CDC Update

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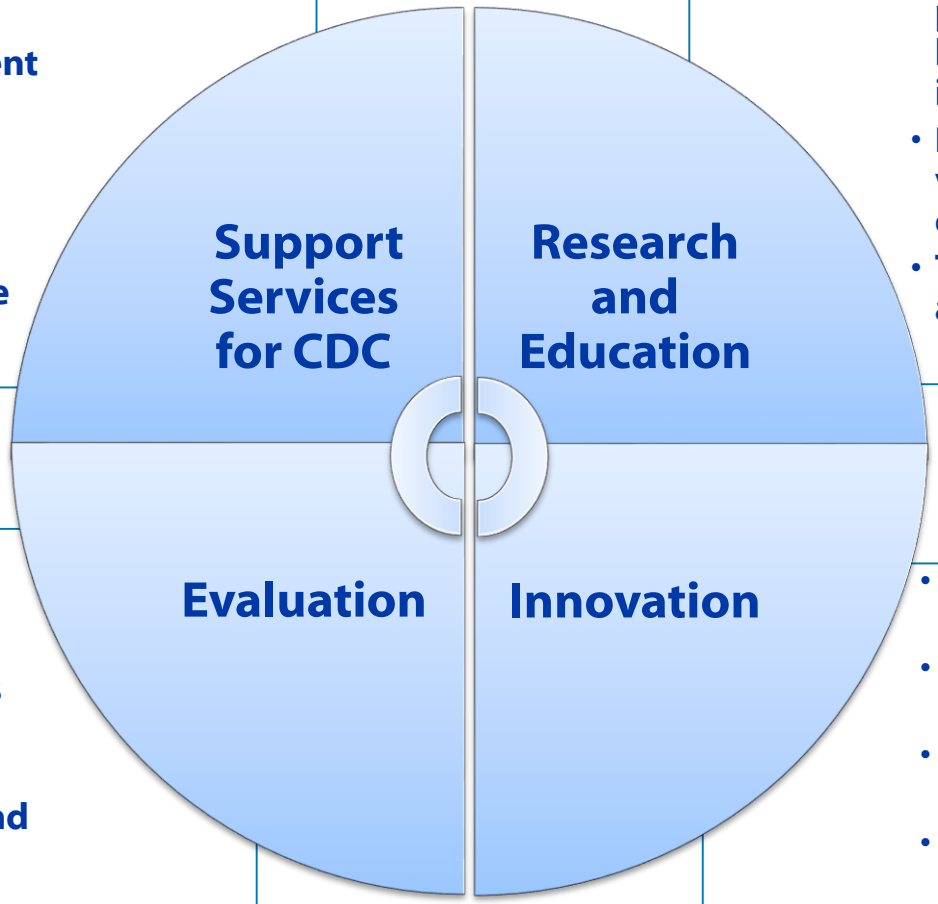
Division of Laboratory Systems

CLIAC Meeting
April 15, 2015
Atlanta, Georgia

Division of Laboratory Systems

- Dual Use Research of Concern
- Specimen management (CASPIR)
- Instructional Design
- Training Distribution
- Web Broadcast
- CDC TRAIN Assistance



- Clinical laboratory and public health/healthcare integration
- Regulatory and voluntary standards development
- Training- public health and clinical workforce

- Measurement of training effectiveness
- Measurement of impact of laboratory practice guidelines and laboratory based continuing education programs

- Multimedia enhanced distance learning
- Clinical decision support
- Passive surveillance with CMS data
- Collaboratives for genetic testing (GeT-RM) and Next-Gen sequencing

