CDC Update

Barbara Zehnbauer, Ph.D.
Acting Director
Division of Laboratory Systems

CLIAC Meeting
November 18, 2015
Atlanta, Georgia

Highlights of Recent DLS Activities

- LabHIT Team Updates
- Cytology Workload Assessment for Automated Screening Devices
- Distribution of Waived Testing and IQCP Educational Materials
- IOM Report
- Laboratory Medicine Best Practices: Effectiveness of Practices to Reduce Blood Sample Hemolysis in Emergency Departments
- Laboratory Practice Guidelines Metrics Projects
- Public Health Laboratory Competencies and Self-assessment Tool
- Public Health Laboratory System Database
- Laboratory Training Website
- CDC Specimen Policies
- CDC and ATSDR Specimen Packaging, Inventory, and Repository

Laboratory Health Information Technology (LabHIT) Team and CSELS

- **EHR Certification Tool:** Continue to work with NIST to include the CLIA requirements in the 2018 certification rule
- **Coding:** Cohosted FDA/CDC/NLM public workshop for Semantic Interoperability of FDA cleared IVDs – Sept. 28, 2015
- **SNOMED:** Continue to work with LabCoP to expand specimen description from a single constrained field (OBX-4) to multiple fields.
  - Completed for microbiology and molecular testing
  - Starting to work on anatomic pathology
- **HL7:** CSELS has the lead on development of a Draft Standard for Trail Use on electronic Initial Case Report.

EHR Certification Tool: CLIA test report elements – 2016-2017

NIST Test Method Category	Laboratory Test Report Elements
CLIA-7 Elements required by CLIA and incorporated into MU by reference	Patient name and identifiers
	Laboratory name and address
	Test report date
	Test performed (test name)
	Specimen source, when appropriate
	Test results and interpretation
	Specimen condition and disposition
CLIA-4 Elements specified by CLIA and incorporated into MU by reference	Reference intervals
	Critical result flags
	Reference laboratory results cannot be revised
	Corrected report identifier
Additional Elements required by accreditor standards and CLIA general duty clause	Patient's sex
	Patient's age or date of birth
	Specimen collection date and time
Work continues to for **future** inclusion	Name of authorized person requesting the test

Laboratory Health Information Technology (LabHIT) Team

- **Health IT and Patient Safety**
  - ONC launched online health IT complaint form
    - https://www.healthit.gov/healthitcomplaints
  - LabHIT website updated for health IT safety event reporting:
    - http://www.cdc.gov/labhit/ehr_patient_safety_event_reporting.html
- **Patient Access:**
  - Small Business Innovation Research grants posted on NIH site for patient education app : https://sbir.nih.gov/sites/default/files/2015-2_SBIR-STTR-topics.pdf
- **Promoting nomination of laboratory informatics expertise:**
  - FDA Patient Engagement Committee, November 20, 2015
  - ONC Federal Advisory Committee workgroups

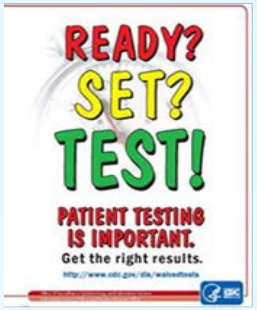
Cytology Workload Assessment for Automated Screening Devices

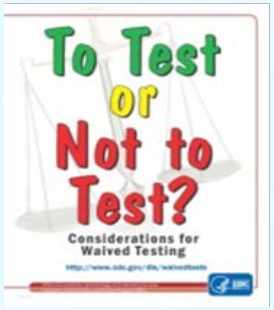
- **Data collection completed – 102 total participants**

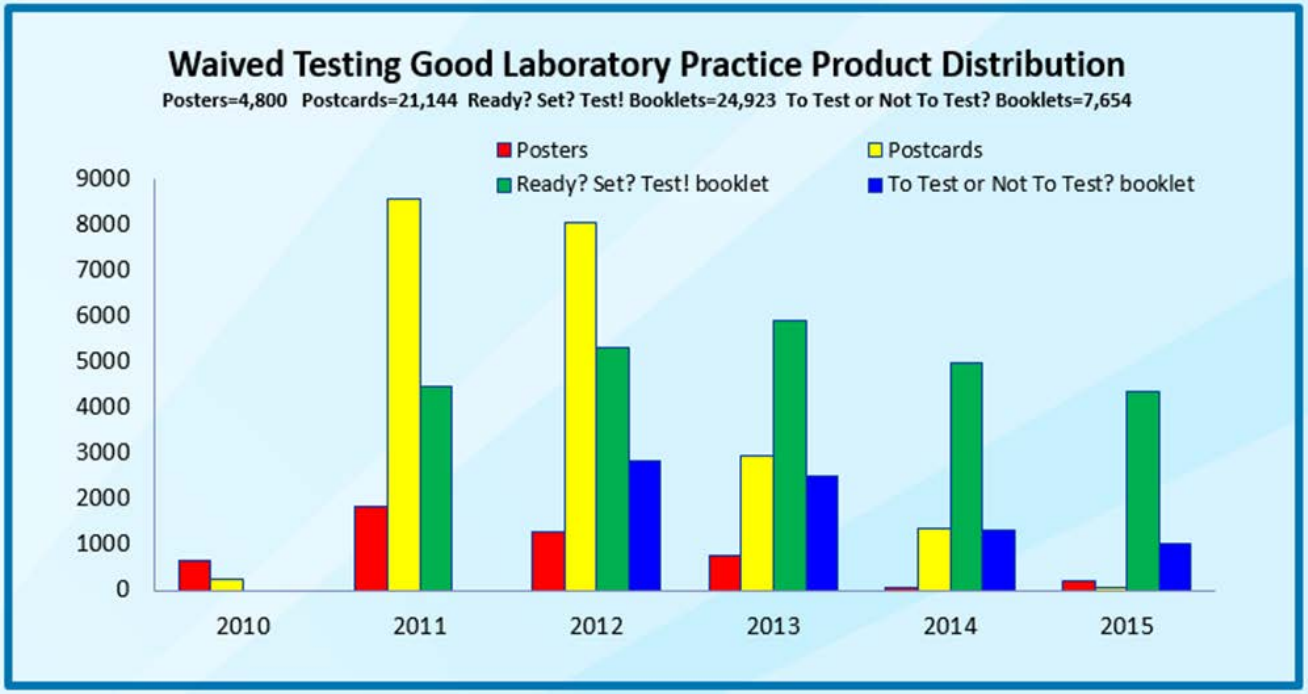
  Breakdown of participants by imaging device used the day of time measure study:

