

CLIA Inspection Guidance for LRN-C, RADIOBIOASSAY & BIOMONITORING LABORATORIES

TABLE OF CONTENTS

Introduction.....	1
List of Acronyms.....	2
CLIA Inspection Checklist & Guidance for LRN-C Laboratories.....	2
Proficiency Testing.....	4
Quality Assessment Plan Elements.....	5
Laboratories Performing High Complexity Testing and Personnel Qualifications & Responsibilities.....	7
Inspection.....	12
Enforcement.....	10
Overarching Considerations.....	10
Appendix A: Reportable Range for Test Results [493.1253(b)(2)].....	11
Appendix B: Role of Laboratory Informatics.....	13
Acknowledgements.....	14
Related APHL Resource.....	14

INTRODUCTION

In 2009 the Centers for Medicare & Medicaid Services (CMS) released a memorandum stating chemical terrorism (CT) laboratories will be added to the CLIA certificate under the umbrella of the main laboratory. In order to help members prepare for CLIA inspection of their LRN-C program, APHL, with guidance from CMS, developed a [CLIA Inspection Checklist for LRN-C, Radiobioassay and Biomonitoring Laboratories](#).

The APHL Environmental Health Committee (EHC) developed this guidance as a companion to the Checklist. Readers will find the EHC's comments, references and experiences throughout as footnotes. **The EHC strongly advises users of the Checklist to first read this Guidance Document before employing the Checklist.**

While this document intends to provide guidance to CT laboratories to prepare for a CLIA inspection, the document is NOT all-inclusive. Laboratories should be aware some regions or states may have slightly different or additional requirements. Also, that some items listed in

the document may not be applicable in all situations. If laboratories have any questions or are unclear about specific requirements, the EHC advises laboratories to contact their regional CMS office.

Interpretive Guidelines on CLIA lends more detail for compliance:

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html

LIST OF ACRONYMS

APHL	Association of Public Health Laboratories
CA	Corrective Action
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments are federal requirements that ensure accuracy, reliability and timeliness of clinical laboratory test results.
CMS	Centers for Medicare & Medicaid Services regulates all clinical laboratories testing performed in the United States through the Clinical Laboratory Improvement Amendments.
CT	Referring to ‘chemical threat’ laboratories in the Laboratory Response Network (LRN) .
CTQ	Critical to Quality
EDMS	Electronic Document Management System
EHC	Environmental Health Committee
FDA	Food and Drug Administration
LD	Laboratory Director
LEI	Laboratory Efficiencies Initiative was created to help laboratories maintain their public health testing services despite decreased funding, which causes many laboratories to eliminate or reduce testing for certain diseases.
LIMS	Laboratory Information Management System

LOD	Limit of Detection
LOQ	Limit of Quantitation
LRN-C	Laboratory Response Network for Chemical Threats is part of the larger Laboratory Response Network and comprises 53 laboratories at the local, state or territory level.
PARRSS	Performance specifications for high complexity test systems. This stands for: precision, accuracy, reportable ranges, reference intervals, sensitivity and specificity
PHL	Public Health Laboratory
P&P	Policy & Procedures
PMQAS	Priority Metals Quality Assessment Scheme is a PT scheme designed for laboratories using inductive coupled plasma mass spectrometry to analyze trace elements in blood and urine
PT	Proficiency Testing
QA	Quality Assurance is a process of meeting quality standards and assuring that care reaches an acceptable level. QA is a reactive, retrospective effort to examine why a facility failed to meet certain standards.
QC	Quality Control consists of procedures used to detect errors that occur due to test system failure, adverse environmental conditions and variance in operator performances, as well as the monitoring of accuracy and precision over time.
SOP	Standard Operating Procedures
TS	Technical Supervisor

CLIA INSPECTION CHECKLIST & GUIDANCE FOR LRN-C LABORATORIES

Because of the complex nature of LRN-C laboratory tests, these laboratories are designated as high complexity testing, and must meet CLIA certification requirements.