DLS Role in Ebola Response

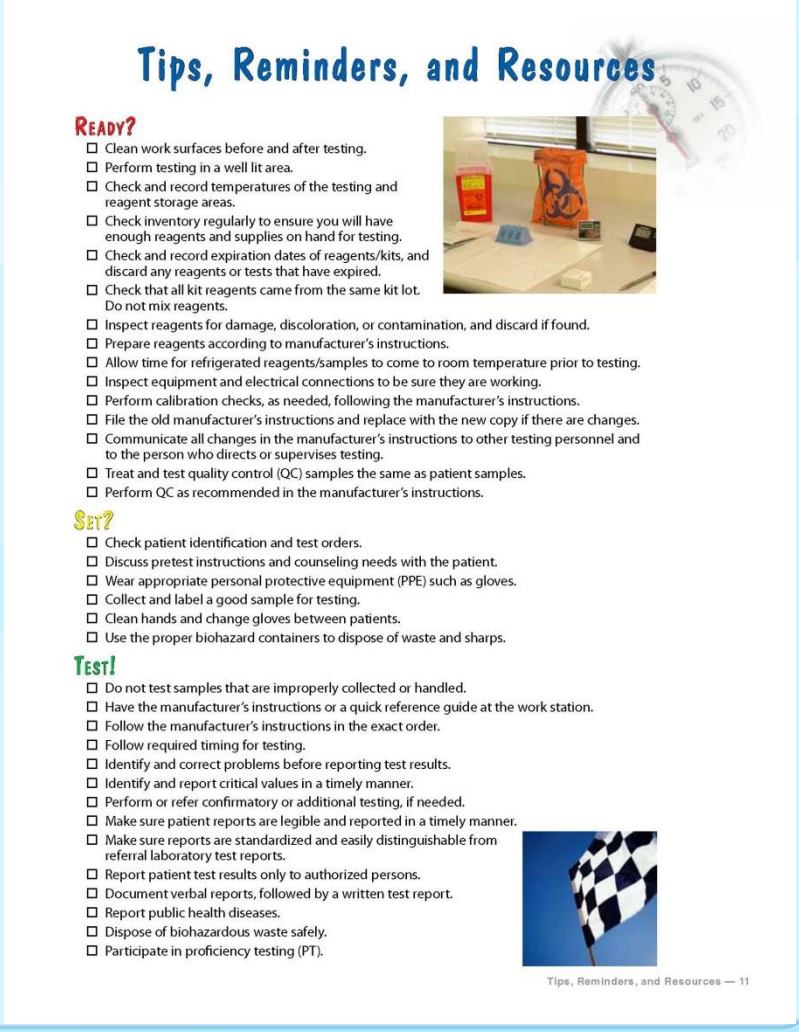
- Advice on clinical laboratory issues, especially safety
  - Support laboratories, clinical and public health, both at home and abroad
  - Coordinate with CDC Emergency Operations Center laboratory teams
  - Videos demonstrating biosafety procedures
  - Amer. Biol. Safety Assoc. certified staff supports triage/ response to inquiries from laboratories and field epidemiologists

DLS and CDC Laboratory Safety Efforts

- Supporting Laboratory Safety workgroup recommendations
  - Creating improved laboratory training in
    - Safety and quality management
    - Competency-based curriculum
  - Laboratory Leadership Service fellowship – CSELS/DLS & DSEPD
- External accreditation for all CDC laboratories
  - CLIA for clinical labs; ISO17025 for research labs
- CASPIR, "CDC and ATSDR Specimen Packaging, Inventory and Repository"
  - Advancing improved IT accession systems, with bar coding
  - Revising specimen collection

Promoting Good Laboratory Practices for Waived Testing - Update to 2014 CLIAC Recommendation

- Development of a voluntary self-assessment checklist-type tool based on recommended practices in the “Ready? Set? Test!” booklet
- Updates being made to “Ready? Set? Test!” and “To Test or Not To Test?” booklets to address off-label use of waived tests



Tips, Reminders, and Resources

Ready?

- ☐ Clean work surfaces before and after testing.
- ☐ Perform testing in a well lit area.
- ☐ Check and record temperatures of the testing and reagent storage areas.
- ☐ Check inventory regularly to ensure you will have enough reagents and supplies on hand for testing.
- ☐ Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired.
- ☐ Check that all kit reagents came from the same kit lot. Do not mix reagents.
- ☐ Inspect reagents for damage, discoloration, or contamination, and discard if found.
- ☐ Prepare reagents according to manufacturer’s instructions.
- ☐ Allow time for refrigerated reagents/samples to come to room temperature prior to testing.
- ☐ Inspect equipment and electrical connections to be sure they are working.
- ☐ Perform calibration checks, as needed, following the manufacturer’s instructions.
- ☐ File the old manufacturer’s instructions and replace with the new copy if there are changes.
- ☐ Communicate all changes in the manufacturer’s instructions to other testing personnel and to the person who directs or supervises testing.
- ☐ Treat and test quality control (QC) samples the same as patient samples.
- ☐ Perform QC as recommended in the manufacturer’s instructions.

Set?

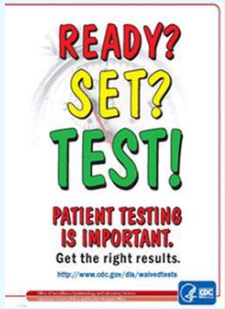
- ☐ Check patient identification and test orders.
- ☐ Discuss pretest instructions and counseling needs with the patient.
- ☐ Wear appropriate personal protective equipment (PPE) such as gloves.
- ☐ Collect and label a good sample for testing.
- ☐ Clean hands and change gloves between patients.
- ☐ Use the proper biohazard containers to dispose of waste and sharps.

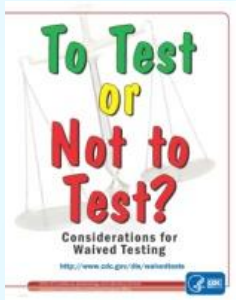
Test!

