all U.S. clinical laboratories

CLIA History
Search and view historical regulations and announcements related to CLIA

CLIAC
Visit CLIA's Federal Advisory Committee website for information on the Committee and their meetings

Resources

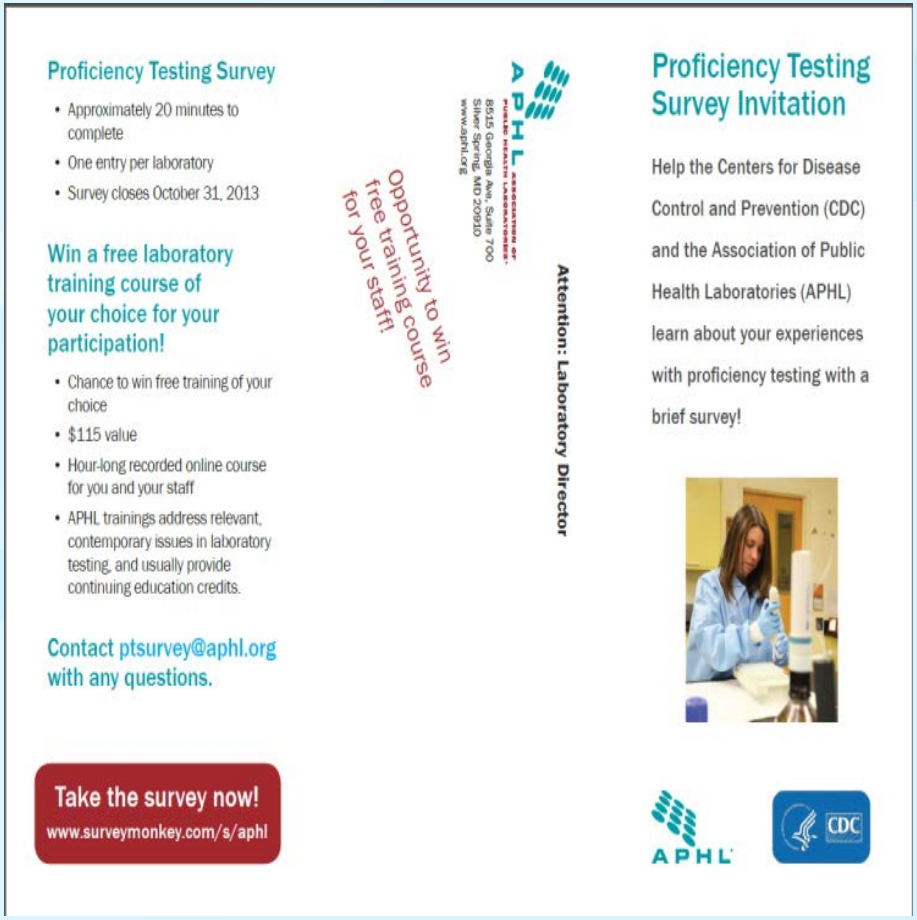
Laboratory Search
Look up demographic information on CLIA-certified clinical laboratories

Test Complexities
Learn how laboratory tests are evaluated by the FDA and how the CLIA regulations apply to different groups of tests

Links
Access laboratory related organizations and resources

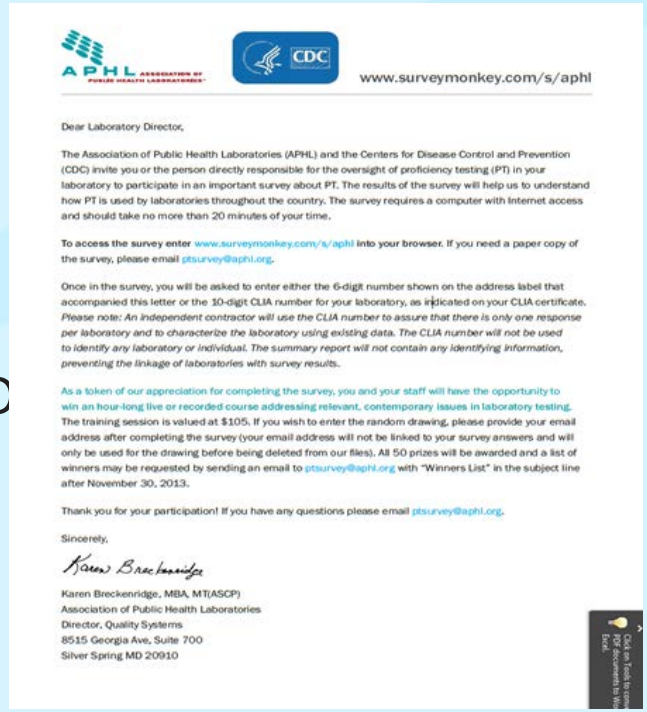
National Proficiency Testing (PT) Survey

