Division of Laboratory Systems

OneLab™

A Unified Response to Training Needs

The Survey Process: What You Need to Know For Your CLIA Survey

Marranda Scott, MT (ASCP)

March 28, 2023

Agenda

- Introduction
  - *New and relevant OneLab™ Resources*
  - *Today's Presenters*
- *The Survey Process: What you Need to Know for Your CLIA Survey*
- Q&A
- Upcoming Events

INTRODUCING OneLab™ REACH

A Learning Management System for Clinical and Public Health Laboratory Professionals

Give your learners access to the newest and most relevant CDC-developed COVID-19 education and training.

- Download free materials
- Earn Continuing Education Units (Including P.A.C.E.®)
- Access OneLab REACH on your mobile device

Register Today!

OneLab REACH™ is part of the CDC OneLab initiative. OneLab's mission is to strengthen interconnections between clinical, public health, and CDC laboratory education and training professionals to collectively support rapid, large-scale responses to public health emergencies.

Learn more at www.cdc.gov/onelab

Presenter

Marranda Scott

Clinical Laboratory Scientist
Quality and Safety Systems Branch
Division of Laboratory Systems
Office of Laboratory Science and Safety
Centers for Disease Control and Prevention

CDC, our planners, and our presenters wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters.

Vision

Exemplary laboratory practice and systems strengthen clinical care, public health, emergency response, and health equity.

Mission

Improve public health, patient outcomes, and health equity by advancing laboratory systems.

THE PRESENTER

Mississippi State University (2007)

Biologist
FSAP Inspector (2010-2015)

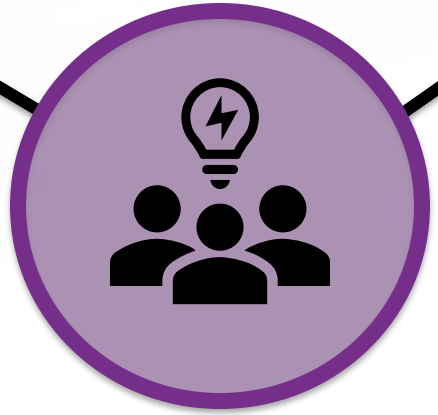
Clinical Laboratory Scientist
CMS CLIA Surveyor (2015-2021)