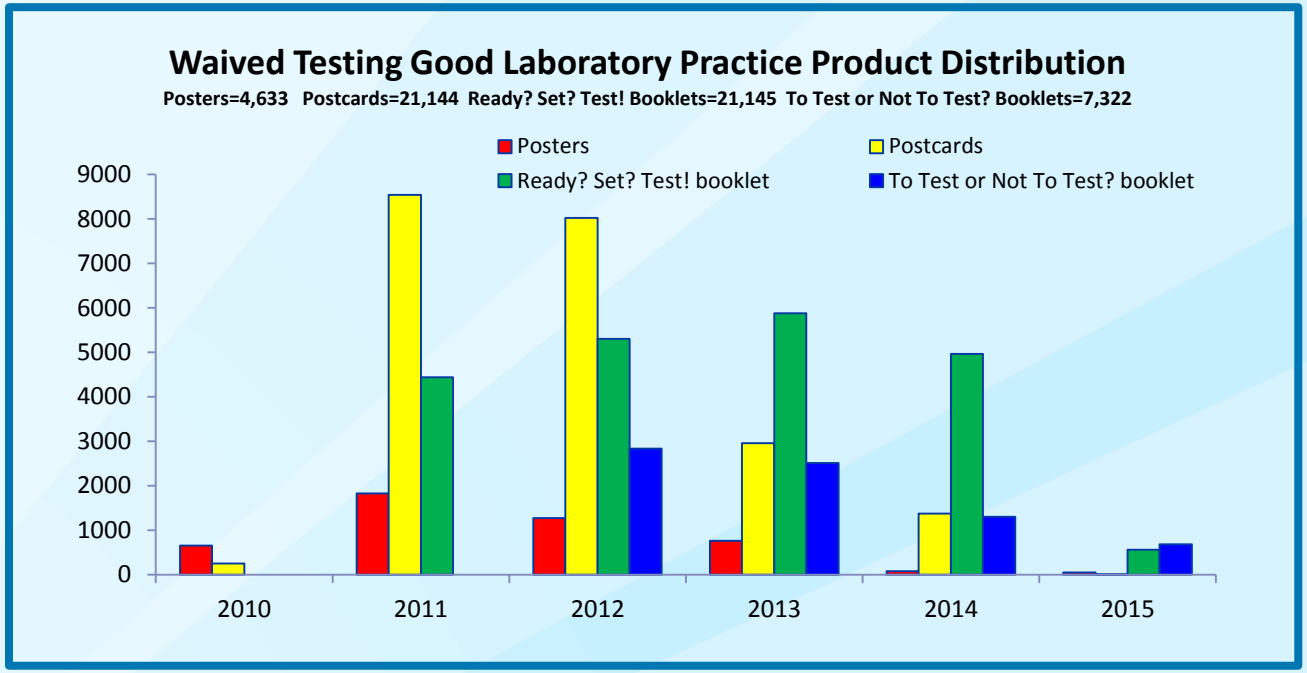
- ☐ Do not test samples that are improperly collected or handled.
- ☐ Have the manufacturer’s instructions or a quick reference guide at the work station.
- ☐ Follow the manufacturer’s instructions in the exact order.
- ☐ Follow required timing for testing.
- ☐ Identify and correct problems before reporting test results.
- ☐ Identify and report critical values in a timely manner.
- ☐ Perform or refer confirmatory or additional testing, if needed.
- ☐ Make sure patient reports are legible and reported in a timely manner.
- ☐ Make sure reports are standardized and easily distinguishable from referral laboratory test reports.
- ☐ Report patient test results only to authorized persons.
- ☐ Document verbal reports, followed by a written test report.
- ☐ Report public health diseases.
- ☐ Dispose of biohazardous waste safely.
- ☐ Participate in proficiency testing (PT).

Tips, Reminders, and Resources — 11

Distribution of Waived Testing Educational Products







Ready? Set? Test! Online Course Participation (Sept 2011- March 2015)

Course Registration	
Total Registered	4293
Completed	3005
In Progress	1173
Withdrawn	115