- **Anonymous survey conducted in collaboration with APHL now open!**
- **Purpose**
  - Gather information to understand how laboratories use PT and perceive its value
  - Identify the types of laboratories that would benefit from additional information regarding PT
  - Determine if there is a need for educational materials



National PT Survey (cont.)

- Invitational letters sent to directors of approximately 34,000 Certificate of Accreditation/Certificate of Compliance laboratories in late July 2013
- One entry per laboratory
- Promotion
  - Articles to be published in MLO and Clinical Microbiology Newsletter
  - Advertisements in CAP Today and MLO
- Access survey at:
  - www.surveymonkey.com/s/aphl
- Email inquiries to:
  - ptsurvey@aphl.org



APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

CDC

www.surveymonkey.com/s/aphl

Dear Laboratory Director,

The Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC) invite you or the person directly responsible for the oversight of proficiency testing (PT) in your laboratory to participate in an important survey about PT. The results of the survey will help us to understand how PT is used by laboratories throughout the country. The survey requires a computer with Internet access and should take no more than 20 minutes of your time.

To access the survey enter www.surveymonkey.com/s/aphl **into your browser.** If you need a paper copy of the survey, please email ptsurvey@aphl.org.

Once in the survey, you will be asked to enter either the 6-digit number shown on the address label that accompanied this letter or the 10-digit CLIA number for your laboratory, as indicated on your CLIA certificate. *Please note: An independent contractor will use the CLIA number to assure that there is only one response per laboratory and to characterize the laboratory using existing data. The CLIA number will not be used to identify any laboratory or individual. The summary report will not contain any identifying information, preventing the linkage of laboratories with survey results.*

As a token of our appreciation for completing the survey, you and your staff will have the opportunity to win an hour-long live or recorded course addressing relevant, contemporary issues in laboratory testing. The training session is valued at $105. If you wish to enter the random drawing, please provide your email address after completing the survey (your email address will not be linked to your survey answers and will only be used for the drawing before being deleted from our files). All 50 prizes will be awarded and a list of winners may be requested by sending an email to ptsurvey@aphl.org with "Winners List" in the subject line after November 30, 2013.

Thank you for your participation! If you have any questions please email ptsurvey@aphl.org.

