



# CDC Update

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**Director, Division of Laboratory Systems**

CLIAC Meeting

November 2, 2016

Atlanta, GA

# Highlights of Recent DLS Activities

- Proficiency Testing Proposed Rule Update
- Improving Waived Testing Performance and Outcomes Through Partnerships
- Using Medical Data Warehouse to inform Laboratory Quality Improvement Initiatives to Improve Health Outcomes
- Laboratory Health Information Technology (LabHIT)
- CDC/FDA/NLM/ONC/CMS Semantic Interoperability Public Workshop
- Laboratory Medicine Best Practices (LMBP™) Initiative
- Laboratory Practice Guidelines Metrics Projects
- New - Waived Testing Self Assessment Checklist
- Distribution of Waived Testing, Provider-Performed Microscopy Procedures, and IQCP Educational Materials
- Clinical Laboratory Integration into Healthcare Collaborative ( CLIHC™)
- Genetic Testing Reference Material (GeT-RM) Program
- The CDC and ASTDR Specimen Packaging Inventory and Repository (CASPIR)
- Laboratory Training Website

# Proficiency Testing Proposed Rule Update

- Identified candidate analytes and changes to propose for microbiology
  - Based upon a process using criteria recommended by CLIAC in September 2010
- Developed and proposed acceptance limits (AL) for PT program simulation
  - For new and some existing analytes (non-microbiology)
  - Proposed ALs were based on clinical needs for diagnosis and monitoring as reflected in biological variability
  - Impact of 2 - 3 proposed ALs were simulated per analyte by PT programs using real PT results from 2011-12, peer grouped as usual
  - CDC refined the proposed limits and added some concentration-based limits for 2<sup>nd</sup> round of simulations from 2013-14

# Proficiency Testing Proposed Rule Update

- Recent PT regulation revision activities
  - PT programs recently provided 2<sup>nd</sup> round of PT simulations
  - CDC and CMS are collaborating to finalize proposed ALs for 80+ analytes
  - CDC is finalizing Regulatory Impact Analysis
- Future PT regulation revision activities
  - CDC and CMS will complete proposed rule draft and clear through HHS
  - Federal Register publication of proposed rule with request for comments
  - Comment analysis and development/publication of final rule for implementation

# Improving Waived Testing Performance and Outcomes Through Partnerships

- A 5-year cooperative agreement was awarded to COLA Resources, Inc. (CRI®) beginning October 1, 2016
- The project is intended to support and expand the efforts of stakeholder partners such as the CDC, the Centers for Medicare and Medicaid Services (CMS) and others to instill quality practices and recommendations at CW sites in order to improve patient safety and health outcomes.

<http://www.criedu.org/cri-receives-1-5-million-cooperative-agreement-award-improve-waived-testing-practices/>

# Improving Waived Testing Performance and Outcomes Through Partnerships

- As part of the grant project, CRI will:
  - Develop and/or expand systems, including a special information portal, which will include information on regulatory requirements and good laboratory practices; training/ educational materials; and quality improvement (QI) tools and resources
  - Conduct assessments on practices and waived testing performance in CW sites to identify areas needing improvement
  - Increase CW sites' participation in quality assessment and QI activities
  - Long-term, the project is intended to decrease inappropriate performance and use of waived tests at CW sites, and to improve the use of waived test results for making healthcare decisions

# Using Medical Data Warehouse to Inform Laboratory Quality Improvement Initiatives to Improve Health Outcomes

3 Cooperative Agreement Awards (Begin ~ Oct. 1, 2016 for 3 years)

- Kaiser Foundation, Denver Colorado
- Children's Mercy Hospital, Kansas City, Missouri
- University of Alabama School of Medicine,  
Birmingham, Alabama

CDC, through the Division of Laboratory Systems, will be actively collaborating with each of these awardees to leverage and disseminate findings for nationwide benefit

# Improving Data-driven Processes and Assessment to Assure Optimal Cost-effective Health Outcomes

Entry to  
Medical System



- Data:**
- Clinical workup
  - Test Ordering
  - Specimen Collection
  - Costs / Recovery
  - Method(s) used
  - Analysis
  - Reporting
  - Costs / Recover
  - Interpretation
  - Management Decisions
  - Costs / Recovery



- Analysis:**
- Health benefits, impact on morbidity and mortality
  - Process mapping, efficiencies, and shortcomings
  - Cost effectiveness