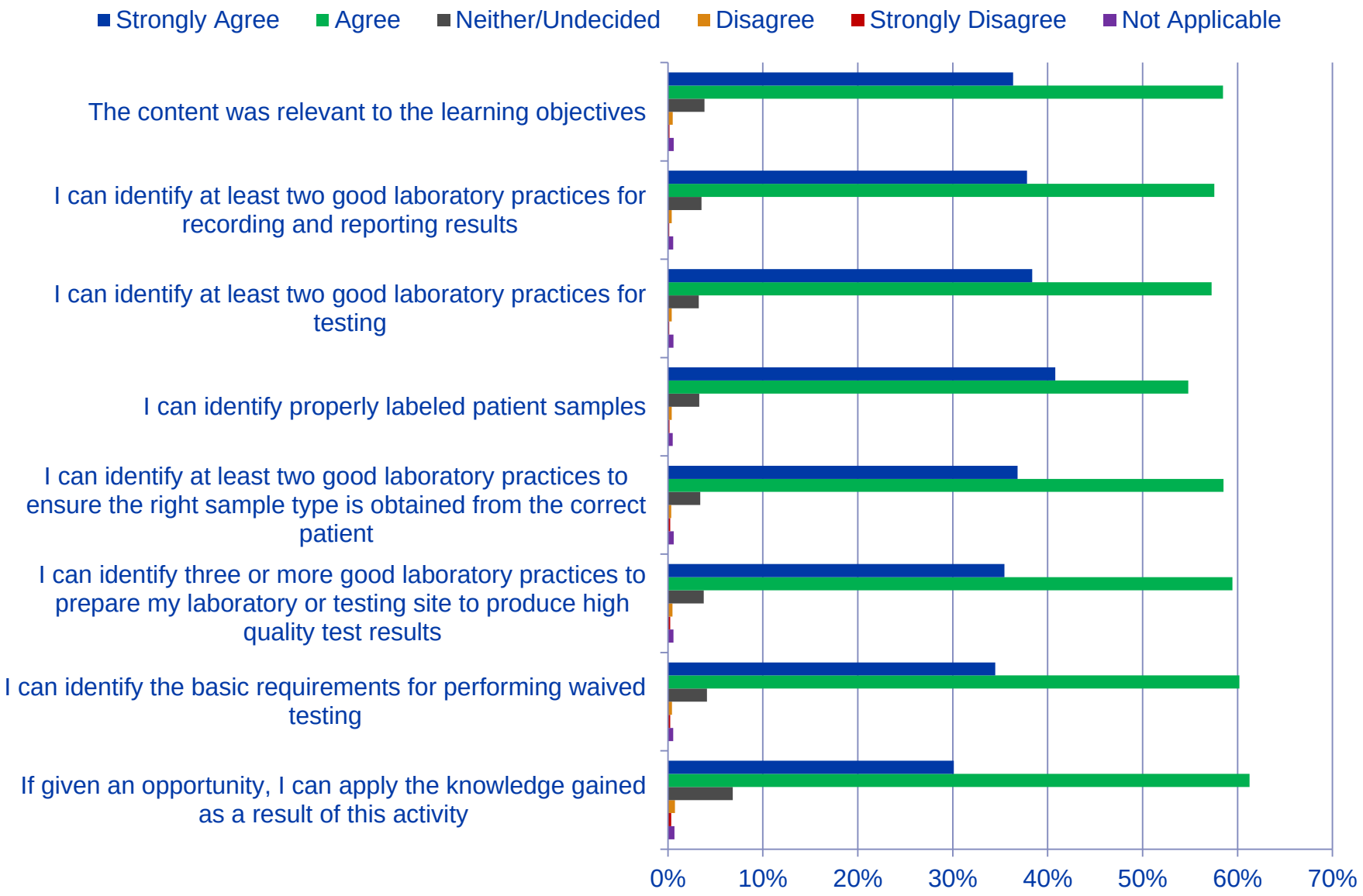
Credit Type	Total Hours Awarded
CEU/CE (0.1 hours)	127.1
CME (1.0 hours)	234
CNE Contact Hours (1.0 hours)	397
Pharmacists Contact Hours (0.1 hours)	6.3