CLIA Reg #	Certification
	Item: Laboratories must be in compliance with regulations with regard to their services.
	SubPart A
§493.25	Laboratories performing tests of high complexity.
	(a) A laboratory must obtain a certificate for compliance (or be added to PHL list of specialties).
	(b) And must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part.

Proficiency Testing

CLIA Reg #	Certification: Laboratory Requirements
§493.801	SubPart H – Proficiency Testing (PT)
	Enrollment for each analyte
	Process as regular workload, just like patients, repeat only if you would for patient
	Same personnel using routine methods
	Analyst and Laboratory Director (LD) or Technical Supervisor (TS) attest to integrity of samples. Any attestation statement provided by the PT program to be signed by analyst and lab director documenting that the PT sample was tested in the same manner as patient samples.
	No collaboration with another lab, don't send sample out for analysis ¹
	Primary method only: if two or more methods for same analyte, compare twice a year
	Document receipt, testing, reporting
§493.803	Successful participation
§493.1236	Twice-a-year accuracy verification for all analytes not included in subpart I42CFR493 or not covered by CMS CLIA-approved PT providers: review and evaluate results, investigate all unacceptable results
	Review and evaluate results, investigate and document corrective actions for any unacceptable results

The “twice-a-year accuracy for all analytes not covered by approved PT providers review” and “evaluate results, investigate any unacceptable results” sections can be interpreted as follows:

- a) If covered by an approved PT provider, then the provider will send sample results to the local or regional CLIA office (laboratory should confirm this practice with PT provider).
- b) Since there is not a PT program in place for every test performed in a laboratory,

¹ No collaboration or communication is allowed between laboratories (or testing sites for those laboratories with multiple testing sites) until after the PT reporting date.

laboratories may create their own PT blank or control samples, which are blind to the analysts. This practice must be properly documented. Also acceptable are round robin study with other labs.

- c) PT, whether internally- or commercially-provided, must be completed twice a year at minimum. The minimum number of specimens per challenge can vary with the test type. Some states, programs or regional CLIA offices require PTs three times a year.² Those analytes listed in 42 CFR 493 SubPart I must be done three times per year, five samples each. These are referred to regulated analytes. Those not on the list, labs compare twice a year for accuracy verification.

Quality Assessment Plan Elements

§493.1200 Quality Systems

Each laboratory performing non-waived testing must establish and maintain written policies and procedures to implement and monitor the quality system for all phases of the testing process including pre-analytic, analytic, post-analytic and general laboratory systems, and to ensure continuous monitoring and improvement. Typical steps in a quality system followed by laboratories include:

- document policy and procedure
- implement
- monitor
- investigate non-compliance
- take corrective action for non-compliance
- review and evaluate corrective action
- change policy or process as needed
- monitor changes

Following are conditions for each subspecialty for specific regulations that apply under the following sections:

CLIA Reg #	Certification: Laboratory Requirements
§493.1200	SubPart K – Quality Systems
	(a) Written policies and procedures that implement and monitor quality systems for all phases of testing, pre-analytic, analytic, post-analytic and general lab systems
	(b) Each has an assessment component that ensures continuous improvement through ongoing monitoring
§493.1230	General Laboratory Systems – policy and procedures (P&P) to monitor and evaluate
1231	Confidentiality of patient information
1232	Specimen identification and integrity (through testing & reporting)
1233	Complaint investigations (& resolution)
1234	Communications (system to identify & document provider, patient, staff failures to communicate)
1235	Personnel competency assessment policies (establish P&P, see 1451 for specifications)

² This is a regulation that should be confirmed with state or regional CLIA offices.

