

CDC Update

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CLIAC Meeting
April 13, 2016
Atlanta, Georgia



Division of Laboratory Systems – Mission

- Improve the quality and safety of laboratory practices in the United States and globally through the development and evaluation of innovative training, standards, guidelines, and reference materials



Highlights of Recent DLS Activities

- **DLS Funding Opportunity Announcements (FOAs)**
- **New - Provider-Performed Microscopy Procedures Educational Booklet**
- **Distribution of Waived Testing and IQCP Educational Materials**
- **Genetic Testing Reference Material (GeT-RM) Program**
- **Laboratory Medicine Best Practices**
- **Laboratory Practice Guidelines Metrics Projects**
- **Laboratory Health Information Technology (LabHIT)**
- **Laboratory Informatics Curriculum and Training**
- **Global Health Security Agenda (GHSA) and International Health Regulations (IHR)**
- **Laboratory Training Website**

DLS Funding Opportunity Announcements (FOAs)

- **CDC-RFA-OE16-1602 *Use of a Medical Data Warehouse in a Laboratory Quality Improvement Initiative that Links to Patient and System Outcomes.***

The purpose of this project is to support a collaborative opportunity to develop, implement, and evaluate a process to assess the usefulness of data contained within a medical data warehouse to document and address quality gaps in the pre-, intra-, and/or post-analytic phases of clinical laboratory medicine that can be linked to patient and/or system outcomes.

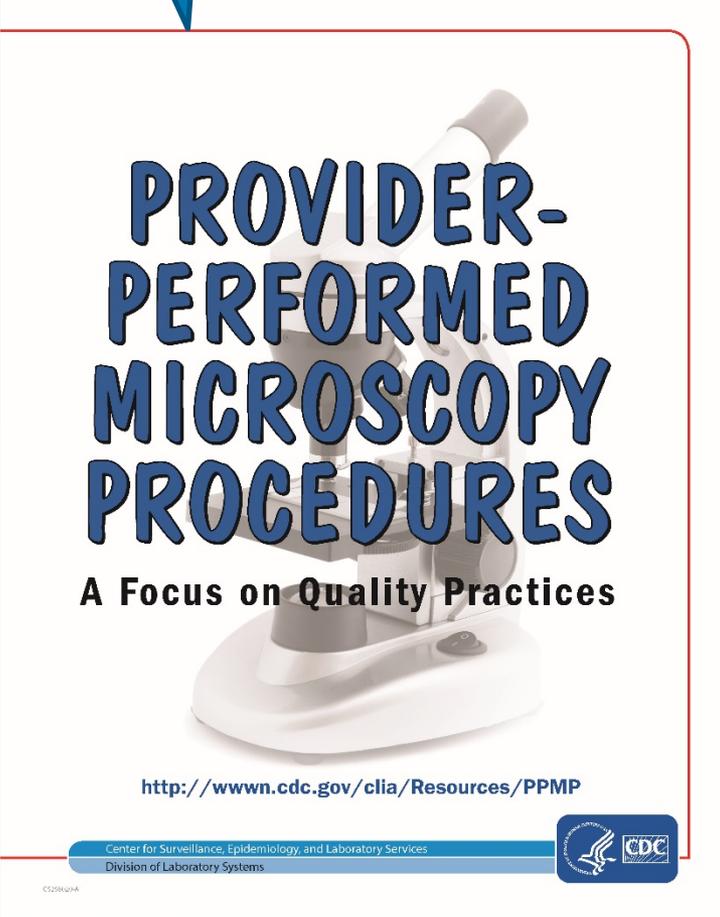
Please go to <http://www.grants.gov/web/grants/search-grants.html>, for more information and an application. Applications are due April 22, 2016.
- **CDC-RFA-OE16-1603 *Improving Waived Testing Performance and Outcomes through Partnerships.***

The purpose of the project is to support and expand the efforts of the laboratory and stakeholder organizations to instill quality practices, including applicable minimum Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements and good laboratory practice recommendations, in Certificate of Waiver (CW) sites nationwide to improve patient safety and health outcomes.

Please go to <http://www.grants.gov/web/grants/search-grants.html>, for more information and an application. Applications are due April 22, 2016.