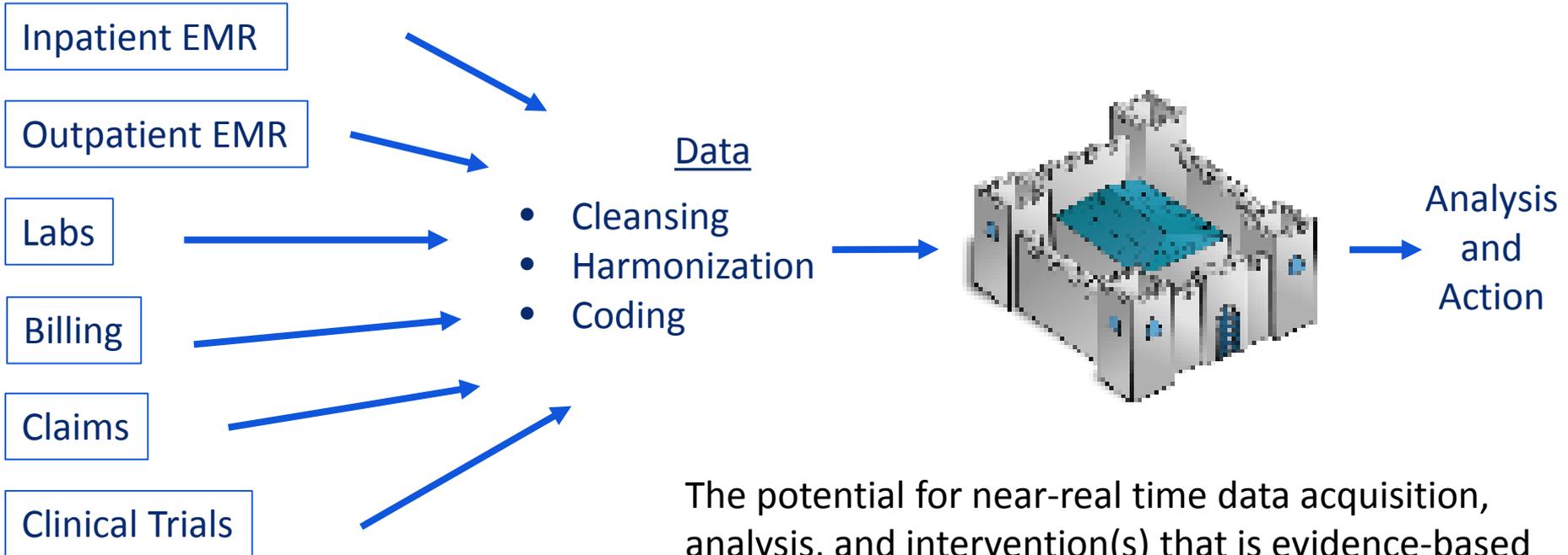


**Interventions:**  
Improve healthcare delivery



# The Usefulness of a Medical Data Warehouse

Electronically linked healthcare delivery and payment data housed in a secure electronic repository



The potential for near-real time data acquisition, analysis, and intervention(s) that is evidence-based

# Topics Under Consideration for Use of a Medical Data Warehouse to Inform Laboratory Quality Improvement Initiatives

- Topics under consideration for studies (examples)
  - Duplicate testing
  - Appropriate test selection and ordering
  - Specimen collection
  - Blood culture contamination
  - Discordance of antibiotic resistance results and prescription practice
  - Reflex testing
  - Timely result reporting
  - Time to diagnosis
  - Time to treatment
  - Patient comprehension of test results

# Laboratory Health IT (LabHIT)

- Provided presentation at NIST Workshop titled, “Enabling Reporting of Patient Safety Events to Improve Health IT” (September 7, 2016)
- FDA data for EHR related health IT events between 2010-2016 identified:
  - 3 deaths
  - 85 injuries
  - 23 malfunctions
- Preliminary data suggest “Notifications” are a high risk area
  - Data of consequence deposited in record without notification
  - Example: Patient with standing potassium orders with new reports of normal or elevated potassium results going unnoticed, leading to overdose

See CDC LabHIT website for the NIST presentation and other interoperability and coding related publications available online:

<http://www.cdc.gov/labhit/>

# Laboratory Health IT (LabHIT)

- FDA data also revealed numerous reports of IVD data manager related events when extracting keywords for LIS and “laboratory information system” related health IT events
- Data searches for “LIS” and “Laboratory Information System” between 2010-2016 (this data was not included in the EHR related data presented at NIST workshop):
  - 10 deaths
  - 55 injuries
  - 722 malfunctions
  - 95 NA & other
- Events occurred across multiple vendors and devices
- Opportunity for more analysis to identify patterns and potential mitigations to prevent patient safety events

# CDC/FDA/NLM/ONC/CMS Semantic Interoperability Public Workshop

## Public Workshop - Workshop on Promoting Semantic Interoperability of Laboratory Data, November 8, 2016

- CDC, FDA, the National Library of Medicine (NLM) of the National Institutes of Health (NIH), the Office of the National Coordinator for Health Information Technology (ONC), and the Centers for Medicare and Medicaid Services (CMS) are announcing the following public workshop entitled "CDC/FDA/NLM/ONC/CMS Workshop on Promoting Semantic Interoperability of Laboratory Data." The purpose of this public workshop is to receive and discuss input from stakeholders regarding proposed approaches to facilitate the adoption and implementation of interoperability standards in a manner that enables consistent, accurate, and harmonized descriptions of *in vitro* diagnostic tests and results.

### Date, Time and Location

- This meeting will be held November 8, 2016, beginning at 8:00 am – 5:00 pm at the following location:  
**National Institutes of Health (NIH) Campus**  
**8600 Rockville Pike**  
**Bldg. 38A, Lister Hill Auditorium**  
**Bethesda, MD, 20894**
- To register for the meeting and view the meeting agenda: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm523316.htm>

# FDA/CDC/NLM Semantic Interoperability Public Comments

## Comments that address industry concerns:

- Should not be an FDA mandated regulated activity
- Need a specified disclaimer (address product promotion concerns)
- Industry-defined publishing format, not in product insert
- Focus should be on LOINC<sup>®</sup> first; two years to implement
- Should not expand the FDA's Global Unique Device Identification Databases (GUDID) deadlines
- Regenstrief review to promote consistency
- Generic codes could be used to allow for different uses

# FDA/CDC/NLM Semantic Interoperability Public Comments

## Comments that address laboratory concerns:

- Suggest formation of a standard coding review committee
- Define format/structure for vendors to describe coding
- Support all federal agencies' use of same standards
- Continue evaluation of Unified Code for Units of Measure (UCUM<sup>®</sup>)
- Sustainability and maintenance issues
- Issues around coding of molecular tests
- Need to make it easier to select correct code from many