Sincerely,

Karen Breckenridge

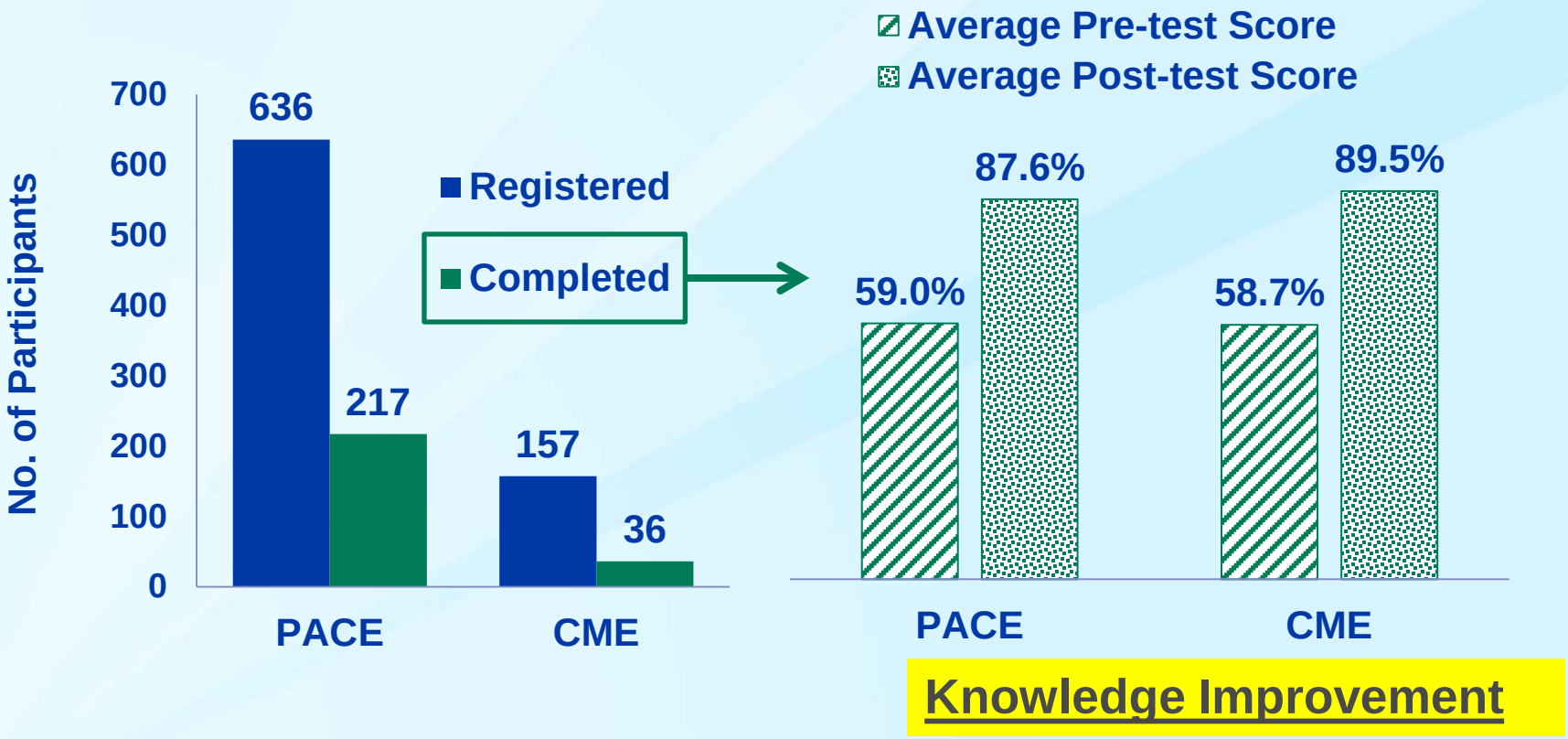
Karen Breckenridge, MBA, MT(ASCP)
Association of Public Health Laboratories
Director, Quality Systems
8515 Georgia Ave, Suite 700
Silver Spring MD 20910

Cytology Workload Assessment

- **Contract to be awarded to assess workload for both of the FDA-approved image-assisted slide screening systems**
  - Year 1: Survey laboratory and cytotechnologists regarding practices for cytotechnologist workload assessment and limits
  - Year 2: Collect time measurement data for cytotechnologists screening Pap test glass slides using an automated review microscope
- **Contract solicitation closes August 21, 2013**

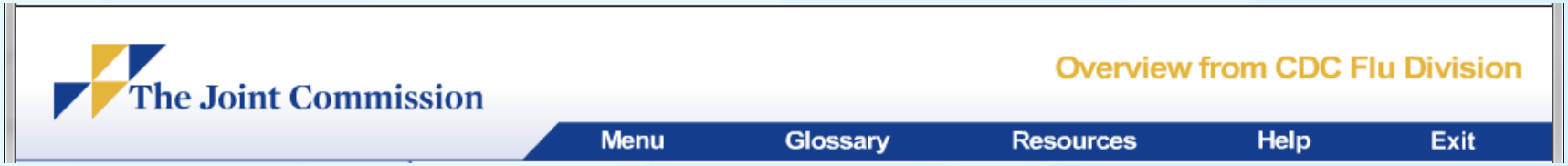
Update on Good Laboratory Practices for Molecular Genetic Testing Online Course