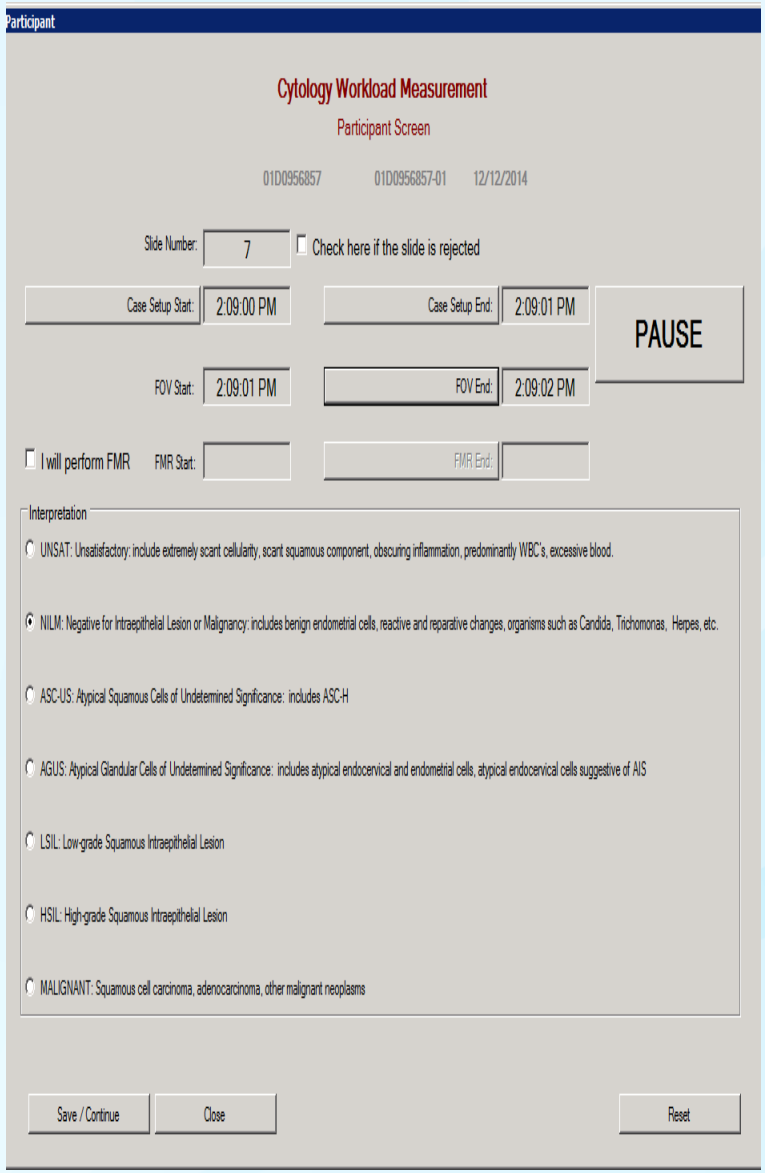
http://wwwn.cdc.gov/clia/Resources/WaivedTests/

Ready? Set? Test! Online Course

- Free training based on booklet promoting good laboratory practices for waived testing
- Includes knowledge checks and realistic waived testing scenarios to reinforce learning
- Templates, checklists, resources to save/download

Course Evaluation (Sept 2011 - March 2015)





Cytology Workload Assessment and Measure

- **Purpose – evaluate gynecologic cytology workload requirements for cytotechnologists using image-assisted devices**
- **American Society for Cytotechnology Services, Inc. –** onsite observations of image-assisted screening in 8-hour workday
- **Status of Time Measure Study**
  - 71 Laboratory Observations of Cytotechnologists to be completed by 4/30/2015 – need 29 more volunteers
  - To participate, contact: Timemeasure@asctservices.com
  - More information available at: http://asctservices.com/cytology-workload-study/faqs-time-measure-study

Workload Assessment Project Next Steps

- Partnering with schools of cytotechnology to collect student data to estimate expected workloads for newly trained employees
- CDC will provide a copy of time measure tool to each school that participates
- Students in their last month of training will participate
- CDC will collect and analyze all data
- Compare data to ASCT contracted data
- Target date to begin May 2015

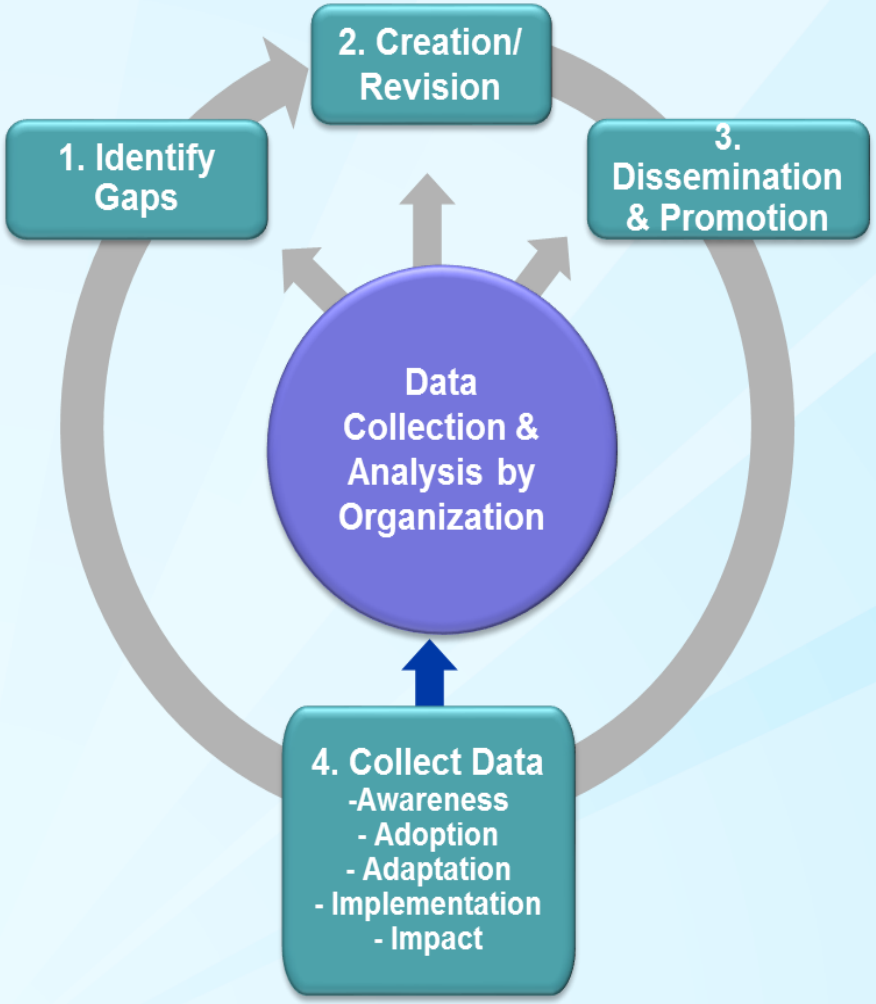
Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™)