NEW

Provider-Performed Microscopy (PPM) Procedures Educational Booklet



PROVIDER- PERFORMED MICROSCOPY PROCEDURES

A Focus on Quality Practices

<http://www.cdc.gov/clia/Resources/PPMP>

Center for Surveillance, Epidemiology, and Laboratory Services
Division of Laboratory Systems



- Describes recommended practices under a CLIA Certificate for PPM Procedures for
 - physicians,
 - midlevel practitioners (nurse midwife, nurse practitioner, or physician assistant), and
 - dentists.
- Contains an overview of
 - the regulatory requirements,
 - resources including forms and examples, and
 - images of common microscopic findings for the nine specific microscopic examinations that may be performed under a Certificate of PPM Procedures.
- Request hardcopies of the booklet through email at PPMP@cdc.gov or online at <http://www.cdc.gov/clia/Resources/PPMP>

NEW

PPM Procedures Educational Booklet: Contents

- **Regulatory Requirements**
- **Personnel**
- **Safety**
- **Location for Testing**
- **Performing PPM Procedures**
- **PT Requirements**
- **Quality Systems**
- **Tips and Resources**
- **Appendices**



NEW

PPM Procedures Educational Booklet: Appendices

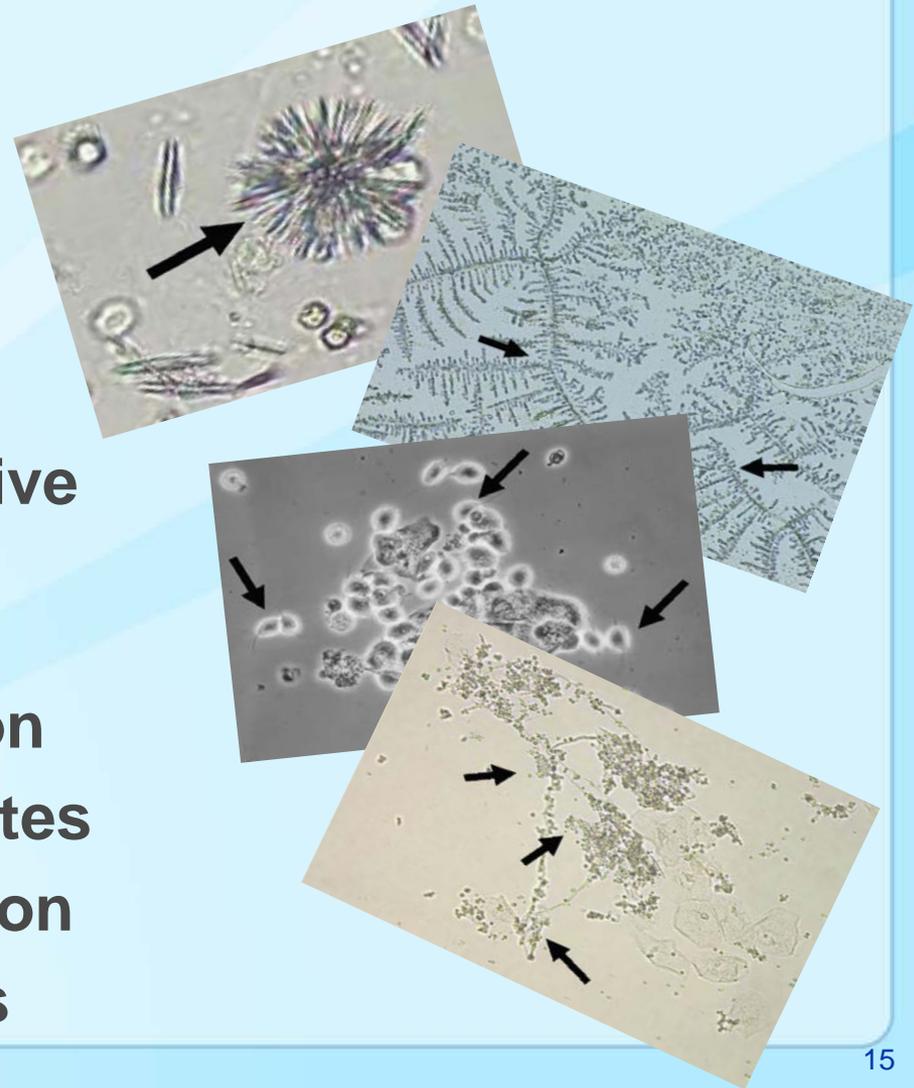
- **Security and Confidentiality Agreement**
- **Training Checklist**
- **Training Evaluation**
- **Eyewash Station Weekly Maintenance Log**
- **Safety Plan**
- **Incident Report Instructions**
- **Common Disinfectants and Antiseptics**
- **Care and Maintenance of the Microscope**
- **PPM Procedures with Images**