Clinical Laboratory Scientist
Division of Laboratory Systems

THE SURVEY PROCESS

GET READY

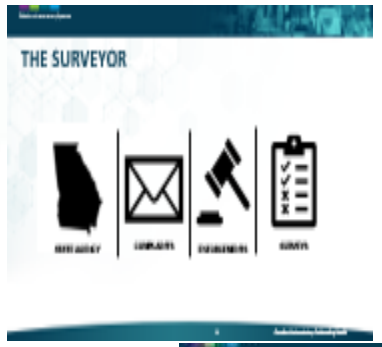
THE SURVEYORS ARE HERE



THE SURVEY SAYS

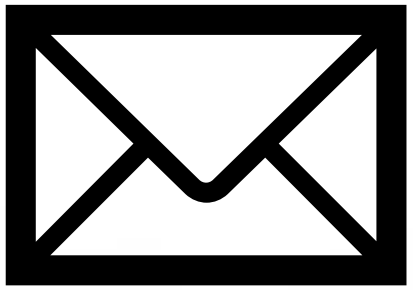
RESOURCES

THE SURVEY PROCESS



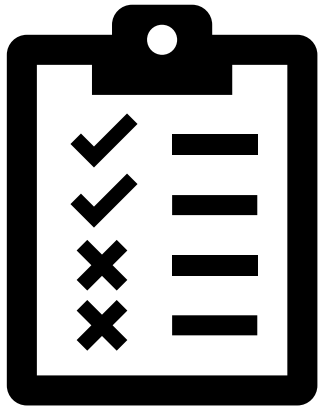
THE SURVEYOR

STATE AGENCY



COMPLAINTS

ENFORCEMENTS



SURVEYS

THE SURVEYOR

How Surveyors Prepare

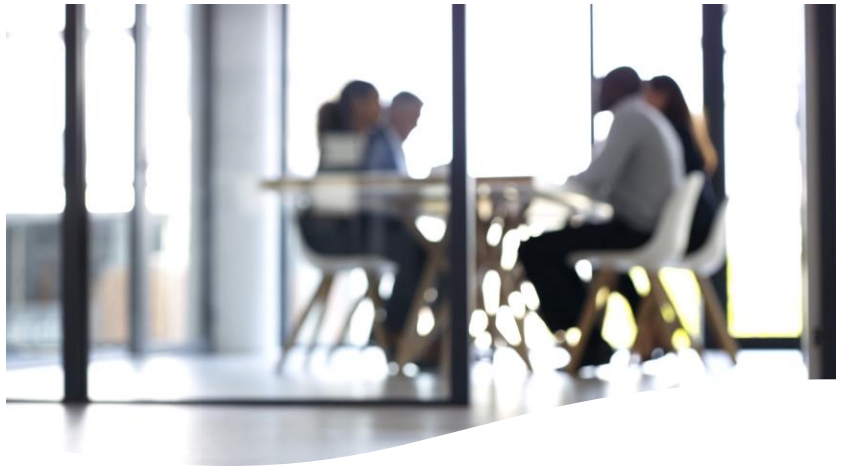
Check Survey Fees Are Paid

Pull Information From Last Survey

1. Were there any changes since the last survey?
2. Were there any citations or recommendations?
3. What was the last test volume reported?
4. How many specialties did the laboratory have?