- **CDS Tools**
  - Vetting new coagulation test selection algorithms
    - New anticoagulants
    - Interruption of treatment
    - Reversal of anticoagulation
    - Targeting specific conditions (VTE, DVT, PE, etc.)
- **Mobile applications**
  - CDC GA Tech Seed Grant
    - Translating coagulation algorithms to mobile app
  - Evaluating Mobile Application CDS utility
    - PTT Advisor app
    - Veteran's Administration hospital physicians - pilot

CLIHC™ Projects

- **Emory Medical Quality Improvement**
  - Survey Emory clinicians to better understand their laboratory test nomenclature challenges and solutions
- **Education**
  - A ‘Dueling Docs’ scenario based skit highlighting importance of clear communication for appropriate laboratory test utilization is being developed for the CLIHC website
- **Partnerships**
  - Institute of Medicine (IOM): Diagnostic Errors in Health Care – Report expected 2015 with laboratory focus
  - Society to Improve Diagnosis in Medicine (SIDM) Coalition to Improve Diagnosis
  - CLMA’s Increasing Clinical Effectiveness (ICE) coalition
  - Coordinating Council on the Clinical Laboratory Workforce (CCCLW)’s Measuring Value Initiative

Laboratory Practice Guidelines (LPG) Metrics Projects



Project Goals

- Improve uptake and use of LPGs
- Identify gaps in awareness/use
- Partners develop surveys to better understand gaps and strategies to address them
- Use AGREE II tools to assess quality of representative LPGs to learn how to improve them

CDC will create a clearinghouse to promote use of LPG Metrics

- Survey design/sampling
- Focus groups
- IOM reports and related research

LPG Metrics Awardees' Projects

- **Clinical and Laboratory Standards Institute**
  - Evaluate awareness, distribution, and utility of two POC glucose monitoring (GM) LPGs for sites with (POCT 12) and without (POCT 13) laboratory support
    - LPGs chosen because both documents are relatively unknown by most of the ~85,000 testing sites
- **College of American Pathologists**
  - Immunohistochemistry (IHC) Assay Validation
    - Follow-up survey to CAP 2010 assessment
    - IHC labs to include CAP and Non-CAP PT customers
  - Acute Leukemia Algorithm
    - Joint LPG with American Society of Hematology
    - 2016 Acute Leukemia Practices and Procedures Pre-Survey will provide the baseline data to measure uptake of the published LPG

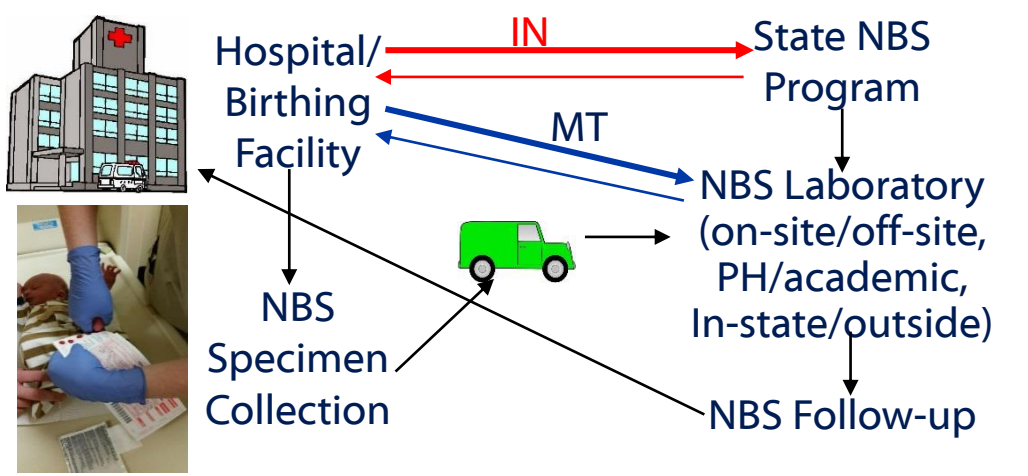
LPG Metrics
Awardees' Projects

- **American Society for Microbiology**
  - Evaluate effectiveness of four evidence-based recommendations (LMBP™)
    - Reduction of Blood Culture Contamination
    - Rapid ID of Bloodstream Infections
    - Proper Handling of Urine Specimens
    - Laboratory diagnosis of *C. difficile* colitis
  - Initial assessment of these LPGs by survey
    - Laboratory Response Network (LRN) to disseminate survey links
      - May establish use of LRN for surveys of sentinel clinical labs
      - Enhance public-private linkages in the states