- Both Hologic TIS Review Scope and BD Guided Screening System - 6
- BD Guided Screening System only - 32
- Hologic TIS only - 64:
  - Hologic Review Scope (original microscope) - 38
  - Hologic Review Scope Plus (new microscope) - 26
- **Next steps**
  - Complete analysis of data
  - Present findings to Tri-agency (CDC-CMS-FDA) cytology working group
  - Working group will determine actions needed to change CLIA
- **Share data at April CLIAC meeting**

Waived Testing Educational Products







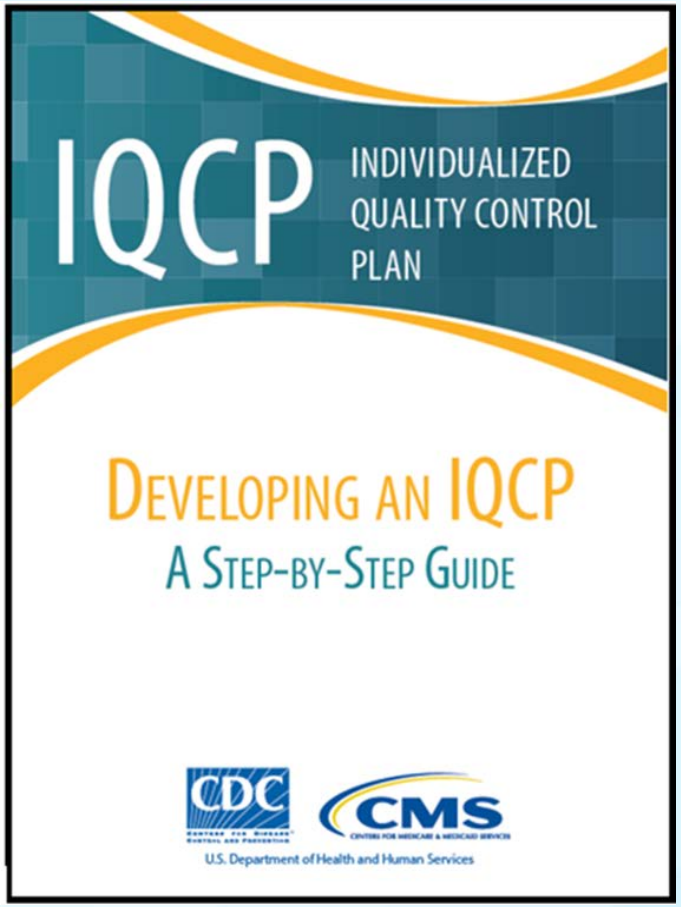
Ready? Set? Test! Online Course Participation (Nov 2011- October 2015)

Course Registration	
Total Registered	6074
Completed	3968
In Progress	1940
Withdrawn	166

Credit Type	Total Hours Awarded
CEU/CE (0.1 hours)	146
CME (1.0 hours)	303
CNE Contact Hours (1.0 hours)	425
Pharmacists Contact Hours (0.1 hours)	6.3

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

CDC/CMS Educational Workbook



- Incorporates examples, scenarios, and fillable forms
- Risk assessment
- Quality assessment
- Can be downloaded at:
  - http://wwwn.cdc.gov/CLIA/Resources/IQCP/
  - http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

Free hardcopies are available by request from CDC

iqcpworkbook@cdc.gov

Example Risk Assessment Questions and Form Workbook Separates Each of Five Components

Do you see a potential risk of an error in test results if:	Answer
Laboratory personnel do not have a formal certification or license if required by the state?	Yes ◯ No ◯
The laboratory does not have adequate personnel to perform patient testing in a safe and timely manner?	Yes ◯ No ◯
There is no documentation of CLIA-required competency assessment for all laboratory personnel?	Yes ◯ No ◯
Laboratory personnel are not trained on specimen requirements (collection and type) required for the test system?	Yes ◯ No ◯
Labora	
Laborat using a	

STEP 1: RISK ASSESSMENT

Steps to complete your laboratory's risk assessment worksheets:

After reviewing the example worksheet for each component, take **your** identified sources of error from the **"Risk Assessment Questions/ Findings"** for each component section, and follow the process taken by Kim to complete **your** laboratory's risk assessment worksheet.

Risk Assessment Worksheet

Laboratory Name_____ Test System Name _____

1	2	3	4
Risk Assessment Components	What are our possible sources of error? What can go wrong?	Can our identified sources of error be reduced?	How can we reduce the identified sources of error?
	Gather information, from the manufacturer's instructions and other resources, on how we should be performing the testing process.	Yes/No Not Applicable (N/A)	Indicate how to reduce possible error sources. • Internal controls • Actions taken by laboratory • Safeguards in the test system or laboratory practices
SPECIMEN			