# Laboratory Medicine Best Practices (LMBP™) Initiative

- Supported and managed by DLS, CDC
- Began in 2006, CDC convened the Laboratory Medicine Best Practices Workgroup (LMBP™ WG)
- LMBP Workgroup panel, a multidisciplinary advisory panel includes 13-15 invited experts
- The LMBP Workgroup is supported by a LMBP™ team, Laboratory Research and Evaluation Branch (LREB), DLS, CDC



# LMBP™

LMBP™ Initiative serves as a resource to

- Establish and use systematic review methods (LMBP™ A-6 Methods)
- Evaluate evidence of laboratory practice effectiveness, especially in the pre-and post-analytic phases
- Develop and disseminate evidence-based LMBP™ Workgroup recommendations for best laboratory practices among laboratory professionals and healthcare stakeholders that allow them to:
  - Determine the strength of evidence for “what works”
  - Inform clinical decision-making
  - Improve patient care and outcomes by implementation of effective practices
- Develop online tutorials about LMBP A-6 methodology



# LMBP™ Projects

Completed and ongoing reviews to evaluate the effectiveness of best laboratory practices

## *Pre-analytic practices*

Practices to reduce:

- Blood Culture Contamination (2012)
- Patient Misidentification: Barcoding (2012)
- Hemolyzed Blood Specimens (2012)
- Blood Stream Infections (2015)
- Patient Misidentification Due to Specimen Labeling Errors (2016)

# LMBP™ Projects

**Completed and ongoing reviews to evaluate the effectiveness of best laboratory practices**

## ***Pre-analytic practices:***

Practices to identify right test ordering:

- Cardiac Biomarkers and other practices to detect MI in ED (2015)
- Lipid Biomarkers to detect CVD events (2016)
- Best practices for accuracy of urine culture microbiology testing (2015)
- Test utilization: Practice(s) laboratories use to support and optimize appropriate laboratory test order utilization (Ongoing)
- C. difficile: Laboratory practices for accurate and rapid diagnosis of C. difficile infection (Ongoing)
- Pre-surgical coagulation testing: Practices for reducing non-essential coagulation testing in non-emergency settings (Ongoing)

# LMBP™ Projects

**Completed and ongoing reviews to evaluate the effectiveness of best laboratory practices**

***Post-analytic practices:***

- Practices for timely and accurate reporting of critical values (2012)
- Results pending at discharge (2015)
- Laboratory trigger tools: Laboratory practices to decrease medication errors and adverse events related to inappropriate, delayed or inadequate follow up of laboratory results (2016)

***Cross cutting topics:***

- Red blood cell utilization: Practices to reduce over-utilized RBC transfusions in surgical and non-surgical patients
- Antibiotic resistance: Practices that promote the appropriate use of antimicrobials (including antibiotics) to reduce microbial resistance

# LMBP™ Projects

## Recommendation updates:

Three recommendation updates in progress:

- Patient Specimen Misidentification: Barcoding (2012)
- Practices for Timely and Accurate Reporting of Critical Values (2012) in collaboration with AACC
- Blood Culture Contamination (2012) in collaboration with ASM

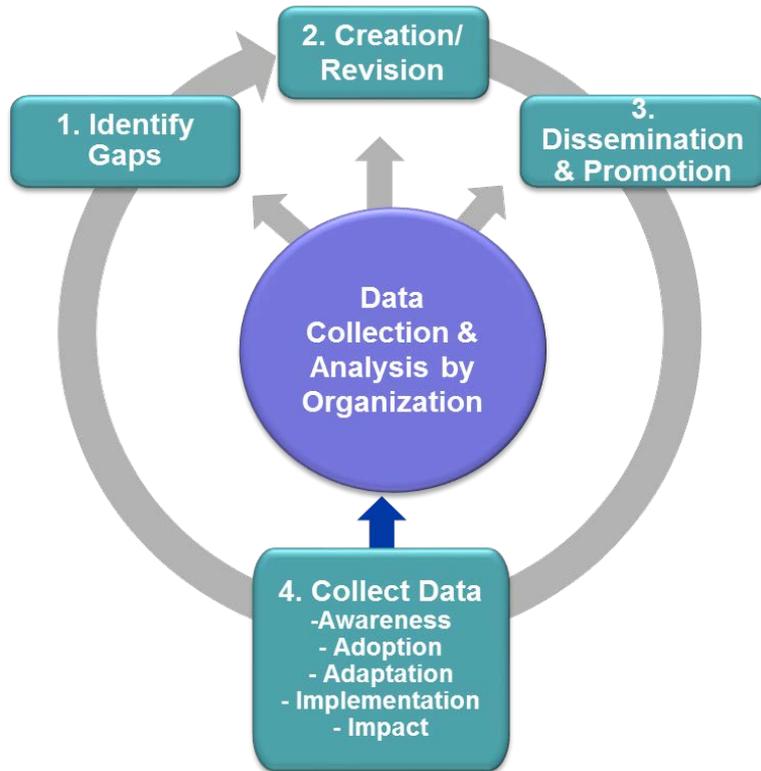
## Educational Training Modules:

- Module 1: The A-6 Cycle: Review and Evaluation Methods for Quality Improvement
- Module 2: Application of Laboratory Medicine Best Practices Initiative (LMBP™) A-6 Methods for Laboratory Practitioners