1236	Evaluation of proficiency testing performance (unacceptable, unsuccessful)
1239	General laboratory systems assessment (P&P, dashboard of elements, score or monitor)
§493.1240	Pre-analytic Systems
1241	Test request (form, written, policy on oral communication documentation, components) – two forms of identification ³
1242	Specimen submission, handling, and referral – P&P for patient prep, collection, labeling, storage & preservation, transport, processing, rejection criteria, specimen referral
	Date & time of lab receipt
	Referred specimens only go to CLIA labs
	Accepting referrals means directions to clients for appropriate specimen & receipt
1249	Pre-analytic systems assessment – P&P to monitor, assess, and correct, then review effectiveness of Corrective Actions (CA)
§493.1250	Analytic Systems
1251	Procedure manual – all 14 elements to be included (see details in the next section) ⁴
1252	Test systems, equipment, instruments, reagents, materials, and supplies – identify acceptability criteria, monitor & document (read package inserts & operator's manuals)
1253	Establishment and verification of performance specifications (PARRSS) ⁵
1254	Maintenance and function checks – per manufacturer, perform & document at established frequency
1255	Calibration and calibration verification procedures – use appropriate type, concentrations, frequency, and acceptability criteria
1256	Control procedures – establish ranges, use number, type, concentration and acceptability criteria, monitor and document and review for trends
1281	Comparison of test results – multiple instruments, methods or sites, compare twice per year ⁴
1282	Corrective actions – documentation, investigation, root cause, corrective action, monitor, preventive action, and evaluate & document effectiveness
1283	Test records – able to retrieve patient identification, date & time, condition & disposition, test records, QC, QA, investigations
1289	Analytic systems assessment – P&P to monitor, assess, correct, then review effectiveness of CA
§493.1290	Post-analytic Laboratory Systems
1291	Test report – accurate, timely calculations, secure transfer of data (electronic or manual) & reports retrievable
	Demographic info – two forms of identification ⁶ , location performed, date reported & performed, specimen type, results, or disposition
	Reference range, interpretation, alert or critical value protocol ⁷ , corrected or amended report protocol and documentation (preliminary, final, amended all maintained)
1299	Post-analytic systems assessment – P&P to monitor, assess, correct, then review effectiveness of CA

³ Most states do not require two IDs at time of submission, but that the second ID can be generated after the sample is received or at the laboratory. An ID can be a name, birth date, the facility name, etc. Two identifiers are preferred to ensure specimen identification. Judy Frost and Jody Frost are not the same specimen, but easily confused.

⁴ It is acceptable to have one procedure for an element.

⁵ PARRSS are the performance specifications for high complexity test systems. This stands for: precision, accuracy, reportable ranges, reference intervals, sensitivity and specificity. (See [Definitions](#) for more information).

⁶ If you have multiple instruments, you have to compare them every six months to make sure they produce similar reportable ranges and control specifications using the same methodology (i.e., same PT, QCs, patient samples, etc.).

§493.1251 Standard: Procedure Manual (14 Elements)

- 1) The procedure manual must include the following when applicable to the test procedure:
Requirements for:
 - a) patient preparation
 - b) specimen collection, labeling, storage, preservation, transportation, processing, and referral
 - c) criteria for specimen acceptability and rejection.
- 2) Information about microscopic examination, including the detection of inadequately prepared slides. This must be listed, but can be designated as N/A (Not Applicable).
- 3) Instructions for step-by-step performance of the procedure, including test calculations and interpretation of results.
- 4) Directions for the preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.
- 5) Calibration and calibration verification procedures.
- 6) The reportable range for test results for the test system as established or verified in §493.1253.
- 7) Control procedures.
- 8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
- 9) Limitations of the test method, including interferences (this can be from the package insert, references or validation testing).
- 10) Reference intervals (normal values) or reference ranges, if available (for example from CDC's National Exposure Report).
- 11) Imminently life-threatening test results or alert or critical values.
- 12) Pertinent literature references.
- 13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminent life threatening results or alert values.
- 14) Description of the course of action to take if a test system becomes inoperable, including back-up/downtime procedures and COOP plans.

Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet requirements in the list above. *Any items not provided by the manufacturer must be developed, approved and provided by the Laboratory Director.*

Procedures and changes in procedures must be approved, signed and dated by the current CLIA Laboratory Director as appears on the CLIA certificate before use. And document review of changes by testing personnel.

The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in §493.1105(a) (2).

⁷ A critical value protocol is a protocol for action to be taken by the laboratory when a patient sample results show critical value of the chemical being tested.