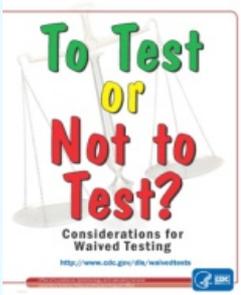
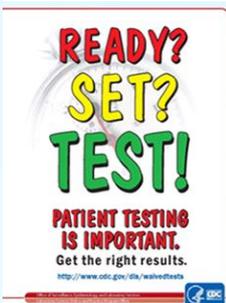
NEW

PPM Procedures Educational Booklet: PPM Procedures with Images

- Wet Mount
- KOH Preparation
- Pinworm Examination
- Fern Test
- Post-Coital Direct, Qualitative Examination of Vaginal or Cervical Mucus
- Urine Sediment Examination
- Nasal Smear for Granulocytes
- Fecal Leukocyte Examination
- Qualitative Semen Analysis



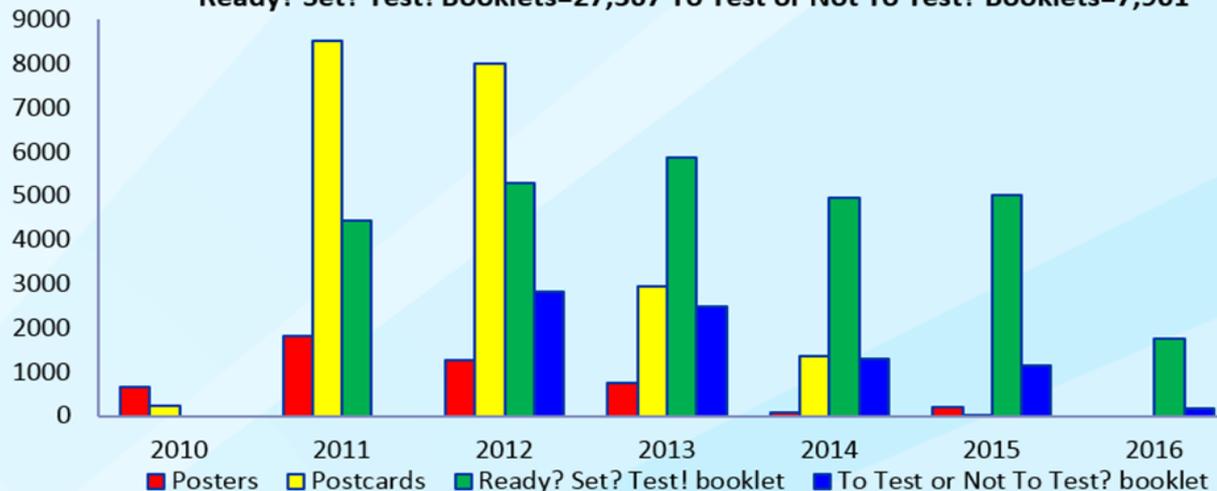
Waived Testing Educational Products



Waived Testing Good Laboratory Practice Product Distribution

Posters=4,800 Postcards=21,144

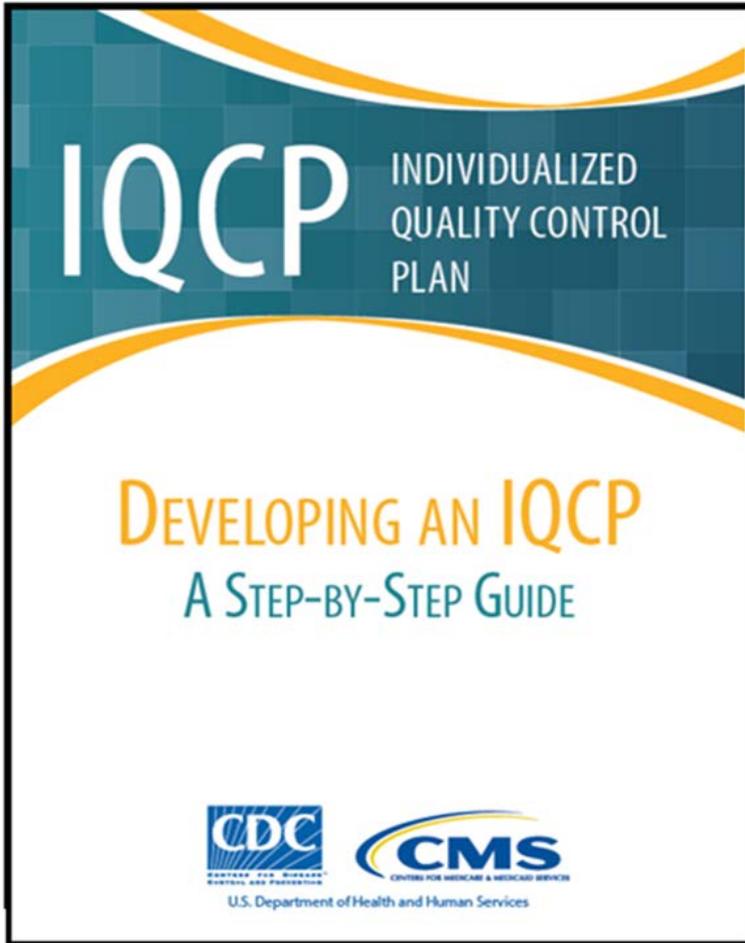
Ready? Set? Test! Booklets=27,367 To Test or Not To Test? Booklets=7,961



Ready? Set? Test! Online Course Participation (Nov 2011-February, 2016)

Total Registered	6922	Credit Type	Total Hours Awarded
			Completed
In Progress	2256	CME (1.0 hours)	322
Withdrawn	218	CNE Contact Hours (1.0 hours)	472
		Pharmacists Contact Hours (1 contact hour or 0.1 CPE)	81

IQCP Educational Workbook



Total Workbooks Distributed = 3,221

Request hardcopies of the booklet through email at: iqcpworkbook@cdc.gov

or

download the PDF online at:

<http://www.cdc.gov/CLIA/Resources/IQCP/>

Genetic Testing Reference Material Program

Characterization of 137 Genomic DNA Reference Materials for 28 Pharmacogenetic Genes

J Mol Diagn 2016;18:109-123; <http://www.ncbi.nlm.nih.gov/pubmed/26621101>

- Pharmacogenetic testing is increasingly available from clinical laboratories
- Only a limited number of quality control and other reference materials are currently available to support clinical testing
- Characterization that addresses the need for pharmacogenetics reference materials

Pharmacogenetic Allele Nomenclature: International Workgroup Recommendations for Test Result Reporting

Clin Pharmacol Ther 2016;2:172-185; <http://www.ncbi.nlm.nih.gov/pubmed/26479518>

- Accurate and standardized reporting of pharmacogenetics test results is important toward achieving meaningful test results
- Sequence variant identified by pharmacogenetics tests are presently described using different nomenclature systems

Laboratory Medicine Best Practices (LMBP™)

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 2016;29:105-147, <http://cmr.asm.org/content/29/1/105.full.pdf+html>