STEP 1: RISK ASSESSMENT

Completed EXAMPLE

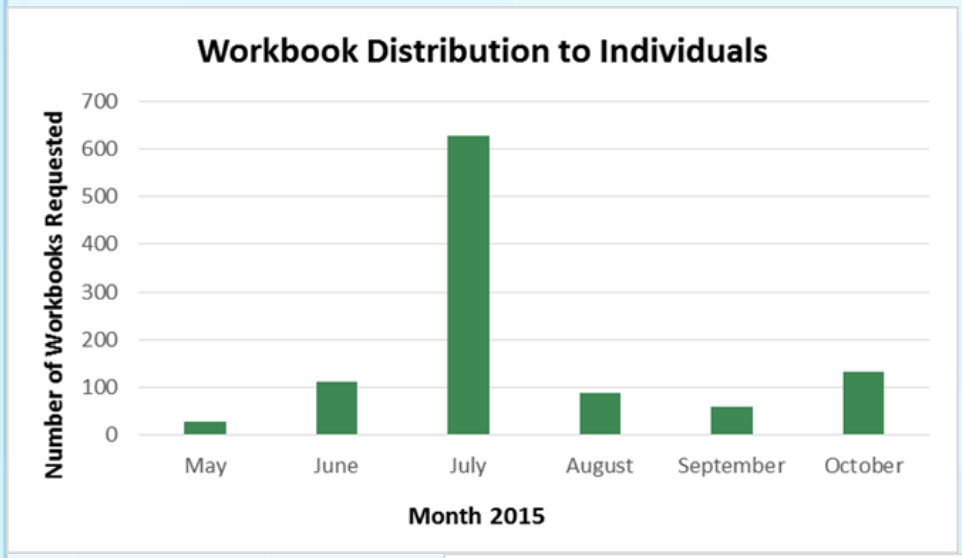
The example below shows the complete Risk Assessment containing the merged information from all five components for Happy Day Physicians Group's Acme Chemotrific System-Magnesium test system.

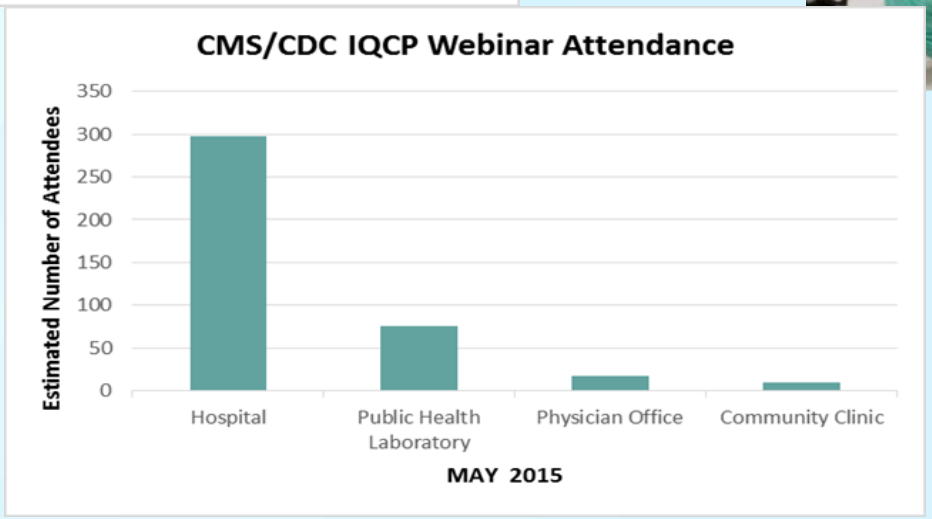
Happy Day Physicians Group Risk Assessment Worksheet Acme Chemotrific System-Magnesium (Showing all 5 components)

1	2	3	4
Risk Assessment Components	What are our possible sources of error? What can go wrong?	Can our identified sources of error be reduced?	How can we reduce the identified sources of error?
	Gather information, from the manufacturer's instructions and other resources, on how we should be performing the testing process.	Yes/No Not Applicable (N/A)	Indicate how to reduce possible error sources. • Internal controls • Actions taken by laboratory • Safeguards in the test system or laboratory practices
SPECIMEN	Documentation of specimen re-collection. Manufacturer's instructions: • Use lithium heparin tubes for whole blood or plasma specimens • Use no additive or serum separator tubes for serum specimens	Yes	Retrain testing personnel on re-collection policy. Train testing personnel to verify use of proper specimen collection tubes.
	Testing time frame/stability of specimen. Manufacturer's instructions: • Whole blood - run within 60 minutes of collection • Store serum or plasma in capped tubes at 2°C to 8°C for 48 hours or at -10°C for up to 5 weeks	Yes	Train testing personnel to verify and document: • Collection time and time of receipt in laboratory • Proper storage and processing of specimen

continued on next page...

IQCP Educational Outreach by CDC/CMS





A National Academies of Science Report from the Institute of Medicine

IMPROVING DIAGNOSIS IN MEDICINE

Published September, 2015
CDC/DLS was a co-sponsor

http://iom.nationalacademies.org/reports/2015/improving-diagnosis-in-healthcare

Three Principles in Developing Document

- *Improving Diagnosis in Health Care* exposes a critical type of error in health care—diagnostic error—that has received relatively little attention since the release of *To Err Is Human.*
- Patients are central to the solution.
- Diagnosis is a collaborative effort.

Goals for Improving Diagnosis and Reducing Diagnostic Errors: Intersections with CDC/DLS Initiatives

- Facilitate effective teamwork among health care professionals, patients, and their families in the diagnostic process
  - DLS Working with the Veterans' Administration to improve test ordering and result reporting processes (relevant to genetic testing)
- Enhance health care professional education and training in the diagnostic process
  - CLIHC™ - Yale Univ. School of Medicine survey of medical schools' laboratory education
  - Molecular and Biochemical Testing best practice guidelines and recommendations and online training tools

Goals for Improving Diagnosis and Reducing Diagnostic Error and Intersections with Work of DLS (examples)

- Ensure that health information technologies support patients and health care professionals in the diagnostic process
  - aLOINC Project - standardized use of LOINC codes
  - Working with the Office with the National Coordinator to promote laboratory interoperability
- Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice
  - PTT Advisor (clinical decision support for coagulation tests)
  - Individual Quality Control Plan
  - Work to advance patient's rights to access laboratory test reports

Laboratory Medicine Best Practices: Reducing Blood Sample Hemolysis in Emergency Departments*

Quality gap: Hemolyzed blood samples

- Produce unreliable results in 39 different lab tests
- Rejected by laboratories and need to be redrawn
- Hospital EDs major source of hemolyzed samples
  - Hemolysis rates range from 6.8 to >30% (American Society of Clinical Pathology benchmark is 2% or less)
  - Wide range of standard practices for drawing blood samples depending on personal preference of ED medical staff