AMERICAN SOCIETY FOR MICROBIOLOGY

Newborn Screening (NBS) Laboratory Testing

- **Improve NBS -** integrate birth notification with NBS specimen collection, submission, transport, process tracking to improve timeliness & quality
- **Current milestones**:
  - MT: Established 2-way messaging system between state NBS lab and birthing facility
  - IN: 3 large hospital systems + 4 additional hospitals participating; birth notification/filter paper card match rates being analyzed



Laboratory Medicine Best Practices (LMBP™)

Systematic reviews in progress:

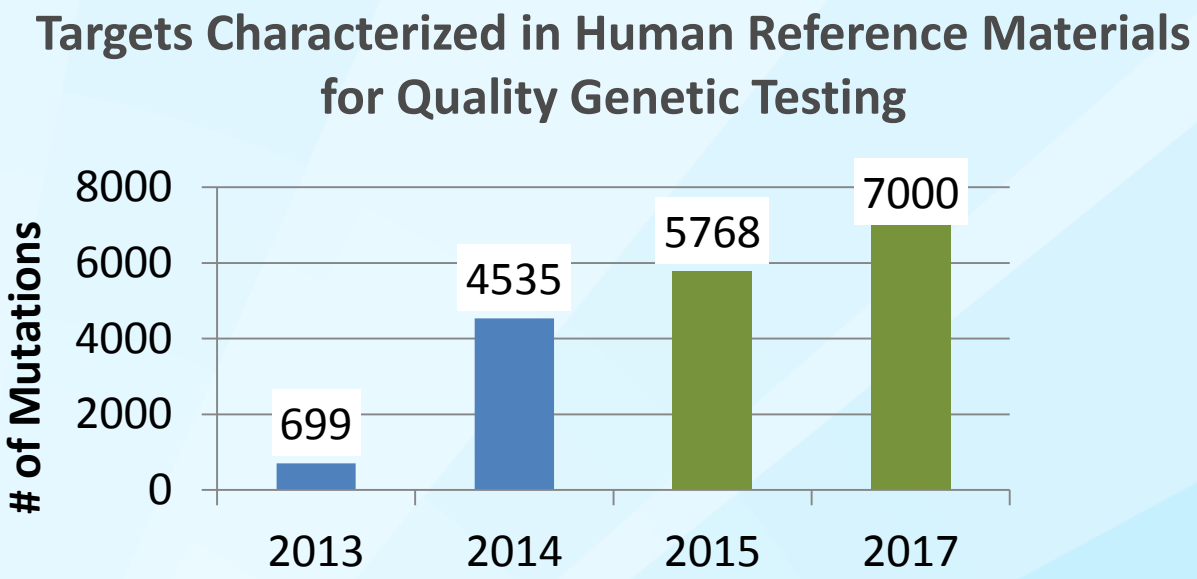
- **Laboratory Test Utilization:** What practices can Labs use to support and optimize appropriate Lab Test Utilization (the right test for the right patient at the right time?)
  - Practices to assess:
    - Computerized Physician Order Entry (CPOE), CDS, education, feedback, test review, lab test utilization teams, reflex testing
  - Results pending at discharge
  - Specimen rejection

LMBP™ ASM
Systematic reviews collaboration

- **Completed**
  - Blood Stream Infection, Rapid Identification Methods
  - Urine Specimen Handling Collection and Transport

- **New**
  - *Clostridium difficile* – 4 focus areas:
    1. Highest diagnostic accuracy testing algorithms
    2. Increased diagnostic yield for repeat of enzyme immunoassay (EIA) or nucleic acid amplification testing
    3. Clinical utility of toxigenic culture and cytotoxin assay
    4. Clinical utility of PCR-positive and cytotoxin-/EIA-negative results

Genetic Testing Reference Materials Program (Get-RM)