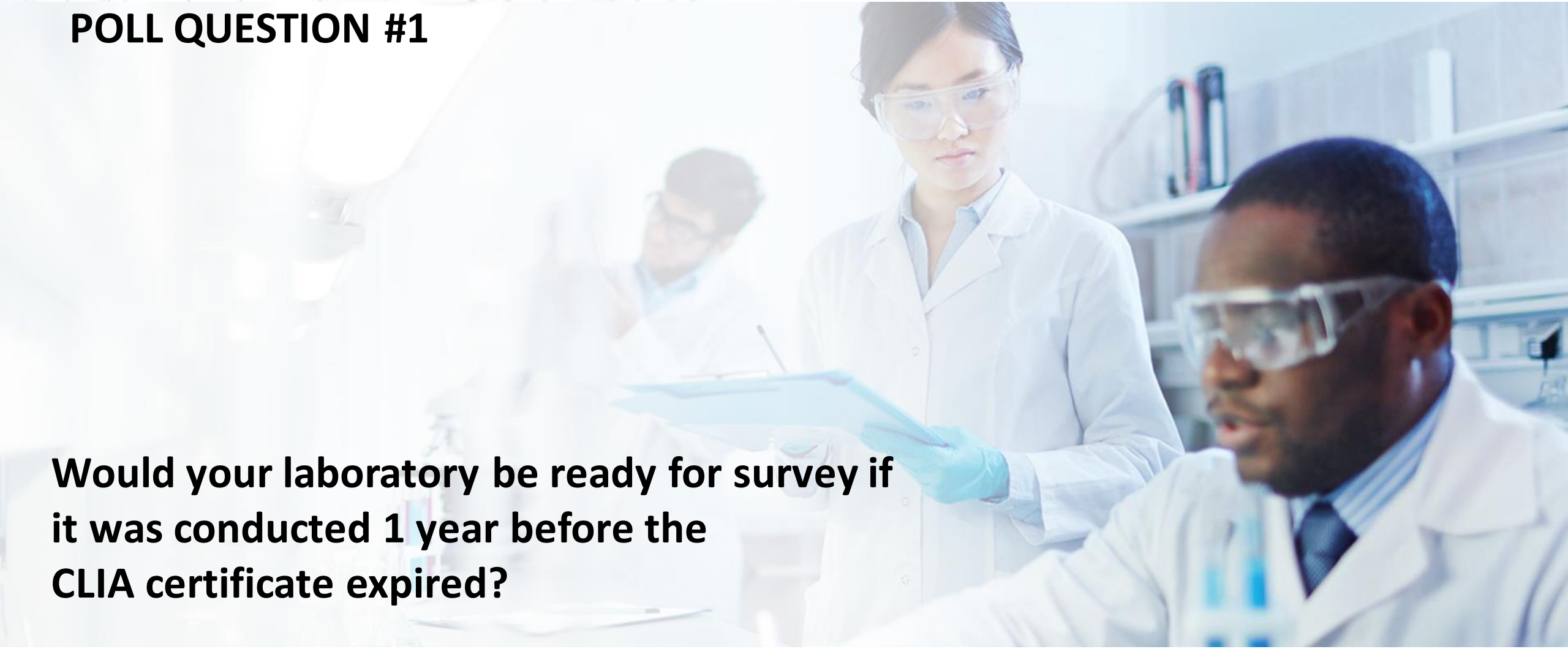
Proficiency Testing Report

Open Enforcement Cases



THE LABORATORY

POLL QUESTION #1



Would your laboratory be ready for survey if it was conducted 1 year before the CLIA certificate expired?

THE LABORATORY

care, therefore, to only cite to the portions of this document that are applicable to the laboratory operations and the complexity of testing performed.

I. Identifying Sources of Information
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

A. Scheduling Surveys

There are three activities associated with scheduling surveys:

- The intention to survey which is the in-office formulation of a work plan,
- Announcing the survey, which is notifying the laboratory (when applicable) of the survey date and time, and
- Performing the survey, which is the actual on-site inspection.

For efficiency when scheduling, attempt to cluster surveys geographically to include initials, recertifications, complaints and validations. Extenuating circumstances require RO review. In instances where the State requires a laboratory survey at a different time frame than CLIA, the State must meet both survey scheduling requirements as efficiently as possible. For example, the State requires a survey before the laboratory can operate in that State. The SA can survey the laboratory for compliance with the State requirements, and return in the appropriate time frame to survey for compliance with the CLIA requirements.

1. Initial Surveys: In order to permit observation of actual testing during the initial survey, schedule the initial survey to occur at least 90 days after the data entry of the CMS Form-116, but no later than 12 months after the data entry of the CMS Form-116. For example, the CMS Form-116 data entry date is May 10, 2006. The initial survey should be conducted between August 8, 2006 (90th day after May 10, 2006) and May 9, 2007 (365th day after May 10, 2006.) If after the 90 days, a representative from the laboratory states that laboratory testing is not being performed because equipment is not ready, etc., advise the laboratory that the CLIA number will be terminated until such time testing is being performed. If there is suspicion that the laboratory is being operated in a manner that constitutes a risk to human health, schedule an unannounced survey. An unannounced survey is an option any time there is suspicion of risk to human health.