Quality Assurance Review

- a) Periodic review to monitor effectiveness of corrective actions that are documented and signed by the CLIA Laboratory Director.
- b) Policies and revision of policies are communicated to staff (i.e., memos or meeting minutes).
- c) Review and document the:
 - a) effectiveness of corrective action,
 - b) revision of policies, and
 - c) communication with staff.

General Laboratory Policies And Procedures

- a) New methods or new people may be given special attention during the inspection.
- b) Method validations and standard operating procedures (SOPs) should be well documented and readily available for inspection.^{8,9}
- c) Alert or critical or levels requiring a phone call to CDC or medical staff should be noted in SOPs. If no alert or critical values exist, the SOP should reflect this. Reference ranges should be included if available.
- d) Utility of the test should be included in the SOP.

Laboratories Performing High Complexity Testing and Personnel Qualifications and Responsibilities

CLIA Reg #	Certification: Laboratory Requirements
	SubPart M – Personnel Qualifications and Responsibilities
§493.1441	Condition: Laboratories performing high complexity testing; Laboratory Director (responsibilities 493.1445)
§493.1447	Condition: Laboratories performing high complexity testing; technical supervisor (responsibilities 493.1451)
§493.1453 ¹⁰	Condition: Laboratories performing high complexity testing; clinical consultant (responsibilities 493.1457)
§493.1459	Condition: Laboratories performing high complexity testing; general supervisor (responsibilities 493.1463)
§493.1487	Condition: Laboratories performing high complexity testing; test personnel (responsibilities 493.1495)

8 Document Control, often referred to as electronic document management system (EDMS), is used to store, catalog retrieve, view, and print digital documents. Modern EDMS applications typically provide the ability to manage a document throughout its life cycle with functions including document initiation, multiple levels of review, version controls, and security. There are many advantages to keeping document control. Laboratory organization and responsibilities should be recorded at all times. Resources currently available include the [LEI Informatics Self-Assessment Tool](http://www.cdc.gov/ncidod/dlnd/lel/lel_informatics_self_assessment_tool_for_phls.pdf) (http://www.cdc.gov/ncidod/dlnd/lel/lel_informatics_self_assessment_tool_for_phls.pdf) which can be used as a template to create a document control checklist for who has rights, who can review, etc.

9 For document control purposes, discontinued procedures or tests should be readily available for three years following archiving.

10 This applies to laboratories that hire clinical consultants when the staff lacks the experience and qualifications to oversee high complexity testing. This also requires good, clear documentation.

§493.1451 Technical Supervisor¹¹ responsibilities for Personnel Competency

(b) **The Technical Supervisor is responsible for:**

- (8) Personnel competency evaluation and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. **The procedures for evaluation of the competency of the staff must include, but are not limited to—**
- (i) **Direct observations** of routine patient test performance, including patient preparation (if applicable), specimen handling, processing and testing;
 - (ii) **Monitoring**, recording and reporting of test results;
 - (iii) **Review** of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
 - (iv) **Direct observation** of performance of instrument maintenance and function checks;
 - (v) **Assessment** of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
 - (vi) **Assessment** of problem solving skills; and
- (9) **Evaluating** and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the analyst tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes; in which case, prior to reporting patient test results, the analyst's performance must be re-evaluated to include the use of the new test methodology or instrumentation.

NOTE: numbering is based on the Technical Supervisor section in the Interpretive Guidelines.

Inspection

CLIA Reg #	Certification: Laboratory Requirements
§493.1771	SubPart Q - Inspection
§493.1777	Inspection of laboratories that have requested or have been issued a certificate of compliance

§493.1771 Certificate of Compliance

- a) Laboratories are required to obtain a certificate of compliance before opening or beginning clinical testing; then they are subject to routine inspections every subsequent year that clinical testing is performed.
- b) To add or remove or change a PT provider, the laboratory must notify CMS or the state CLIA office and may not make a change the first calendar year of enrollment, 493.801(a). CMS requires 30-day notice of change in name, location, Laboratory Director or Technical Supervisor. Changes in specialties, subspecialties or methodologies must be communicated within six months.