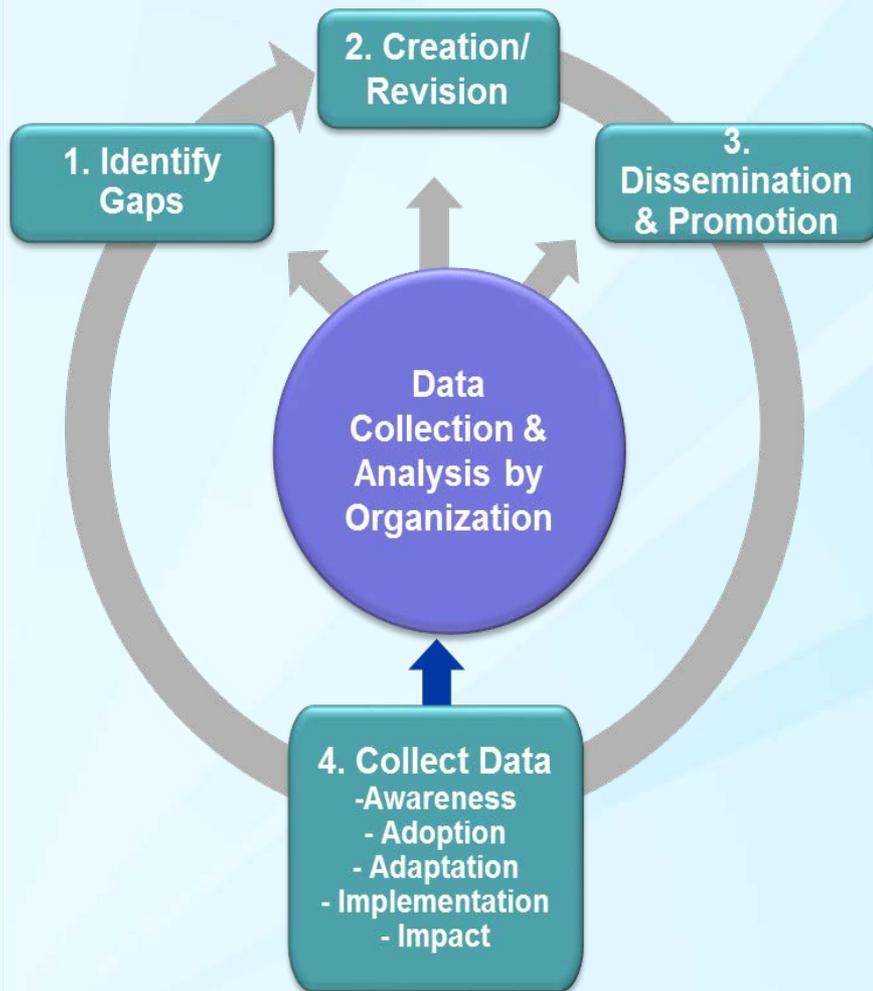
- Urinary tract infection in the United States is the most common bacterial infection
- Reducing opportunities for urine culture contamination during the pre-analytic phase of testing addresses a major concern about obtaining meaningful test results

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 2016;29:59-103, <http://cmr.asm.org/content/29/1/59.full.pdf+html>

- Bloodstream infection is a major cause of morbidity and mortality throughout the world
- Rapid identification of bloodstream pathogens directs timely and effective prescription of appropriate antimicrobials

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 group findings
- IOM reports, related research
- Evaluation plan

LPG Metrics Awardees' Projects

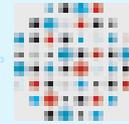


- **Evaluate two POC glucose monitoring LPGs - with (POCT 12) and without (POCT 13) laboratory support**
- **A survey will examine:**
 - Familiarity with the Clinical Laboratory Standards Institute (CLSI) and CLSI documents
 - Use of POCT 12 or POCT 13
 - Reasons for modification or non-implementation of recommendations
 - Opinion of document
 - Ease of use, reading level, utility
 - Whether implementation of recommendation resulted in reduced errors or reduced need for additional tests?
 - Suggested changes that would make document easier to use

LPG Metrics Awardees' Projects



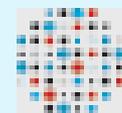
- **Survey is currently open!**
 - Survey sent to 30,000 waived and non-waived testing sites: half POLs (POCT 13), half hospital and clinic labs (POCT 12)
 - Survey recipients from OSCAR, COLA, AHA, The Joint Commission, Dept. of Defense, POCT Coordinators
 - Survey closes April 22
 - Free copies of POCT 12 or POCT 13 will be provided to survey recipients who indicated that they are not familiar with them.
These respondents will be resurveyed after 6 months
- **CLSI will use results of survey to improve documents/processes, will resurvey to assess impact of changes**



■ Immunohistochemistry (IHC) Assay Validation

- After data deduplication, the 2015 IHC survey includes 1624 responses for analysis:
 - 1539/3064 (50%) for CAP PT-specific response rate
 - 85/448(19%) for non-CAP PT response rate
- The data will be examined in detail at the April 3rd GMEP meeting and manuscript sections will be assigned
- Follow-up telephone surveys and focus group are planned for Q2/Q3 2016 pending OMB approval
- An abstract of the process/outcome will be submitted to the Guidelines International Network (GIN) meeting