# LMBP™ Publications in 2015-2016

- *Lipoprotein Biomarkers and Risk of Cardiovascular Disease: A Laboratory Medicine Best Practices (LMBP) Systematic Review; JALM . September 2016. 214–229. 01:02*
- Effectiveness of preanalytic practices on contamination and diagnostic accuracy of urine cultures: a laboratory medicine best practices systematic review and meta-analysis. *Clin Microbiol Rev. Jan 2016; 29:105–147. doi:10.1128/CMR.00030-15*
- *Effectiveness of practices to increase timeliness of providing targeted therapy for inpatients with bloodstream infections: a laboratory medicine best practices systematic review and meta-analysis. Clin Microbiol Rev. November 2015; 29:59–103. doi:10.1128/CMR.00053-14*
- Effectiveness of Practices for Improving the Diagnostic Accuracy of Non-ST Elevation Myocardial Infarction in the Emergency Department: A Laboratory Medicine Best Practices Systematic Review; *Clin Biochem. 2015 March ; 48(4-5): 204–212. doi:10.1016/j.clinbiochem.2015.01.014*

# Laboratory Practice Guidelines (LPG) Metrics Projects



## Project Goals

- Improve uptake and use of LPGs
- Identify gaps in awareness/use
- Partners develop metrics to better understand gaps and strategies to address them
- Self-assess their guideline SOPs and use AGREE II tool to assess quality of representative LPGs to learn how to improve them
- Create lasting organizational changes towards use of metrics-based LPG creation, dissemination and promotion

# LPG Metrics Awardees' Projects



- Evaluate two point-of-care (POC) glucose monitoring LPGs - with (POCT 12) and without (POCT 13) laboratory support
- Survey sent to 30,000 waived and non-waived testing sites: half physician office laboratories (POLs) (POCT 13), half hospital and clinic labs (POCT 12)
- Findings:
  - About 50% were aware of CLSI, but a smaller percent were aware of the finger stick glucose LPGs
  - POCT 12 and POCT 13 were considered too expensive by 82%
  - Respondents would like companion documents included in price
  - Free copies of POCT 12 or POCT 13 were provided to survey recipients who indicated that they are not familiar with them. These respondents will be resurveyed after six months

# LPG Metrics Awardees' Projects



- Second Survey – planned for October 2016
  - Sent to recipients who received free copies of POCT12 and POCT 13 following first survey
- Second Survey will examine:
  - Reasons for modification or non-implementation of recommendations
  - Opinion of document such as ease of use, reading level, utility
  - Whether implementation of recommendations resulted in reduced errors or reduced need for additional tests
  - Suggested changes that would make document easier to use

# LPG Metrics Awardees' Projects



## Immunohistochemistry (IHC) Assay Validation

- Two manuscripts are near completion and pending submission:
  - *Analytic Validation of Immunohistochemical Assays: A Comparison of Laboratory Practices Before and After Introduction of an Evidence-Based Guideline*
    - Compared to the 2010 baseline survey, the 2015 survey showed significantly improved validation practices for IHC testing since publication of the 2014 evidence-based guideline. Laboratories now have:
      - written validation procedures for both predictive and non-predictive marker assays
      - procedures that specify the minimum numbers of cases needed for validation
    - Several cited difficulties in guideline adoption such as finding validation cases for rare antigens, the time and staff needed to run validations, and the additional expenses
    - *Analytic Validation of Immunohistochemistry Assays: New Benchmark Data from a Survey of 1624 Laboratories*

# LPG Metrics Awardees' Projects



## Immunohistochemistry (IHC) Assay Validation (cont)

- Two focus group sessions were completed on September 14<sup>th</sup> and follow-up telephone surveys are in progress
- An abstract of the entire process/outcome will be submitted to the 2017 Guidelines International Network (GIN) meeting

## Acute Leukemia Algorithm (ALA)

- Joint LPG *Initial Diagnostic Work-up of Acute Leukemia* recently approved by CAP and American Society of Hematology (ASH) pending publication
- Baseline survey manuscript was submitted to *Archives of Pathology and Laboratory Medicine*
  - Results were presented at USCAP (poster session on March 14, 2016)
- Uptake of the ALA guideline will be promoted and tracked

# LPG Metrics Awardees' Projects



AMERICAN  
SOCIETY FOR  
MICROBIOLOGY

- The CDC Laboratory Response Network (LRN) Coordinator emailed a letter to the Laboratory Director of the LRN Reference Laboratories, who emailed the sentinel laboratories a SurveyMonkey® hyperlink to access the survey tool online
- Completed surveys to evaluate awareness of guidelines for
  - C. difficile diagnosis (closed April 1, 2016)
  - Urine specimen pre-analytical practices (closed June 27, 2016)
- Upcoming surveys to evaluate the awareness of guidelines for
  - Reduction of Blood Culture Contamination
  - Rapid ID of Blood Stream Infection

# LPG Metrics Awardee's Projects



AMERICAN  
SOCIETY FOR  
MICROBIOLOGY

- Systematic reviews (National Guideline Clearinghouse requires updates every 5 years) in progress for
  - Blood culture contamination
  - Rapid identification of bloodstream infections
- Presentation at the 2016 ASM Microbe meeting to train laboratory professionals to perform QI studies using data collection forms specifically designed for urine pre-analytic questions

# Waived Testing Self-Assessment Checklist



- November 2014: CLIA emphasized the need to develop a non-punitive and non-regulatory self-assessment checklist-type tool and recommended it for biennial use by all Certificate of Waiver testing sites. The tool could also be used prior to or at the time a site first applies for a CLIA Certificate.
- This self-assessment checklist emphasizes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver. It can be used as a voluntary tool to help assure good testing practices and reliable, high quality test results.