09/2012 - 06/2013



Knowledge Improvement

Update on Strategies for Improving RIDT in Ambulatory Settings (SIRAS) Online course



Uptake: mid-October 2012 launch through June 2013

5495	hits to the SIRAS website
1287	registered for Module I course (462 completions, 36%)
278	viewed the specimen collection module, Module II
11,880	viewed the specimen collection videos on YouTube

Impact: through June 2013 (completed course responses)

99%	course was useful
97%	improved understanding of subject
36%	planned to change practice
45%	course validated current practices

Next steps:

- dividing course content into shorter learning components
- broader dissemination & content updates

LMBP™* *New* Online Tutorial Released

07/2013

- Practical steps to design and implement evidence-based QI studies
- Module accesses published journal articles, templates, websites
- CME, CEU, CECH credits available

*Laboratory Medicine Best Practices

https://www.futurelabmedicine.org/tutorials/

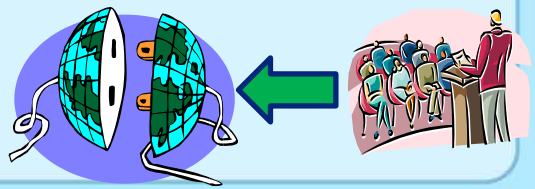
LMBP™ Systematic Reviews

- **Biomarkers and Risk of Cardiovascular Disease:** Effective biomarkers to improve risk stratification of populations at risk for cardiovascular events (using the Framingham Risk Score for myocardial infarction and death)
- **Coagulation Testing:** Coagulation Test Screening of Pre-surgical, Emergency Department or ICU Patients
- **Red Blood Cell (RBC) Transfusion Utilization:** Effective practices for utilization of red blood cell transfusions in surgical patients and non-surgical adult patients with anemia
- **ASM-CDC Urine Specimen Transport:** Effective practices for pre-analytical phase of laboratory testing for urinary tract infections

https://www.futurelabmedicine.org/get_involved/data_submission/

Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™)