*Effectiveness of practices to reduce blood sample hemolysis in EDs: A Laboratory medicine best practices systematic review and meta-analysis; Heyer et al. Clin Biochem, 45 (2012) 1012-1032

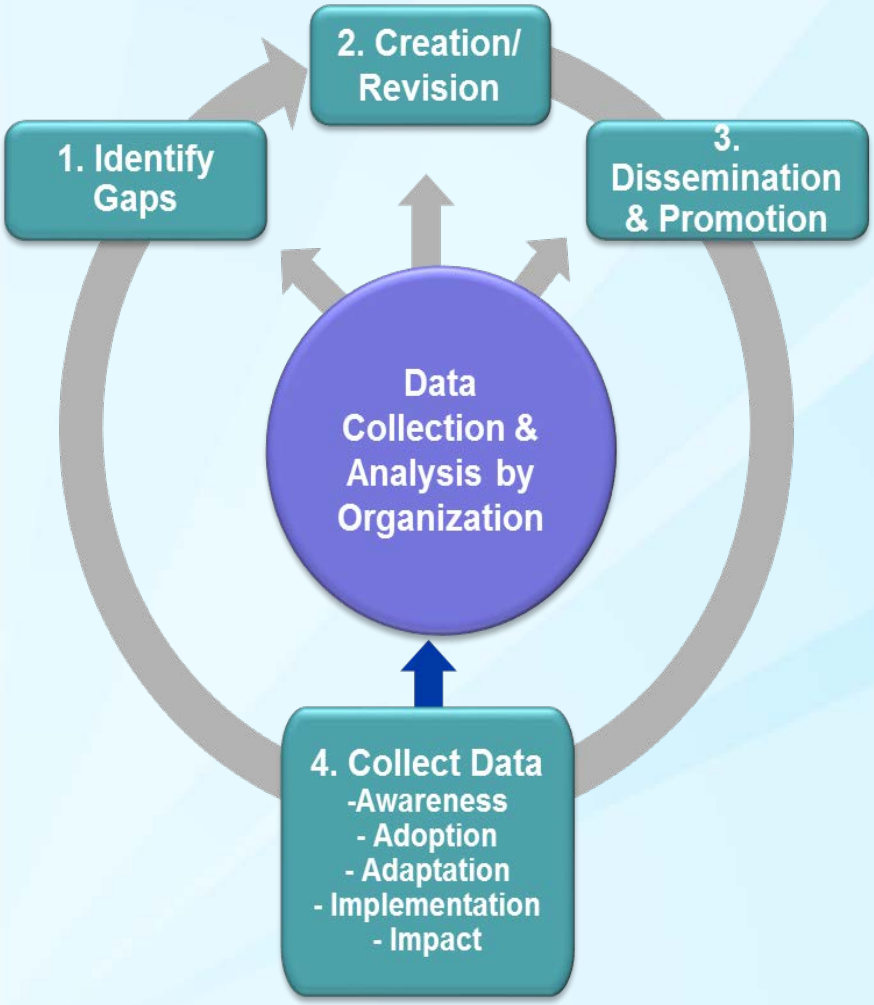
Laboratory Medicine Best Practices: Effectiveness of Practices to Reduce Blood Sample Hemolysis in Emergency Departments

New Project:

Evaluation of efforts to reduce patient sample hemolysis among multiple emergency department among multiple institutions or facilities

Awarded to University of Texas Southwestern Medical Center, Awarded, October 2015

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

CDC will create a web resource to promote use of LPG Metrics

- Survey design/sampling/free tools
- Focus groups
- IOM reports, related research
- Evaluation plan

LPG Metrics Awardees' Projects

- Evaluate two POC glucose monitoring LPGs - with (POCT 12) and without (POCT 13) laboratory support
  - Surveys will be sent to 30,000 waived and non-waived testing sites: half POLs (POCT 13), half hospital and clinic labs (POCT 12)
  - Blended field: OSCAR, COLA, AHA, The Joint Commission, DoD labs, List of Point-of-Care coordinators
- Expert panel reviewed CLSI processes and performed Agree II analysis of guidelines http://www.agreetrust.org/agree-ii/
  - Identified areas for process improvement
    - committee formation
    - idea generation and approval
    - systematic review and revision
  - Recommendations were made to the Board of Directors

LPG Metrics Awardees' Projects

COLLEGE of AMERICAN PATHOLOGISTS

- **Immunohistochemistry (IHC) Assay Validation**
  - Survey of practices consistent with 2014 IHC LPG was sent to 2885 CAP PT customers and 450 Non-CAP PT customers
  - Survey results will be tabulated in autumn 2015
  - In progress: follow-up telephone survey and focus group application for OMB approval
- **Acute Leukemia Algorithm (ALA)**
  - Joint LPG with American Society of Hematology (ASH)
  - An online acute leukemia practices baseline survey was sent (June) to self-reported hematopathologists in CAP database; 295 responses*
  - Draft ALA recommendations were created/vetted – 780 comments
  - The baseline survey results to be presented at the 2016 US and Canadian Academy of Pathology (USCAP) meeting
  - Uptake of the ALA guideline will be promoted and tracked

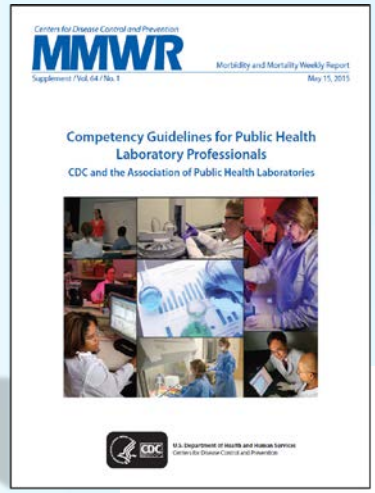
LPG Metrics Awardees' Projects

AMERICAN SOCIETY FOR MICROBIOLOGY

- Four LPGs-planned based on Systematic Review (SR) with Recommendations (guideline) using the A-6 method
  - Reduction of Blood Culture Contamination
  - Rapid ID of Blood Stream Infection (in press)
  - Proper Handling of Urine Specimen (in press)
  - Laboratory diagnosis of *C. difficile* colitis (SR in progress)
- Multiple dissemination/promotion mechanisms for the LPGs
  - Using Laboratory Response Network to disseminate LPG survey links
    - Second ASM use of LRN for surveys of sentinel clinical labs
  - Trade journals, ASM Annual Meeting, ASM regional division meetings, ASM list serves, invited presentations
  - Will provide micro labs with study design and data collection forms to see if this will improve guideline uptake
    - Data will feedback into SR updates