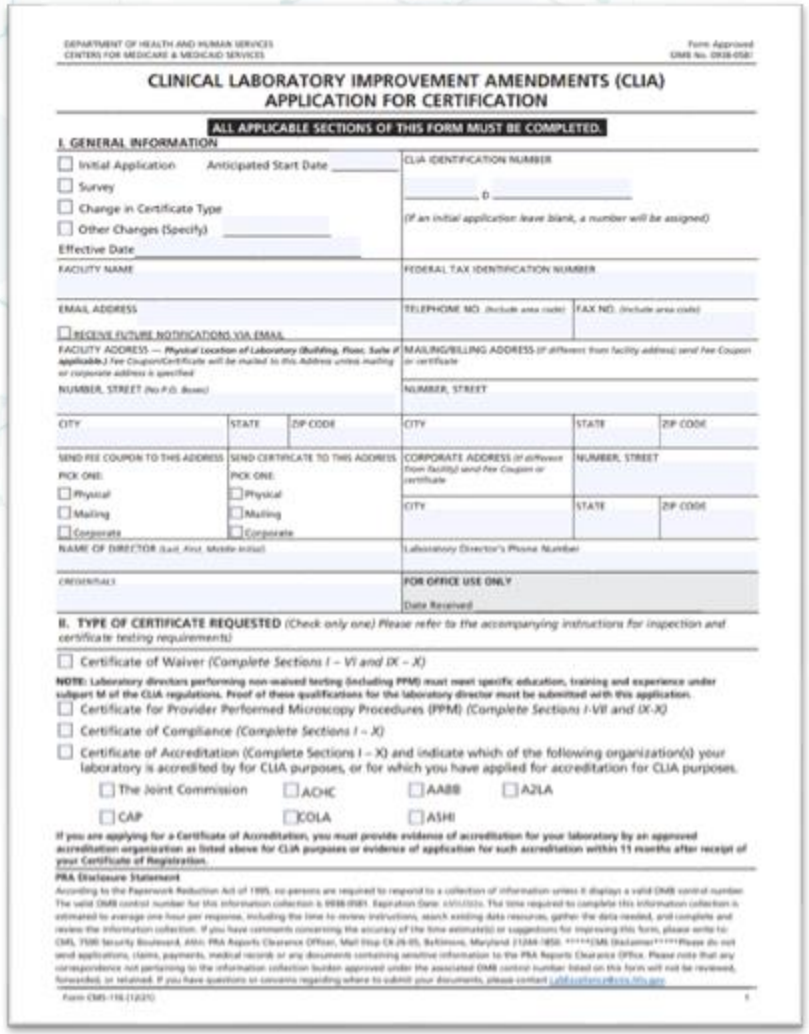
2. Recertification Surveys: Schedule the recertification survey to occur at least 6 months (180 days) prior to the expiration date of the laboratory's current certificate, but no earlier than 12 months prior to the expiration date of the current certificate. For example, the current certificate expiration date is December 31, 2006. The recertification survey should be conducted between December 31, 2005 and July 3, 2006.

Establish a date and time for the survey once the schedule has been completed. If a

2. Recertification Surveys: Schedule the recertification survey to occur at least 6 months (180 days) prior to the expiration date of the laboratory's current certificate, but no earlier than 12 months prior to the expiration date of the current certificate. For example, the current certificate expiration date is December 31, 2006. The recertification survey should be conducted between December 31, 2005 and July 3, 2006.

THE LABORATORY

CMS 116



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

- ☐ Initial Application — Anticipated Start Date _____
- ☐ Survey
- ☐ Change in Certificate Type
- ☐ Other Changes (Specify) _____

Effective Date

CLIA IDENTIFICATION NUMBER

_____ D _____

(If an initial application leave blank, a number will be assigned)

FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS

TELEPHONE NO. (Include area code)

FAX NO. (Include area code)

☐ RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

FACILITY ADDRESS — *Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified*

NUMBER, STREET *(No P.O. Boxes)*

CITY | STATE | ZIP CODE

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*

NUMBER, STREET

CITY | STATE | ZIP CODE

SEND FEE COUPON TO THIS ADDRESS
PICK ONE:
☐ Physical
☐ Mailing
☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS
PICK ONE:
☐ Physical
☐ Mailing
☐ Corporate

CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*

NUMBER, STREET

CITY | STATE | ZIP CODE

NAME OF DIRECTOR (Last, First, Middle Initial)