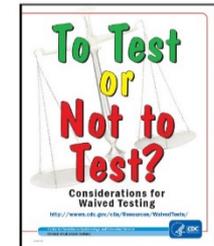
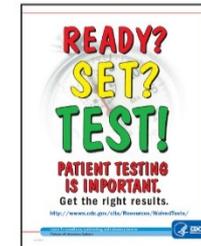
<http://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx>

## SELF-ASSESSMENT CHECKLIST FOR GOOD TESTING PRACTICES

The following self-assessment checklist emphasizes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. It can be used as a voluntary tool to help assure good testing practices and reliable, high quality test results.

Sites that perform testing under a CLIA Certificate of Waiver must meet the following requirements: enroll in the CLIA program; pay applicable certificate fees biennially; and follow the current manufacturer's instructions provided with the test.

Resources that can be used to supplement this checklist include:



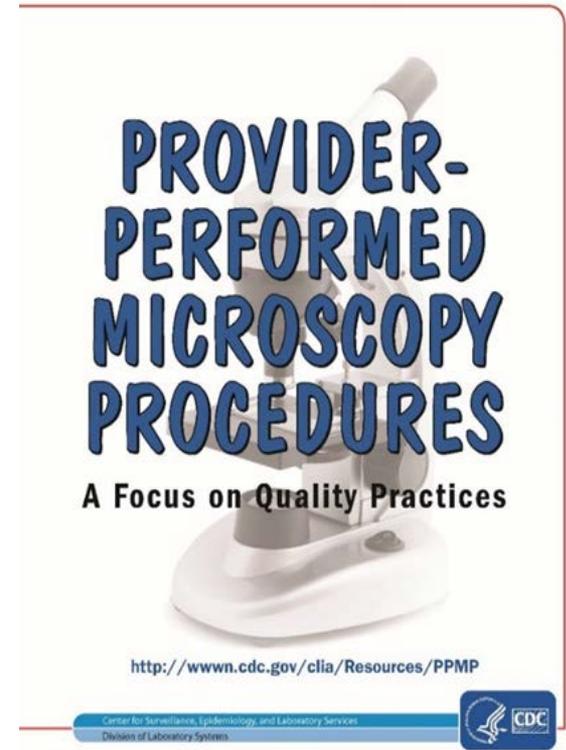
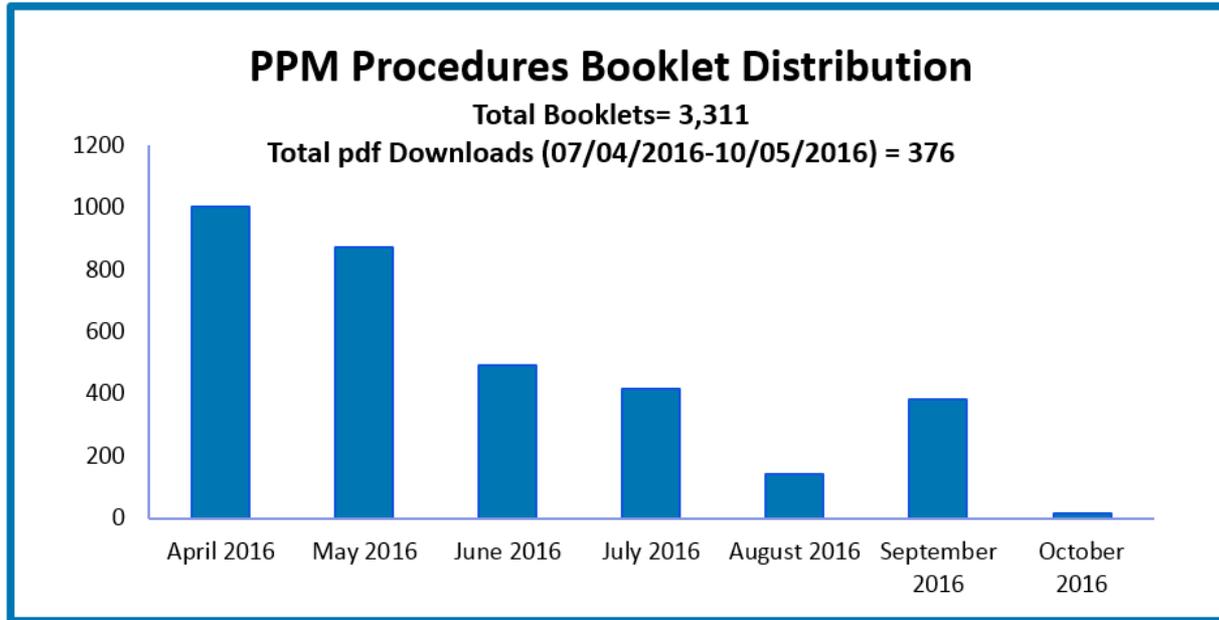
<http://wwwn.cdc.gov/clia/Resources/WaivedTests/>

### DISCLAIMER

*Although some of the recommendations in this self-assessment checklist 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.*