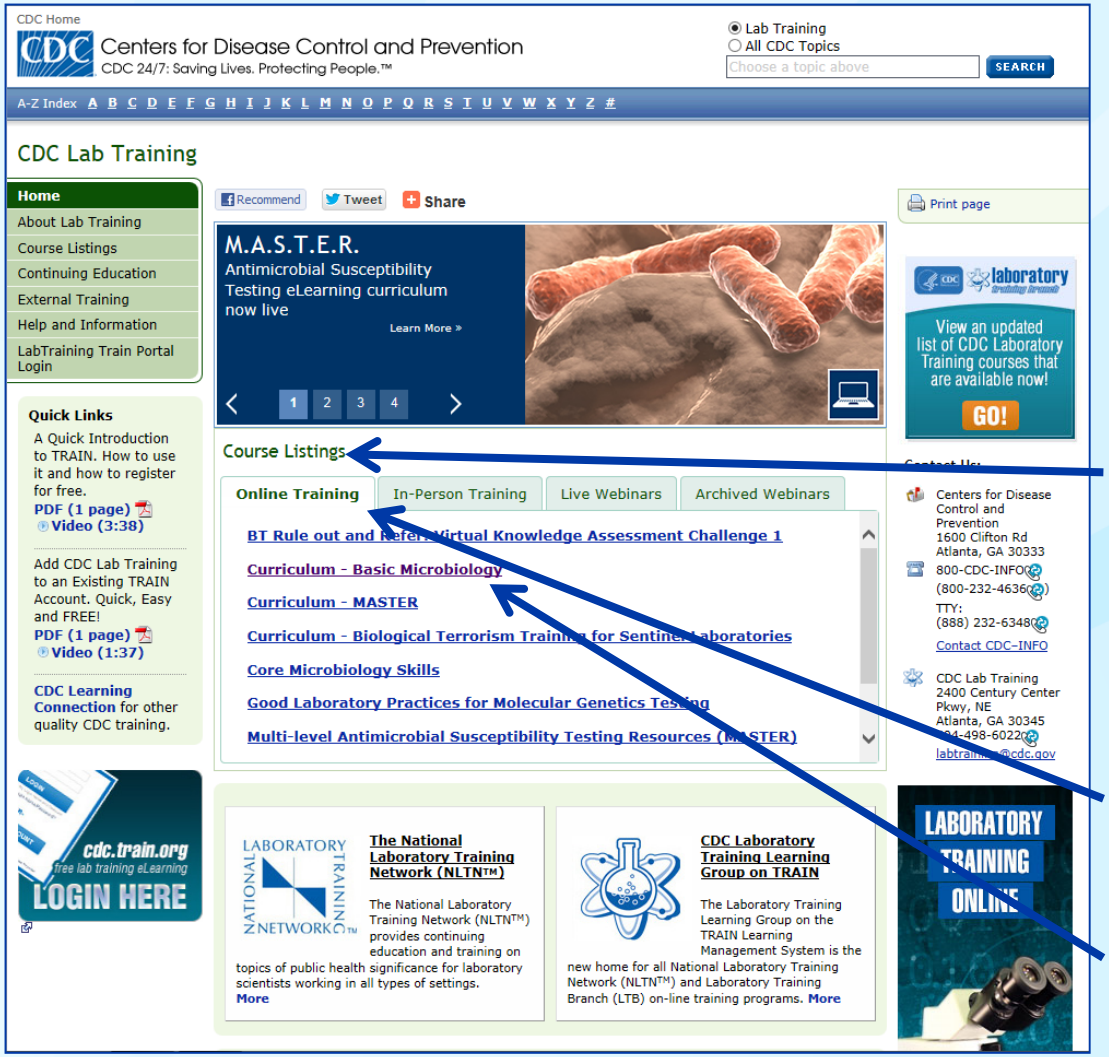


- ~700 cell lines for > 25 human genetic disorders characterized and publicly available
- **New:** HLA Loci and expanded pharmacogenomics haplotype characterized
  - Formed international workgroup to harmonize nomenclature and assay design

Standards for Next-Generation Sequencing in Clinical Laboratories

- **CDC-facilitated national workgroups**
  - "Design and Optimization of a Next-Generation Sequencing Informatics Pipeline" (in press, Nature Biotechnology)
  - A Clinical Grade Variant Template as a model for Sharing Genomic Data generated within the clinical laboratory (e.g., for external quality assurance, to outsource analysis, etc.) (manuscript in preparation)
- **IOM Action Collaborative** (Roundtable on Translating Genomic-based Research for Health)
  - Developing Guiding Principles for Integrating Genomic Information Into the Electronic Health Record Ecosystem

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



- Access to over 50 Online Courses
- Access to live course schedules and announcements
- Course Listings section lists all courses available from the CDC Laboratory Training Group
- Select a Course Format Tab
- Select a Course Topic

Highlighted Training

- **The Methods of Antimicrobial Susceptibility Testing Educational Resource (MASTER)**
- **Basic Microbiology Blended Learning Curriculum**
  - Self -study eLearning modules for didactic course content
  - Locally mentored hands-on exercises for experiential course content.
- **Preparedness**
  - Sentinel Laboratory "Rule out or Refer" Training
  - Sentinel Laboratory "Rule out or Refer" Training Virtual Knowledge Assessment
  - "Packaging and Shipping of Division 6.2 Materials"

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

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