Public Health Laboratory (PHL) Competencies

http://www.cdc.gov/mmwr/preview/mmwrhtml/su6401a1.htm *



- CDC and APHL collaboration to address a large gap in PHL workforce development
- First-ever comprehensive lab competencies
- Broadly applicable to all laboratories
- National vetting by stakeholders
- 15 domains, with QMS as the foundation of every activity

*Ned-Sykes R, Johnson C, Ridderhof JC, Perlman E, Pollock A, DeBoy JM. Competency Guidelines for Public Health Laboratory Professionals. *MMWR Surveill Summ* 2015;64 Suppl 1: 1-95.

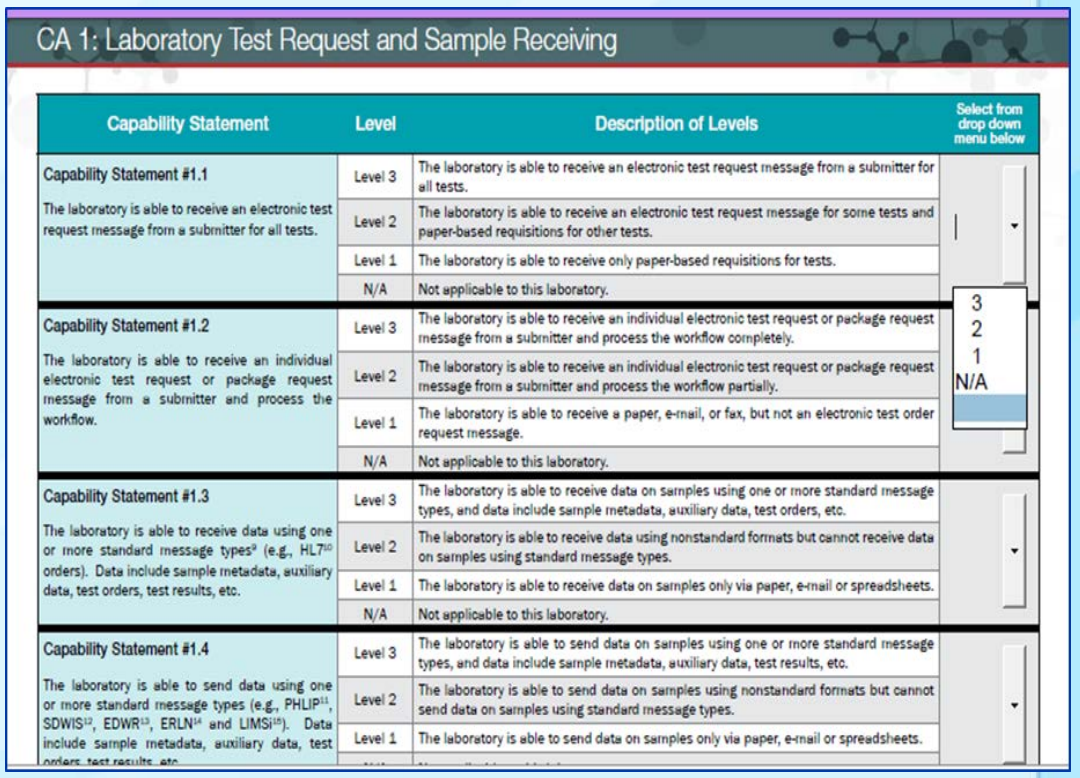
PHL Competency Guideline Implementation

- **CDC implementation:** Laboratory Leadership Service (LLS) Fellowship program; revamping agency's biosafety training program; Bioinformatics Specialist position description
- **PHL and APHL implementation:**
  - Steering committee to guide ongoing state/local PHL implementation strategy and activities.
  - APHL in process of aligning their fellowship programs with the competency guidelines
- ***Clinical labs may also use relevant competencies to improve personnel management, training/professional development programs, and organizational capacity and management.**

Public Health Laboratory (PHL) Informatics Self-Assessment Tool

- Intended for PHLs and is generalizable to clinical labs
- Identify gaps in informatics capabilities through development and use of a 'gold standard' for comparison