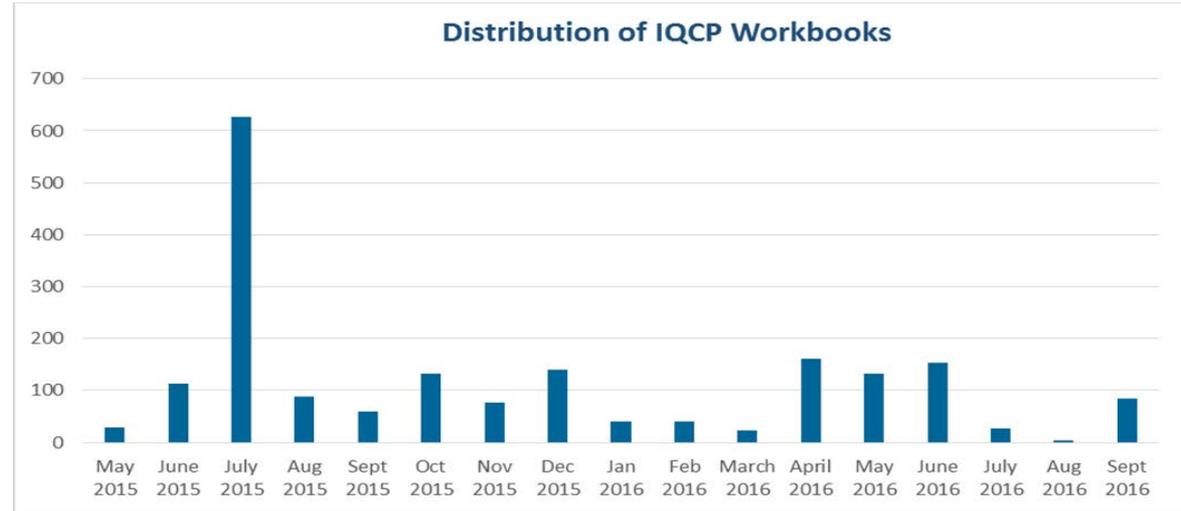
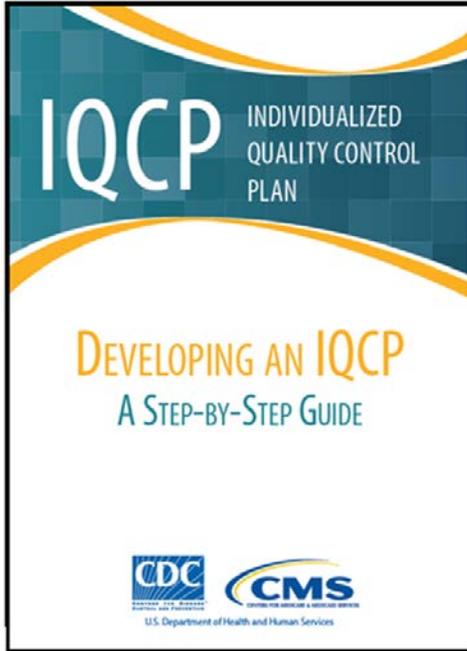


# Provider-Performed Microscopy (PPM) Procedures Educational Booklet



Request hardcopies of the booklet through email at [PPMP@cdc.gov](mailto:PPMP@cdc.gov) or online at <http://www.cdc.gov/clia/Resources/PPMP>.

# IQCP Educational Outreach by CDC/CMS



Total Workbooks Distributed = 3,802

Number of pdf downloads (07/04/2016-10/05/2016) = 149

Request hardcopies of the booklet through email at: [iqcpworkbook@cdc.gov](mailto:iqcpworkbook@cdc.gov)

or download the PDF online at: <http://www.cdc.gov/CLIA/Resources/IQCP/>

IQCP is voluntary. If you do not choose to adopt an IQCP, your laboratory must test two levels of external controls on each test system for each day of testing and follow all specialty/subspecialty requirements in the CLIA regulations for nonwaived testing

# Clinical Laboratory Integration into Healthcare Collaborative ( CLIHC™ )

- CLIHC™ external workgroup of clinical laboratory and medical professionals meeting on Oct 31 – Nov 1, 2016 in Atlanta, GA
- CLIHC™ educational products
  - Medscape expert commentary on “Diagnostic Error and the Need for Better Diagnostic Testing” available at <http://www.medscape.com/viewarticle/855381>
  - “Communicating and Collaborating for the Right Lab Test and Diagnosis” podcast offering continuing education credit (CME, CNE,CEU) available at <http://www.cdc.gov/ophss/csels/dls/eblm/pdf/12-pd2704-after-accreditation-documentr3.pdf>

# Clinical Laboratory Integration into Healthcare Collaborative ( CLIHC™)

- Clinical Decision Support Tools
  - Evaluation study of **PTT Advisor Mobile Application** by engaging Veterans Affairs physicians. Compilation of results by December 2016
  - **Anticoagulation Manager Mobile Application**
    - Helps manage patients on anticoagulants with specific conditions (VTE, DVT, PE, etc.)
    - iTunes launch 1<sup>st</sup> quarter 2017

# Reference Materials: Essential for Quality Testing

## The Problem

Characterized reference materials are not publicly available for most genetic tests and variants; laboratories often use uncharacterized, non-renewable clinical materials for test validation and QC

## Consequences

The quality of genetic tests may be compromised

# Genetic Testing Reference Material Program (GeT-RM)

Since 2004, the GeT-RM program has characterized 408 publicly available genomic DNA reference materials for over 5200 genomic loci (variants in genes) in 60 genes

All projects involved a voluntary collaborative effort with the clinical genetic testing community!