Laboratory Director's Phone Number

CREDENTIALS

FOR OFFICE USE ONLY

Date Received

II. TYPE OF CERTIFICATE REQUESTED *(Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)*

- ☐ Certificate of Waiver *(Complete Sections I – VI and IX – X)*

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

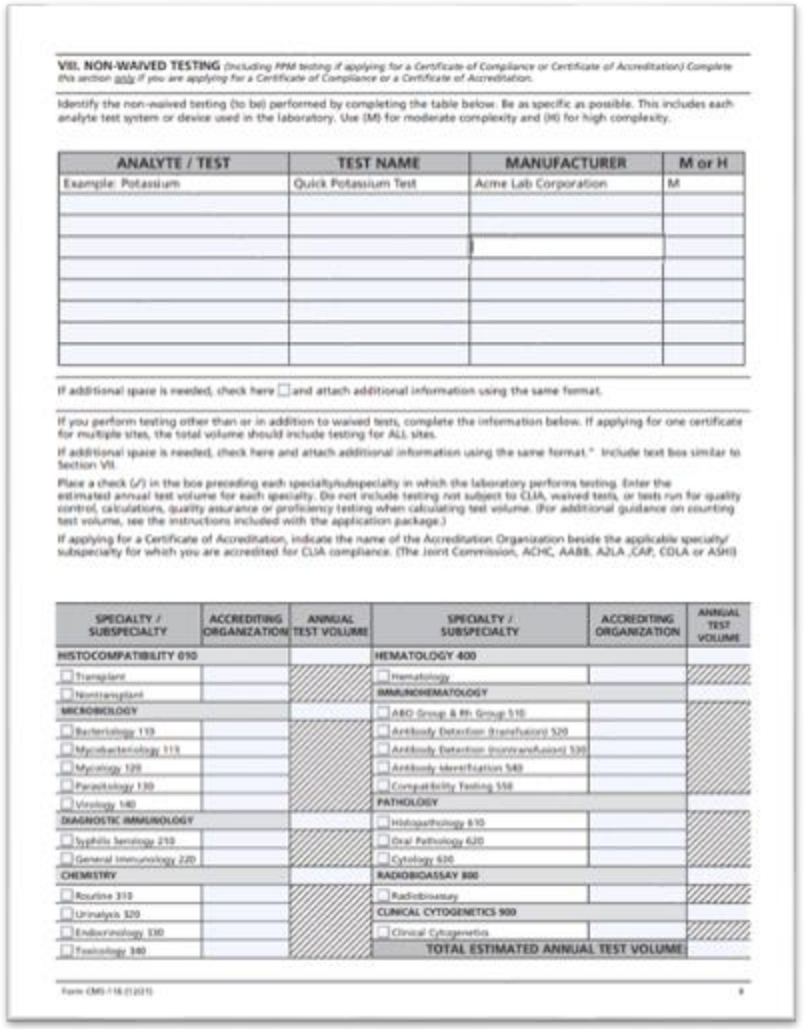
- ☐ Certificate for Provider Performed Microscopy Procedures (PPM) *(Complete Sections I-VII and IX-X)*
- ☐ Certificate of Compliance *(Complete Sections I – X)*
- ☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.
  - ☐ The Joint Commission ☐ ACHC ☐ AABB ☐ A2LA
  - ☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 07/31/2024. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ****CMS Disclaimer**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact cmlaboratory@cms.hhs.gov.

Form CMS-116 (12/21) 1



VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Certificate of Accreditation) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.*

Identify the non-waived testing (to be) performed by completing the table below. Be as specific as possible. This includes each analyte test system or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.

ANALYTE / TEST	TEST NAME	MANUFACTURER	M or H
Example: Potassium	Quick Potassium Test	Acme Lab Corporation	M

If additional space is needed, check here ☐ and attach additional information using the same format.

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

If additional space is needed, check here and attach additional information using the same format.* Include text box similar to Section VII.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