Originally available as fillable PDF document

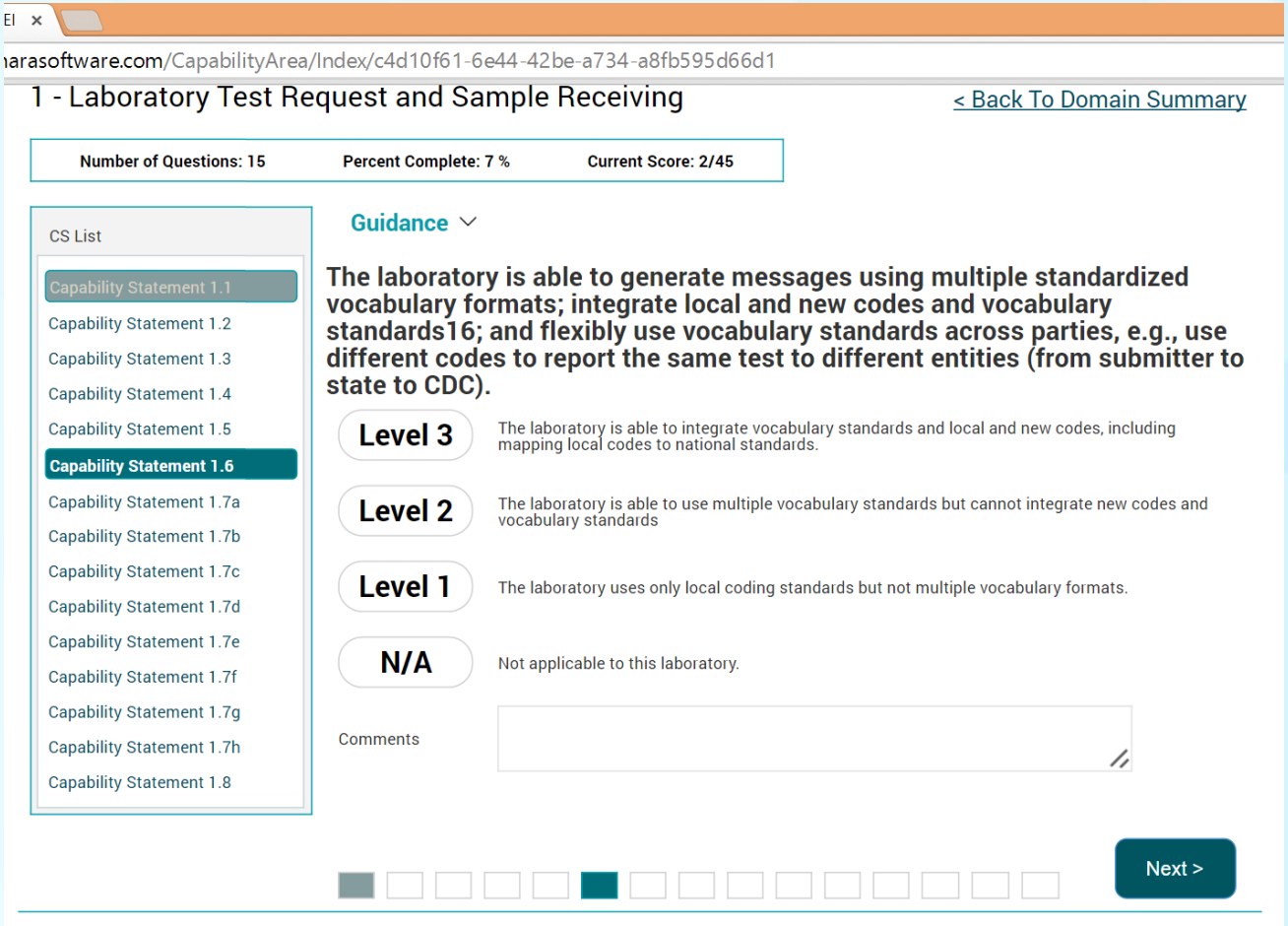


CA 1: Laboratory Test Request and Sample Receiving

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #1.1 The laboratory is able to receive an electronic test request message from a submitter for all tests.	Level 3	The laboratory is able to receive an electronic test request message from a submitter for all tests.	
	Level 2	The laboratory is able to receive an electronic test request message for some tests and paper-based requisitions for other tests.	
	Level 1	The laboratory is able to receive only paper-based requisitions for tests.	
	N/A	Not applicable to this laboratory.	
Capability Statement #1.2 The laboratory is able to receive an individual electronic test request or package request message from a submitter and process the workflow.	Level 3	The laboratory is able to receive an individual electronic test request or package request message from a submitter and process the workflow completely.	3 2 1 N/A
	Level 2	The laboratory is able to receive an individual electronic test request or package request message from a submitter and process the workflow partially.	
	Level 1	The laboratory is able to receive a paper, e-mail, or fax, but not an electronic test order request message.	
	N/A	Not applicable to this laboratory.	
Capability Statement #1.3 The laboratory is able to receive data using one or more standard message types[9] (e.g., HL7[10] orders). Data include sample metadata, auxiliary data, test orders, test results, etc.	Level 3	The laboratory is able to receive data on samples using one or more standard message types, and data include sample metadata, auxiliary data, test orders, etc.	
	Level 2	The laboratory is able to receive data using nonstandard formats but cannot receive data on samples using standard message types.	
	Level 1	The laboratory is able to receive data on samples only via paper, e-mail or spreadsheets.	
	N/A	Not applicable to this laboratory.	
Capability Statement #1.4 The laboratory is able to send data using one or more standard message types (e.g., PHLIP[11], SDWIS[12], EDWR[13], ERLN[14] and LIMSi[15]). Data include sample metadata, auxiliary data, test	Level 3	The laboratory is able to send data on samples using one or more standard message types, and data include sample metadata, auxiliary data, test results, etc.	
	Level 2	The laboratory is able to send data on samples using nonstandard formats but cannot send data on samples using standard message types.	
	Level 1	The laboratory is able to send data on samples only via paper, e-mail or spreadsheets.	

Copy of downloadable PDF file available online:
http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Pages/Informatics.aspx

Public Health Laboratory (PHL) Informatics Self-Assessment Tool (cont)