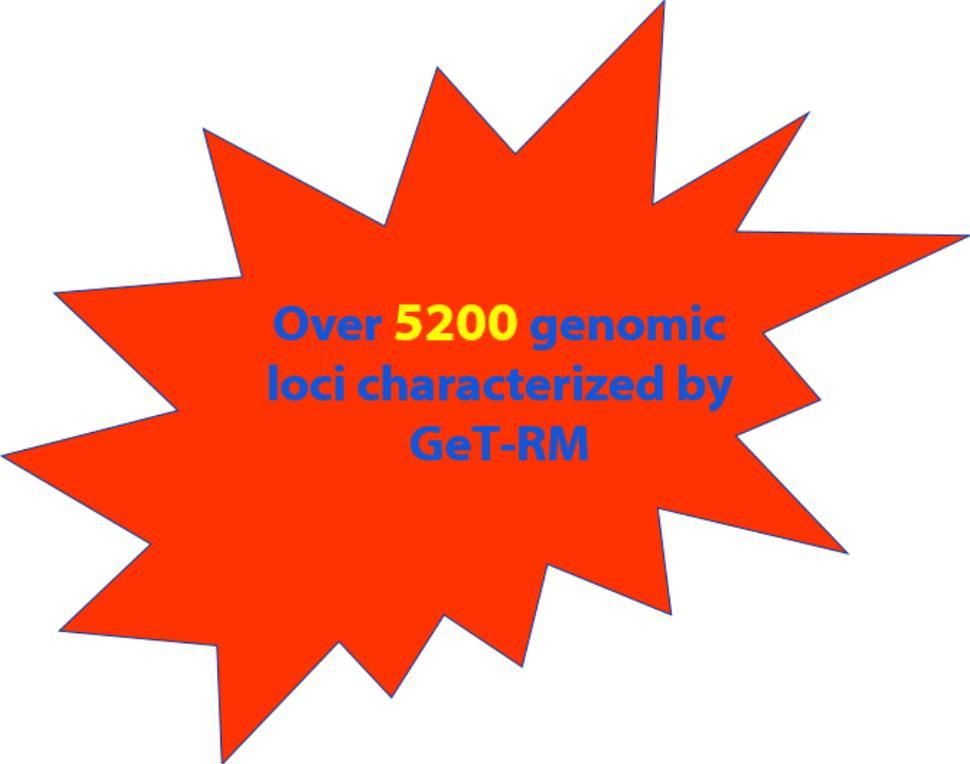
# GeT-RM Projects

## Completed Projects

- Fragile X
- Huntington Disease
- Cystic Fibrosis
- Ashkenazi Jewish Panel
  - 9 disorders including Tay-Sachs and Canavan disease
- BRCA1/2
- MTHFR
- Multiple endocrine neoplasia, Type 2A
- Alpha1-antitrypsin deficiency
- Pharmacogenetics (two projects, 28 loci)
- Duchenne muscular dystrophy
- Myotonic dystrophy
- Rett Syndrome

## Ongoing Projects

- HLA (11 loci)
- CYP2D6- difficult variants



**Over 5200 genomic loci characterized by GeT-RM**

# GeT-RM Papers

- Kalman L, *et al.* Development of genomic reference materials for Huntington disease genetic testing. *Genetics in Medicine* 2007 9:719-723.
- Wilson JA, *et al.* Consensus Characterization of 16 FMR1 Reference Materials: A Consortium Study. *Journal of Molecular Diagnostics* 2008; 10:2-12.
- Kalman LV, *et al.* Characterization of Genomic DNA reference materials for genetic testing of disorders common in people of Ashkenazi Jewish decent. *J Mol Diagn.* 2009 Nov;11(6):530-6.
- Pratt VM, *et al.* Development of Genomic Reference Materials for Cystic Fibrosis Genetic Testing. *J Mol Diagn.* 2009 May;11(3):186-93
- Barker SD, *et al.* Development and characterization of reference materials for MTHFR, SERPINA1, RET, BRCA1, and BRCA2 genetic testing *J Mol Diagn.* 2009 Nov;11(6):553-61
- Pratt VM, *et al.* Characterization of 107 genomic DNA reference materials for CYP2D6, CYP2C19, CYP2C9, VKORC1 and UGT1A1: A GeT-RM and Association for Molecular Pathology collaborative project. *J Mol Diag* 2010 12(6):835-846
- Kalman LV, *et al.* Quality Assurance for Duchenne and Becker Muscular Dystrophy Genetic Testing: Development of a Genomic DNA Reference Material Panel. *J Mol Diag*, 2011 Mar;13(2):167-74
- Kalman L, *et al.* Development of a Genomic DNA Reference Material Panel for Myotonic Dystrophy type 1 (DM1) Genetic Testing. *J Mol Diag* 2013 15:518-525
- Kalman L, *et al.* Development of a genomic DNA reference material 1 panel for Rett Syndrome (MECP2-related disorders) Genetic Testing. *J Mol Diag.* 2014 16:273-279
- **Pratt VM, *et al.* Characterization of 137 Genomic DNA Reference Materials for 28 Pharmacogenetic Genes: A GeT-RM Collaborative Project. *J Mol Diag.* 2016 18:109-123**



Published in 2016

# The CDC and ASTDR Specimen Packaging Inventory and Repository (CASPIR)



CASPIR is managed by CSELS/DLS

- The CASPIR facility stores approximately 6.4 million specimens
- Many of these specimens are unusual microbial isolates or other samples that could be useful to laboratories when developing or validating new assays as well as for quality control and proficiency testing
- Implementing new US government and CDC specimen sharing policies- DLS is working across CDC to develop and facilitate specimen sharing with laboratories outside of CDC



# CASPIR

## CLIA meets CASPIR- An example:



CDC MicrobeNet- Online database of over 2400 rare and unusual pathogens to improve reference diagnostics and facilitate species identification

Contains:

- Genetic sequence information (whole genome, 16S rRNA sequence)
  - Biochemical characterization (results of over 190 tests)
  - Morphological characterization
  - Antibiotic resistance profiles
  - MALDI-TOF MS profiles
- Laboratories perform analysis on their samples and compare results to MicrobeNet data to facilitate identification

# CASPIR

## CLIA meets CASPIR- An example:



Many of the microbial isolates included in the MicrobeNet database are not currently publicly available

Access to these isolates would be useful for laboratories that are developing and validating new assays and for QC. Laboratories could generate data from these isolates using their own assays and compare directly to the MicrobeNet data to assess the accuracy of their results.