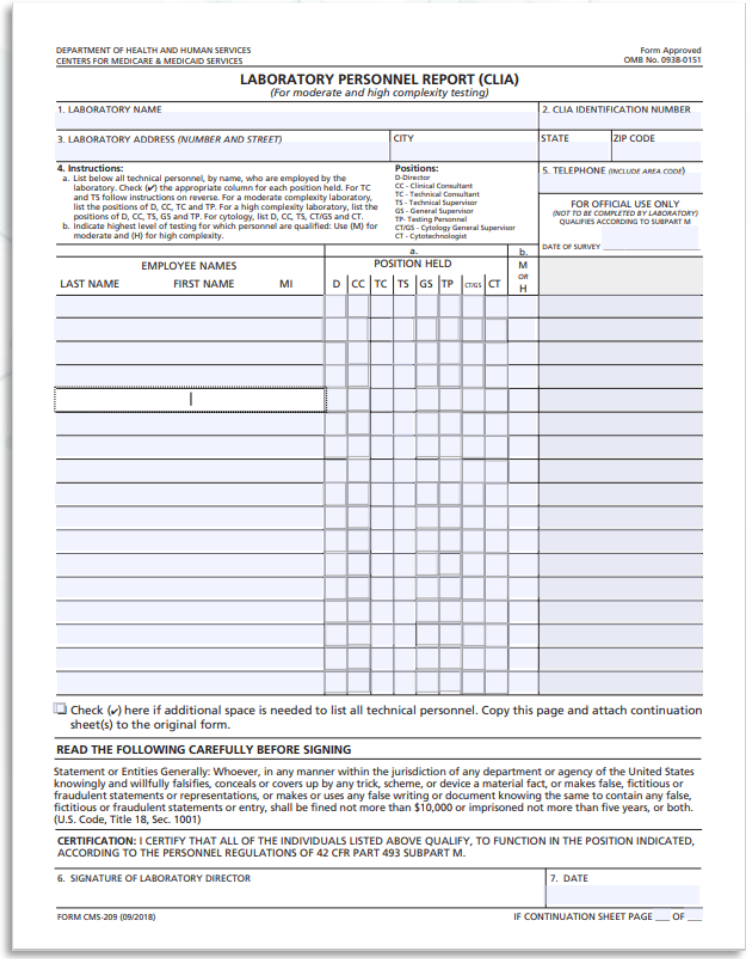
If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, ACHC, AABB, A2LA ,CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			**HEMATOLOGY 400**		
☐ Transplant			☐ Hematology		
☐ Nontransplant			**IMMUNOHEMATOLOGY**		
MICROBIOLOGY			☐ ABO Group & Rh Group 510		
☐ Bacteriology 110			☐ Antibody Detection (transfusion) 520		
☐ Mycobacteriology 115			☐ Antibody Detection (nontransfusion) 530		
☐ Mycology 120			☐ Antibody Identification 540		
☐ Parasitology 130			☐ Compatibility Testing 550		
☐ Virology 140			**PATHOLOGY**		
DIAGNOSTIC IMMUNOLOGY			☐ Histopathology 610		
☐ Syphilis Serology 210			☐ Oral Pathology 620		
☐ General Immunology 220			☐ Cytology 630		
CHEMISTRY			**RADIOBIOASSAY 800**		
☐ Routine 310			☐ Radiobioassay		
☐ Urinalysis 320			**CLINICAL CYTOGENETICS 900**		
☐ Endocrinology 330			☐ Clinical Cytogenetics		
☐ Toxicology 340			**TOTAL ESTIMATED ANNUAL TEST VOLUME**		

Form CMS-116 (12/21) 9

THE LABORATORY

CMS 209



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0151

LABORATORY PERSONNEL REPORT (CLIA)
(For moderate and high complexity testing)

1. LABORATORY NAME | 2. CLIA IDENTIFICATION NUMBER
3. LABORATORY ADDRESS *(NUMBER AND STREET)* | CITY | STATE | ZIP CODE

4. Instructions:
a. List below all technical personnel, by name, who are employed by the laboratory. Check (✓) the appropriate column for each position held. For TC and TS follow instructions on reverse. For a moderate complexity laboratory, list the positions of D, CC, TC and TP. For a high complexity laboratory, list the positions of D, CC, TS, GS and TP. For cytology, list D, CC, TS, CT/GS and CT.
b. Indicate highest level of testing for which personnel are qualified: Use (M) for moderate and (H) for high complexity.

Positions:
D-Director
CC - Clinical Consultant
TC - Technical Consultant
TS - Technical Supervisor
GS - General Supervisor
TP- Testing Personnel
CT/GS - Cytology General Supervisor
CT - Cytotechnologist

5. TELEPHONE *(INCLUDE AREA CODE)*

FOR OFFICIAL USE ONLY
(NOT TO BE COMPLETED BY LABORATORY)
QUALIFIES ACCORDING TO SUBPART M

DATE OF SURVEY _____

EMPLOYEE NAMES			a. POSITION HELD								b.
LAST NAME	FIRST NAME	MI	D	CC	TC	TS	GS	TP	CT/GS	CT	M OR H

☐ Check (✓) here if additional space is needed to list all technical personnel. Copy this page and attach continuation sheet(s) to the original form.