¹¹ A Technical Supervisor is responsible for evaluating and documenting the competency of staff performing high complexity testing. Some provisions allow delegation of technical supervisor duties. Before this may take place, the delegate must demonstrate competency and meets technical supervisor requirements. These requirements must be documented in the SOP or QA manual. Also, a laboratory may have multiple technical supervisors. Laboratories must complete a [CMS-209 Form](#) requested by surveyors before the CLIA inspection.

Enforcement

CLIA Reg #	Certification: Laboratory Requirements
§493.1800	SubPart R – Enforcement
	(1) To protect all individuals served by laboratories against substandard testing of specimens.
	(2) To safeguard the general public against health and safety hazards that might result from laboratory activities.
	(3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

§493.1800 Enforcement

- a) Enforcement is understood when a laboratory receives their CLIA certification.
- b) Laboratories must have documentation for every regulation.

Overarching Considerations

Personnel Records for all Laboratory Staff

- a) New analysts may be questioned or tested during the inspection.
- b) Personnel Records ensure each analyst has a technical degree related to their position, as CLIA inspectors can request transcripts and diplomas.
- c) Clinical testing completed on a part time basis may be considered as experience.

Proficiency Testing Records

- a) Specify in SOPs that ‘PT samples will be treated in the same manner as real samples,’ with the exception of extra documentation.
- b) Lead is considered regulated under CLIA and requires five PTs, three times per year, that fall within 10% or 4mcg/dL. However, no accepted PT vendors currently exist for the other CT analytes; thus the CDC is considered an acceptable vendor if all other CLIA requirements are followed (as is PMQAS out of CTQ located in Quebec, Canada).
- c) Corrective action reports are required for all failed PTs. The report should also include how failing the PT would affect any real samples tested, and what will be done if real samples were affected.
- d) Monitor effectiveness of corrective action taken.

Instrument and Equipment Maintenance and Function Check Records

- a) Ensure an instrument log is maintained for each instrument used in the laboratory and available for review by supervisor or director.
- b) Ensure records for instrument calibration and tuning are maintained and available for review.
- c) Ensure that all instrument maintenance and validations are documented and available for review.

Other

- a) For some samples, if approved by submitter, it is acceptable to report results to two locations (i.e., CDC and the submitter).
- b) The laboratory is responsible for pre¹²- and post-analytical sample handling and storage.

¹² Laboratories are responsible for the appropriate identification of the type of samples collected: pre-analytic.

APPENDIX A: REPORTABLE RANGE FOR TEST RESULTS [493.1253(B)(2)]

About Reportable Range:

- Modified FDA-cleared or approved test systems
- New test systems not subject to FDA clearance or approval, including methods developed in-house and standardized methods
- Test systems for which the manufacturer does not provide performance specifications
- Prior to reporting patient test results the laboratory must establish the following performance specifications for high complexity test systems:
 - This is similar to verifying Performance Specifications (accuracy, precision, reportable range, reference intervals, and any others necessary)
 - But also requires analytical sensitivity and analytical specificity

Descriptions:

Accuracy

The **accuracy** of a measurement system is the degree of closeness of measurements of a quantity to that quantity's actual (true) value. The laboratory is responsible for establishing that the method produces correct results.

Precision

The **precision** of a measurement system, also called **reproducibility** or **repeatability**, is the degree to which repeated measurements under unchanged conditions show the same **results**. The laboratory is responsible for establishing the reproducibility of the test system:

- day-to-day
- run-to-run
- within run
- operator variance

Reportable Range

The laboratory is responsible for establishing how high and how low results can be reported.

Reference Intervals or “Normal values”

The reference intervals must be appropriate for the laboratory's patient population.

The laboratory may establish their own reference range or they may verify other published ranges.

Analytical Sensitivity

This is the lowest concentration of the analyte that the test can detect or distinguish from a blank usually referred to as the limit of detection (LOD).