CSELS/DLS is hoping to make aliquots of these important pathogens available to clinical and public health laboratories via the CASPIR Repository.

# CASPIR

DLS is working to improve CASPIR and add new services in the near future

## **Current efforts:**

- Seeking ISO 9001:2015 accreditation
- Hiring new FTEs
- Opening new storage facility to increase capacity by 30%
- Developing internal/external catalog to facilitate specimen sharing

## **Future possibilities:**

- Creation of BSL2 laboratory that could offer services:
  - Production and distribution of cultures and nucleic acids
  - Sample characterization (e.g. sequence analysis, testing for levels of specific analytes)
  - Development of standards (typed strains, etc.)
  - Specimen authentication (e.g. STR profiling for cell lines)
  - Specimen QC (check for contamination, etc.)
  - Provision of kits, reagents

# CDC Laboratory Training

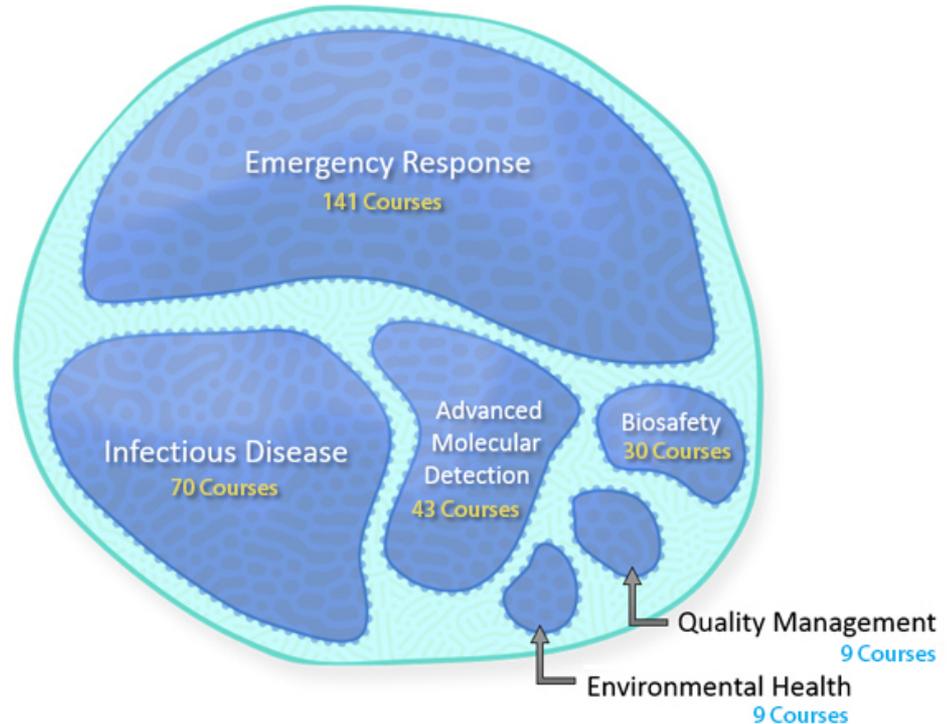
The screenshot shows the CDC Laboratory Training website. At the top left is the CDC logo with the text "Centers for Disease Control and Prevention" and "CDC 24/7: Saving Lives, Protecting People™". To the right is a search bar. Below the header is a navigation bar with "CDC-A-Z INDEX" and "CDC Laboratory Training". The main banner features a collage of laboratory-related icons (microscope, laptop, certificate, flask) and the text "CDC Laboratory Training" and "Live and archived laboratory training online and in-person for FREE!". Below the banner are social media icons for Facebook, Twitter, and a plus sign. The main content area is divided into four columns: "Register for Live Training" with a registration timer and a "Sign-up now" button; "24/7 Online Training" with a link to a current schedule; "External Training Links" with a link to a list of additional training; and "Help/FAQs" with a link to a help page.

- **FY 2016**
  - 302 courses offered
  - 98 different course titles
  - 18,918 people completed courses
  - 92% indicated training objectives aligned with training needs
  - 77% applied training to their laboratory

- **Training Link:** <http://www.cdc.gov/labtraining/>

# 302 Training Courses in FY2016

- **Emergency Response 47%**
- **Infectious Disease 23%**
- **Advanced Molecular Detection 14%**
- **Biosafety 10%**
- **Quality Management 3%**
- **Environmental Health 3%**



# Most Popular Training Courses

## ■ Packaging and Shipping of Division 6.2 Materials

- Seminar
  - 45 local seminars
  - 17 states
  - 787 completed courses
- Online Course
  - 2349 completed courses
- 3136 people qualified for certification or recertification by their employer

## ■ Basic Microbiology

- Online multimedia courses blended with locally mentored laboratory exercises
- Topics:
  - Basic Microscopy
  - Routine Microscopy Procedures
  - Basic Culture Media
  - Biochemicals and Gram Negative Organism Identification
  - Biochemicals and Gram Positive Organism Identification
  - Antimicrobial Susceptibility Testing
- 1554 completed courses

# 2017 Laboratory Training Focus

- Review and clear new CDC biosafety courses for use by clinical and public health laboratories
- Continue development of the CDC biosafety curriculum
- Expand the virtual exercise concept to cover biosafety issues
- Bring TinCan API capability online to allow laboratories with Learning Management Systems to link directly to CDC courses for local hosting
- Investigate the benefits of gaming formats for laboratory training

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

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.