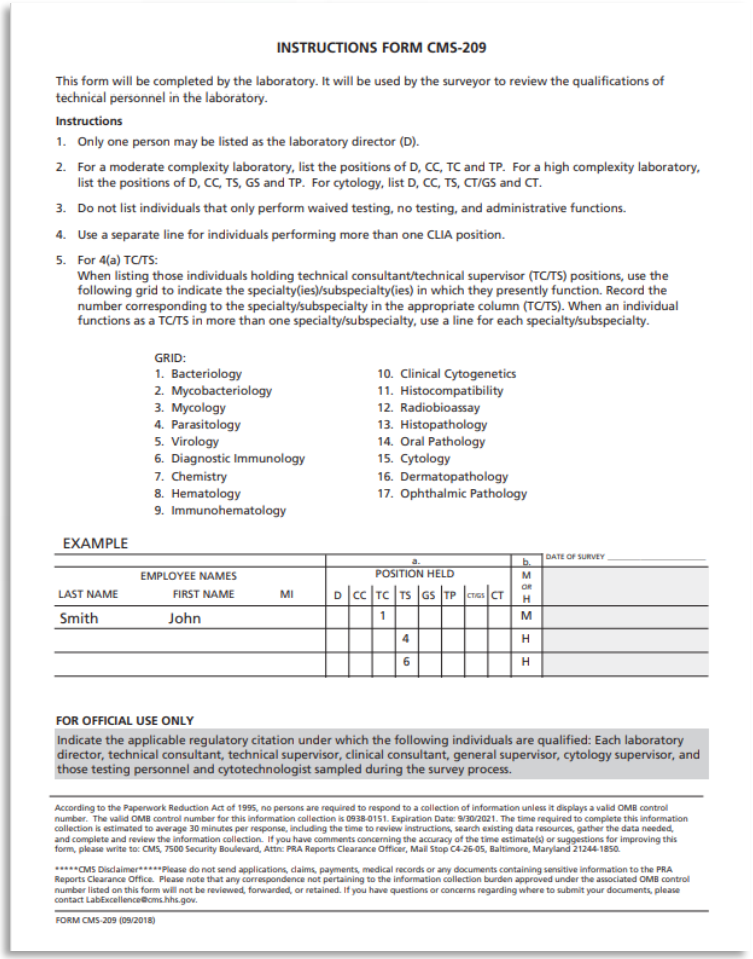
READ THE FOLLOWING CAREFULLY BEFORE SIGNING

Statement or Entities Generally: Whoever, in any manner within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both. (U.S. Code, Title 18, Sec. 1001)

CERTIFICATION: I CERTIFY THAT ALL OF THE INDIVIDUALS LISTED ABOVE QUALIFY, TO FUNCTION IN THE POSITION INDICATED, ACCORDING TO THE PERSONNEL REGULATIONS OF 42 CFR PART 493 SUBPART M.

6. SIGNATURE OF LABORATORY DIRECTOR | 7. DATE

FORM CMS-209 (09/2018) IF CONTINUATION SHEET PAGE ___ OF ___



INSTRUCTIONS FORM CMS-209

This form will be completed by the laboratory. It will be used by the surveyor to review the qualifications of technical personnel in the laboratory.

Instructions

1. Only one person may be listed as the laboratory director (D).
2. For a moderate complexity laboratory, list the positions of D, CC, TC and TP. For a high complexity laboratory, list the positions of D, CC, TS, GS and TP. For cytology, list D, CC, TS, CT/GS and CT.
3. Do not list individuals that only perform waived testing, no testing, and administrative functions.
4. Use a separate line for individuals performing more than one CLIA position.
5. For 4(a) TC/TS:
   When listing those individuals holding technical consultant/technical supervisor (TC/TS) positions, use the following grid to indicate the specialty(ies)/subspecialty(ies) in which they presently function. Record the number corresponding to the specialty/subspecialty in the appropriate column (TC/TS). When an individual functions as a TC/TS in more than one specialty/subspecialty, use a line for each specialty/subspecialty.