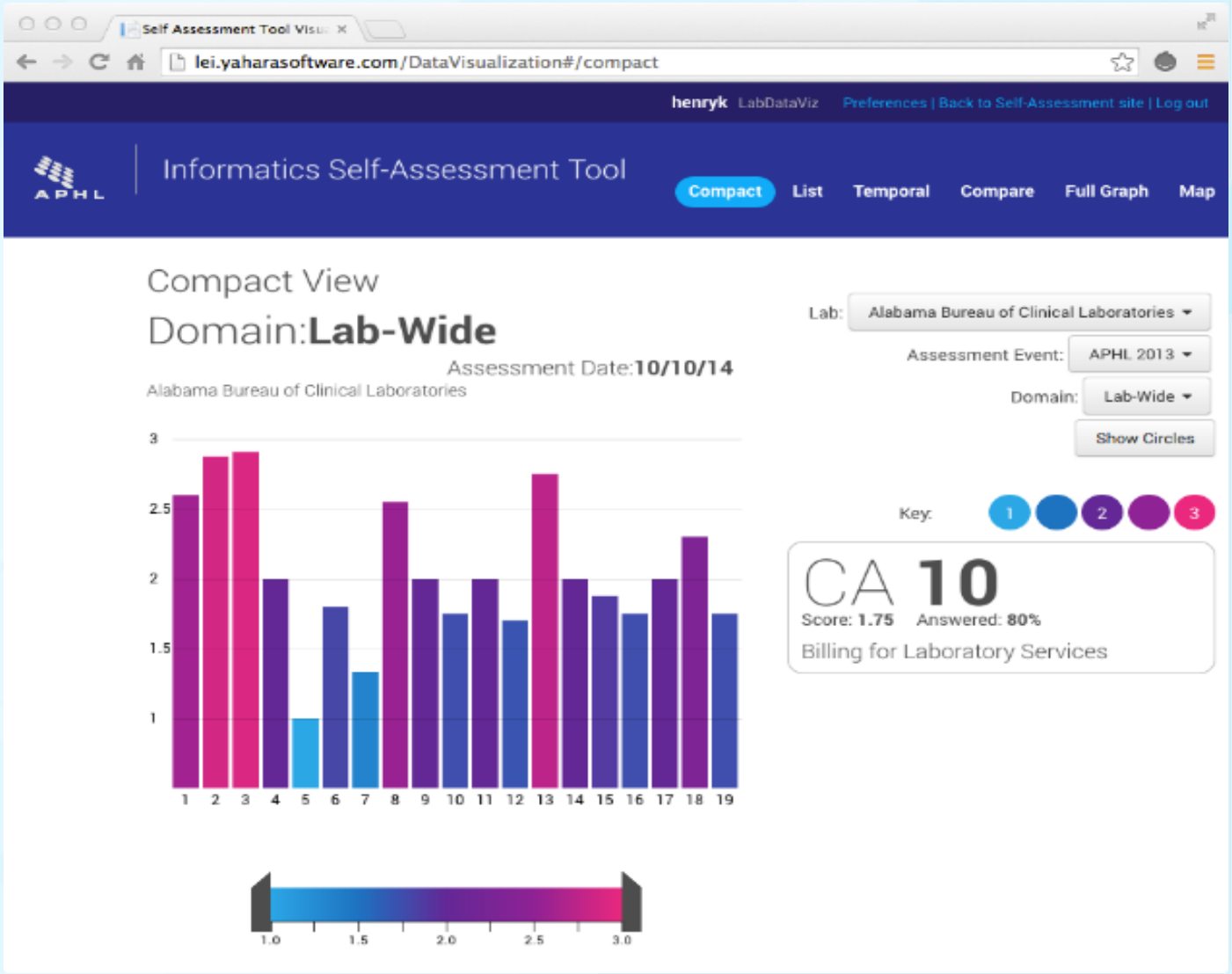


Now available as a web-based tool

http://www.aphl.org/aphlprograms/informatics/collaborations/Pages/LEI-Informatics.aspx

Public Health Laboratory (PHL) Informatics Self-Assessment (cont)

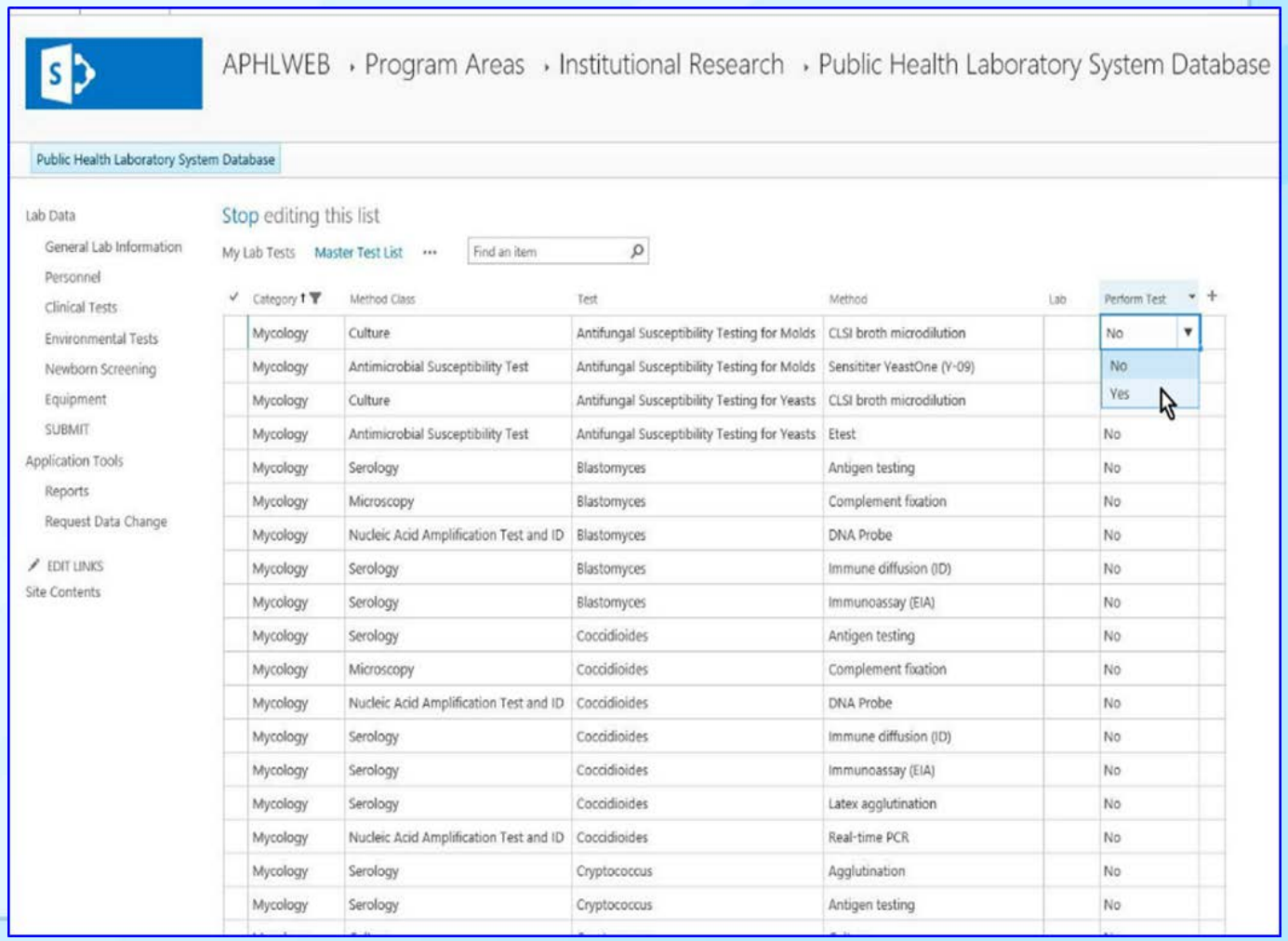
Web version has data visualization functionality