- This must be done for modified FDA-approved test systems, new tests developed by the lab, standardized textbook methods, or methods which the manufacturer has not established performance specifications
- May perform multiple level dilutions of a known sample, using analytically-accurate materials (Class A pipettes), then run the dilutions to determine the test system's lowest level of accurate detection
- Specimens with values below the lowest limit should be reported as “none detected....” the test systems lowest verified level (e.g., LOD)
- This is not to be confused with the reportable range—may be the same number or a

different number. The reportable range is the lowest concentration that the lab has decided it will report. The lowest quantity that can be accurately measured is the limit of quantitation (LOQ).

Analytical Specificity Includes Interfering Substances

This is the extent to which the method measures the specific analyte being tested in the presence of other common interfering substances.

- Common interfering substances include lipemia, hemolysis, turbidity, medications, disease states, common drugs, bilirubin (icterus)
- Prior analyzed samples, known to contain other analytes commonly found in patient specimens, should be analyzed to make sure the test can recover the analyte being tested. Basically, the laboratory should use spiked samples and make sure that the interfering substances will not decrease or add to the measurement of the desired analyte.
- The laboratory must note established interfering substances in the procedure manual.

Determination of Calibration & Control Procedures [§493.1253(b)(3)]

The laboratory must determine the test system's calibration and control procedures based upon the performance specifications verified or established by the laboratory.

- Calibration and quality control procedures must include the following:
- Numbers of controls run
- Types of controls run
- Concentrations of calibrator materials
- Concentrations of control materials
- Performance intervals

§493.1253(c) Documentation

The laboratory must document all of the preceding activities. Are you reviewing QC and PT since the **establishment** of the performance specifications?

- You must have director's approval
- Ensure training and competency of testing personnel is current for changes in test systems and document.

APPENDIX B: ROLE OF LABORATORY INFORMATICS

Another overarching consideration to assist with compliance with CLIA is modern laboratory informatics. A laboratory information management system (LIMS) allows documentation, storage, and tracking of all information essential to obtaining and maintaining CLIA certification.

Many modern laboratory informatics solutions include LIMS that come pre-defined with an extensive administrative interface so that end users can configure the application without programming or direct database intervention. Examples of LIMS configured capabilities that may come “pre-packaged” or have ability to build interfaces to assist management of CLIA requirements include:

- Sample tracking, including audit trails and chain of custody
- Sample scheduling
- Data entry and storage of quality control/quality assurance information
- Data Verification and Validation processes and procedures
- Electronic data transfer management from instruments to LIMS and from LIMS to clients
- Storage of instrument calibration data, analyst training certificates, and instrument repair records
- Document Control, including SOP's, training (Ethics, Safety, Confidentiality, Reporting Policies etc.)
- Maintaining and managing chemical inventories and reagent controls
- System security features
- Customized hardcopy and softcopy report generation

ACKNOWLEDGEMENTS

The APHL Environmental Health Committee members played an important role in the shaping of this document.

Sanwat Chaudhuri, Chair

Utah Public Health Laboratory

Jack Bennett

Katherine A. Kelley Public Health Laboratory,
Connecticut

Ewa King

Rhode Island State Health Laboratories

Jack Krueger

Consultant

Tara Lydick

Delaware Public Health Laboratory

Jyl Madlem

Indiana State Department of Health

Martina McGarvey

Pennsylvania Department of Environmental
Protection

George Mills

Vermont Public Health Laboratory

Paul Moyer

Minnesota Department of Health

Blaine Rhodes

Washington Public Health Laboratories

Michael Wichman

State Hygienic Laboratory

RELATED APHL RESOURCE

APHL created an [LRN-C toolkit](#) where users have a platform to share templates, forms and other resources to help one another out, as well as a discussion board to post questions to the entire group. The latest feature includes a section where laboratorians can tell APHL when they have information for a story. This and other related documents can be found on the Toolkit.

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) is a national nonprofit dedicated to working with members to strengthen laboratories with a public health mandate. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

This publication was 100% financed by federal funds. The total amount of funding received for the EH Program is \$679,747. This publication was supported by Cooperative Agreement # U60HM000803 from CDC. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.



8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
Phone: 240.485.2745
Fax: 240.485.2700
Web: www.aphl.org