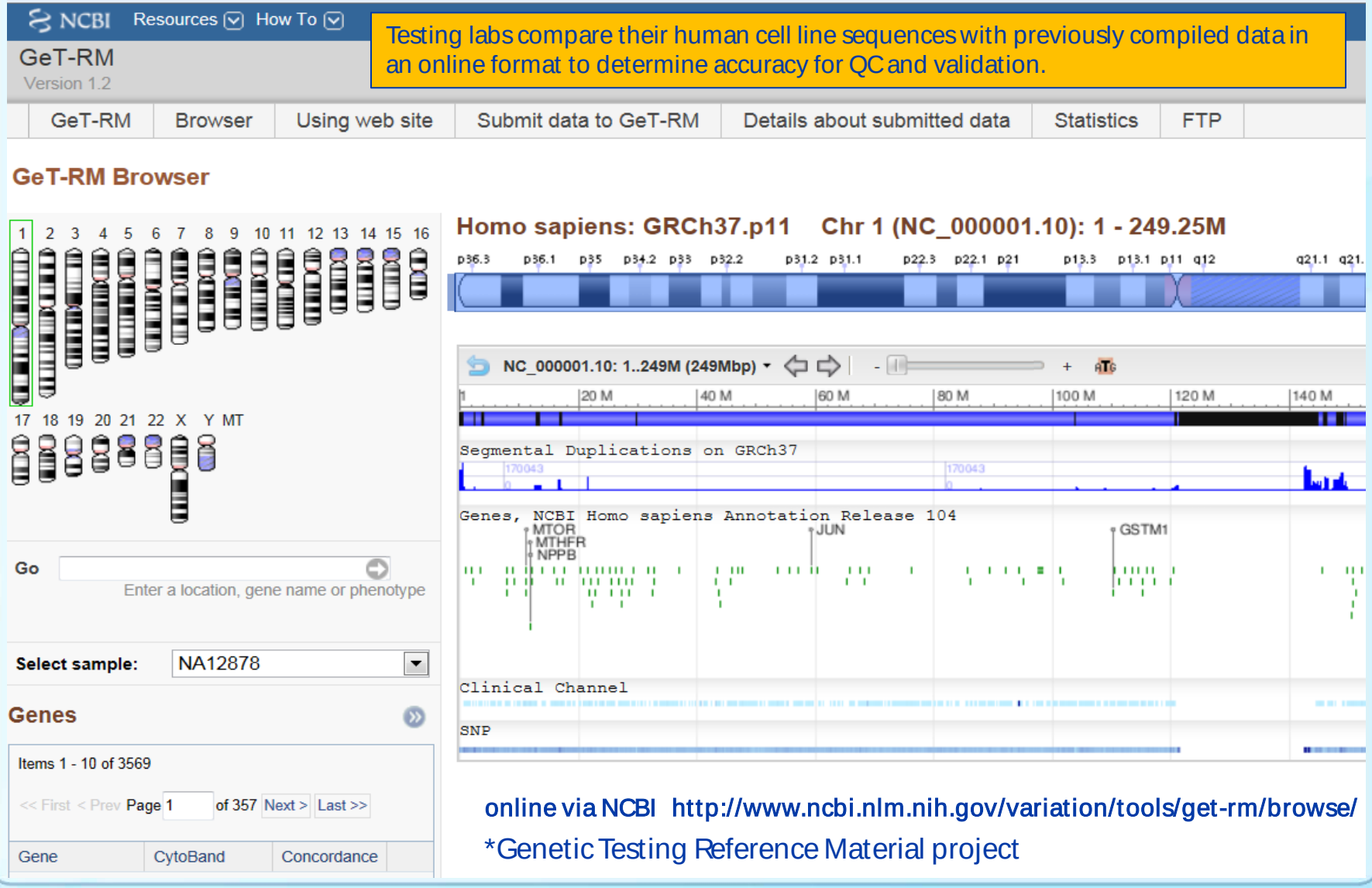
- Developed new strategic goals
  - Assist laboratories by defining more effective communication strategies with physicians (e.g., consultation services, diagnostic management teams, result reporting models)
  - Improve utilization of clinical laboratory services by integrating electronic tools into the EHR (e.g., test algorithms, clinical decision support, consultation alerts)
  - Broaden scope of communication and enhance collaboration in development of CLIHC™ products (e.g., with informatics experts, messaging media, evaluation studies of impact)
- Build on CLIHC™ achievements
  - identifying physician challenges with test ordering, interpretation, nomenclature
  - algorithm design and integration into the EHR



Genetics Publications

- Lisa Kalman, et al. **Development of a Genomic DNA Reference Material Panel for Myotonic Dystrophy type 1 (DM1) Genetic Testing**. J Molec Diag 2013 15:518-525
- Lisa V. Kalman, et al. **Current Landscape and New Paradigms of Proficiency Testing and External Quality Assessment for Molecular Genetics**. Arch Pathol Lab Med 2013 137:983-998
- Book Chapter: Lubin IM, Kalman L, Gargis AS. **Guidelines and Approaches to Compliance with Regulatory and Clinical Standards: Quality Control Procedures and Quality Assurance**. *In* Translational Next Generation Sequencing, edited by Lee-Jun C. Wong. Elsevier, (2013)