• Public Health Laboratory System Database (PHLSD)

- PHLs manage and control their own capacity data
- Ability to create test lists and reports for CLIA

Aggregated test service data from PHLs will allow creation of a nationwide PHL test service directory

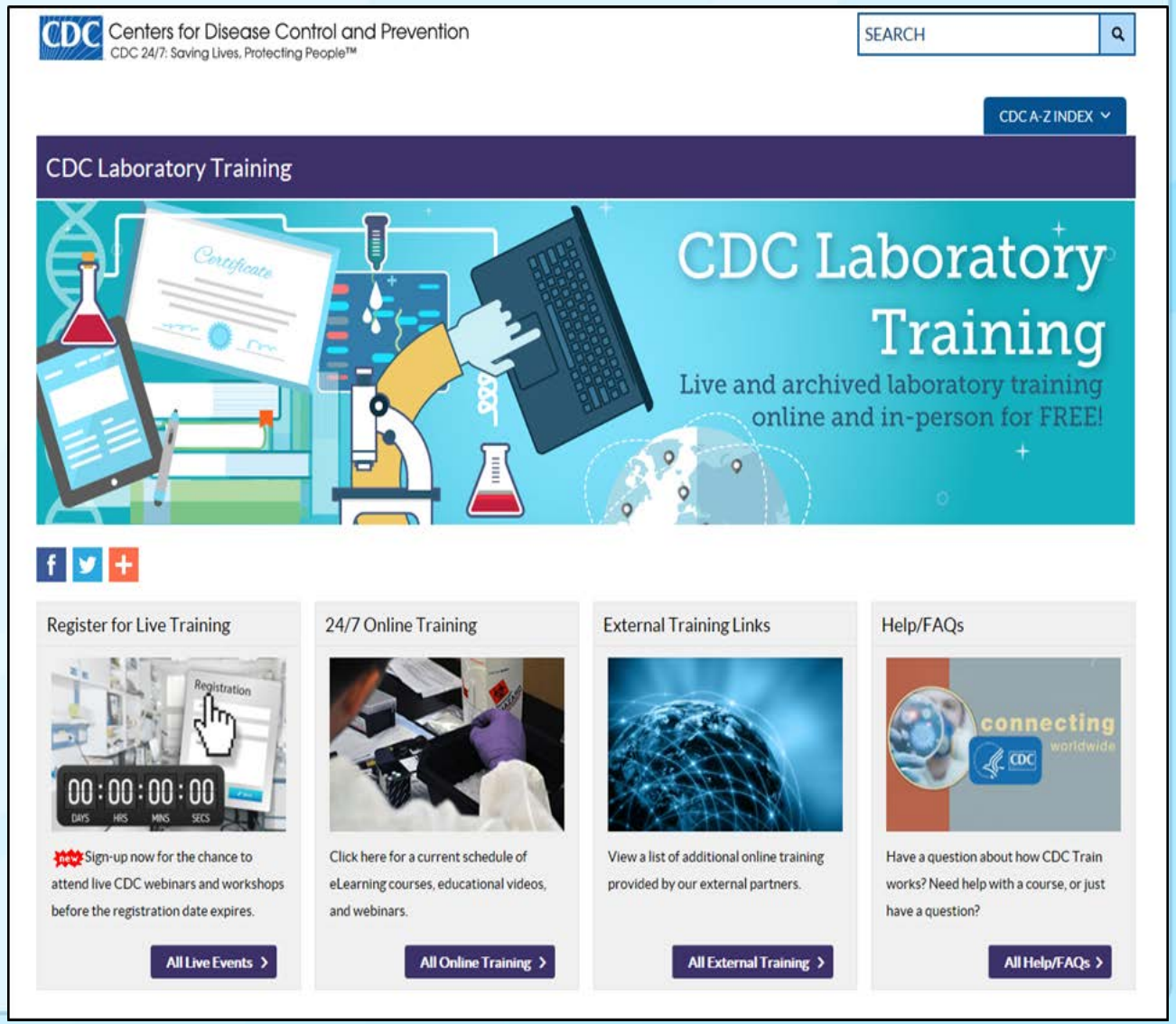


New CDC Laboratory Training Website
http://www.cdc.gov/labtraining/

New website designed to more easily connect you to live and online laboratory training options offered by DLS.

Don't see what you need? External Training Links will connect you with other laboratory training providers.

Want to list your organization as a link? Contact Rick Parry at rtp0@cdc.gov .



CDC Specimen Policies

- CDC Specimen Management Policy
  - Adopted December 2013
  - Among requirements, established standardized unique identifiers for specimen tracking
- Scientific Collection Management and Access Policy
  - (NEW: In-progress) with CDC's Specimen Policy Board
  - Mandated by the White House Office of Science and Technology Policy
  - Enhanced management and access to broader scientific community
- Respectful disposition of American Indian/Alaska Native Specimens (AIAN)
  - (NEW: In-progress) in collaboration with CDC's Specimen Policy Board and the OSTLTS

CDC and ATSDR Specimen, Packaging, Inventory and Repository (CASPIR)

- Critical role in assisting programs with completing agency-wide inventory (clean sweep)
- Implemented web-based application to improve inventory management and access to specimen information (locator)
- CASPIR Policy Revisions (in progress)
  - Harmonize with the CDC Specimen Management Policy
  - Updated requirements and criteria for maintaining specimens and overall quality management of CASPIR

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