LPG Metrics Awardees' Projects



COLLEGE of AMERICAN
PATHOLOGISTS

- **Acute Leukemia Algorithm (ALA)**
 - Joint LPG between CAP and American Society of Hematology (ASH)
 - An online acute leukemia practices baseline survey was sent (June 2015) to self-reported hematopathologists in CAP database; 295 responses
 - Results were presented at USCAP (poster session on March 14, 2016)
 - Draft ALA recommendations were created/vetted – 780 comments
 - The CAP / ASH expert panel is finalizing the recommendations in conjunction with feedback from the open comment period
 - The manuscript will be refined at the April 3rd GMEP meeting
 - Final guideline approval and submission to journal(s) is expected by end of Q2 2016
 - Uptake of the ALA guideline will be promoted and tracked

LPG Metrics Awardees' Projects



- Surveys to evaluate awareness of guidelines for
 - *C. difficile* diagnosis (closed April 1, 2016)
 - Urine specimen pre-analytical practices (opens April 2016)
- Surveys upcoming to evaluate awareness of guidelines for
 - Reduction of Blood Culture Contamination
 - Rapid ID of Blood Stream Infection
- Systematic reviews (National Guideline Clearinghouse requires updates every 5 years) in progress for
 - Blood culture contamination
 - Rapid identification of bloodstream infections
- Presentation scheduled for 2016 ASM Microbe meeting to train laboratory professionals to perform QI studies using data collection forms specifically designed for urine pre analytic questions

Laboratory Health Information Technology (LabHIT) Team

- Support **interoperable health IT** standards
 - Creating relational database and mapping tool for SNOMED CT® Human Specimen Descriptors and term definitions
 - Microbiology terms incorporated; molecular testing in queue to review
 - Chemistry and anatomic pathology specimen terms to be completed
- Promote **patient safety**
 - Supporting development of a Laboratory EHR Safety Checklist with researchers at the VA Health Services Research Center of Innovation
 - Analyzing laboratory related health IT patient safety events reported to FDA
- Participate in **federal rulemaking**
 - Reviewing Proposed Rule: “ONC Health IT Certification Program: Enhanced Oversight and Accountability”
 - Public comments are encouraged. Due May 2, 2016: <http://go.usa.gov/cAxPA>

Development of Laboratory Informatics Curriculum and Training

- Strengthening informatics competencies in the laboratory workforce identified as a priority by multiple stakeholders (CDC, CMS, APHL, many others)
- APHL funded to collaborate with CDC and develop a curriculum and training materials to address competencies for all laboratory staff in addition to informatics specialists
- RFP released for instructional design
- Emphasis on multiple learning modalities and access through learning management systems
- Next steps include input and SME consensus around topics, modules, training formats

Global Health Security Agenda (GHSA) and International Health Regulations (IHR)

- GHSA and IHR are initiatives to strengthen country capacity to detect and respond to threats (e.g. SARS and Ebola)
- Now both GHSA and IHR country assessments combined and reviewed by external teams---U.S. scheduled for May 2016
- National Laboratory System is a priority focus along with quality standards to ensure capacity and accuracy to detect
- CLIA documented as a major US strength providing universal regulation, PT, and standards
- Question: Is further flexibility required to enable response to novel threats and accommodate new technologies?

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.

The screenshot shows the CDC Laboratory Training website homepage. 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 with the word "SEARCH" and a magnifying glass icon. Below the search bar is a "CDC A-Z INDEX" dropdown menu. The main header is a dark purple bar with "CDC Laboratory Training" in white. Below this is a large blue banner with the text "CDC Laboratory Training" and "Live and archived laboratory training online and in-person for FREE!". The banner features illustrations of a DNA helix, a certificate, a laptop, a microscope, and a globe. 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 timer and a registration button; "24/7 Online Training" with a photo of a person at a computer and a link to the schedule; "External Training Links" with a globe icon and a link to external partners; and "Help/FAQs" with a "connecting worldwide" logo and a link to help resources.

Highlighted Training

- **The Methods of Antimicrobial Susceptibility Testing Educational Resource (MASTER)**
- **Brain-Eating Amoebas – Challenges in Diagnosis and Treatment**
- **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

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.