GeT-RM* and Next-Generation Sequencing, Virtual Reference Material tool –

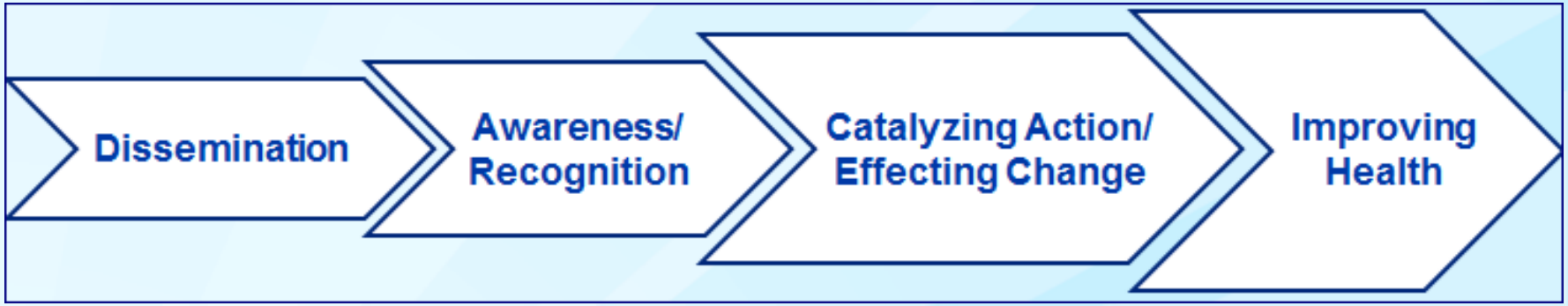


online via NCBI http://www.ncbi.nlm.nih.gov/variation/tools/get-rm/browse/

*Genetic Testing Reference Material project

Evaluating the Effectiveness & Impact of CDC Recommendations

- Conceptual model for progression of science impact*



- Recognizes impact at distinct, consecutive stages
- Guides identification of indicators for each stage
- Guides systematic evaluation of science impact

* Based on CDC Science Impact Framework , developed by extending IOM “Degrees of Impact” model

Studies to Evaluate Laboratory Practice Recommendations and Guidelines

- Evaluate the effectiveness of implementation of recommendations in laboratory settings with measured changes: Do they make a difference?
- Three pronged approach for evaluation:
  - Evidence-based, LMBP™ recommendation to reduce hemolysis of clinical specimens (1 site)
  - Framework to measure impact of good laboratory practices for biochemical genetics and newborn screening (CDC MMWR - from CLIAC recommendations) (1 organization)
  - Promoting impact assessments of national laboratory organizations' laboratory practice guidelines (3 organizations)

Informatics Self-Assessment Tool

for Public Health Laboratories 2013

APHL Association of Public Health Laboratories

LEI Laboratory Efficiencies Initiative
Transforming to a Sustainable Public Health Laboratory System

CDC Centers for Disease Control and Prevention

Tool Highlights

- Developed as a collaboration between CDC and APHL
- To assist state and local public health laboratories (PHL) in assessing their own informatics capabilities and gaps across a broad range of topics
- Not a survey, no information is collected
- Not limited to use by informatics experts or PHLs
- Flexible, generalizable and applicable to clinical laboratories
- Supports the long term goal/strategy of moving toward greater interoperability and harmonization
- Available on the APHL website: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Pages/Informatics.aspx

Informatics Capability Areas

Table 1: 19 Capability Areas

CA #1	Laboratory Test Request and Sample receiving
CA #2	Test Preparation, LIMS Processing, Test Results Recording and Verification
CA #3	Report Preparation and Distribution
CA #4	Laboratory Test Scheduling
CA #5	Prescheduled Testing
CA #6	Specimen and Sample Tracking/Chain of Custody
CA #7	Media, Reagents, Controls: Manufacturing and Inventory
CA #8	Interoperability and Data Exchange
CA #9	Statistical Analysis and Surveillance
CA #10	Billing for Laboratory Services
CA #11	Contract and Grant Management
CA #12	Training, Education and Resource Management
CA #13	Laboratory Certifications/Licensing
CA #14	Customer Relationship Management
CA #15	Quality Control (QC) and Quality Assurance (QA) Management
CA #16	Laboratory Safety and Accident Investigation
CA #17	Laboratory Mutual Assistance/Disaster Recovery
CA #18	Core IT Services: Hardware, Software and Services
CA #19	Policies and Procedures, including Budgeting and Funding

Laboratory Self-Assessment Benefits

- Enhance basic understanding of laboratory informatics processes and efficiencies
- Monitor informatics capabilities by repeating the assessment at desired intervals
- Use assessment findings to develop policies and inform management of needed IT improvements and projected costs
- Prioritize use of existing resources

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333
Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
Visit: www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info