GRID:
1. Bacteriology
2. Mycobacteriology
3. Mycology
4. Parasitology
5. Virology
6. Diagnostic Immunology
7. Chemistry
8. Hematology
9. Immunohematology
10. Clinical Cytogenetics
11. Histocompatibility
12. Radiobioassay
13. Histopathology
14. Oral Pathology
15. Cytology
16. Dermatopathology
17. Ophthalmic Pathology

EXAMPLE

DATE OF SURVEY _____

EMPLOYEE NAMES			a. POSITION HELD								b.
LAST NAME	FIRST NAME	MI	D	CC	TC	TS	GS	TP	CT/GS	CT	M OR H
Smith	John				1						M
						4					H
						6					H

FOR OFFICIAL USE ONLY

Indicate the applicable regulatory citation under which the following individuals are qualified: Each laboratory director, technical consultant, technical supervisor, clinical consultant, general supervisor, cytology supervisor, and those testing personnel and cytotechnologist sampled during the survey process.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0151. Expiration Date: 9/30/2021. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

*****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

FORM CMS-209 (09/2018)

THE LABORATORY
TEST DIRECTORY

Test Performed	New Test since last survey? Yes or No	Annual Test Volume	Instrument /Kit	Comments
Chikungunya IgM	No	0	Dynex Agility/InBios CHIKjj Detect IgM ELISA	Test Discontinued, CDC Sendouts
Chlamydia/Gonorrhea by DNA Probe	No	105,589	Hologic Panther/Aptima Combo 2	
Dengue IgM	No	0	Dynex Agility/InBios DENV Detect IgM	Test Discontinued, CDC Sendouts
Hepatitis A IgG	Yes	1	CMIA, Abbott, Architect i1000SR	
Hepatitis A IgM	Yes	0	CMIA, Abbott, Architect i1000SR	
Hepatitis B Core Antibody (IgM)	No	262	Abbott Architect i1000SR/ Architect CORE-M	
Hepatitis B Core Antibody (Total)	No	235	Abbott Architect i1000SR/ Architect CORE	
Hepatitis B Surface Antibody	No	317	Abbott Architect i1000SR/ Architect AUSAB	
Hepatitis B Surface Antigen	No	286	Abbott Architect i1000SR/ Architect HBsAg Qualitative	
Hepatitis C EIA	No	34,892	CMIS, Abbott Architect i1000SR/ Architect Anti-HCV	
Hepatitis C RNA (Qual)	Yes	4027	Hologic Panther/ Aptima HCV	

THE LABORATORY

PROCEDURES,POLICIES, and DOCUMENTS

- All tests, assays, and examinations
- Personnel Records
  - Board of Certification for Laboratory Director
  - Diplomas, Degrees, and Transcripts
  - Training Records
  - Competency Assessment
- Proficiency Testing
  - Test runs with PT results
  - Printouts
  - Signed attestation sheets
  - Remedial action and review for unsatisfactory results
  - Twice a year verification

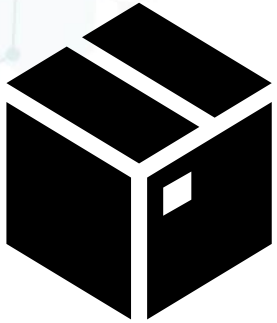
THE LABORATORY

PROCEDURES,POLICIES, and DOCUMENTS

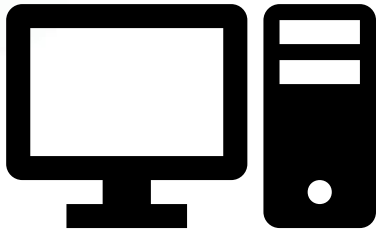
- Quality Control Records
  - Calibration/Calibration Verification Records
  - Statistical Limits
  - Remedial Action Information
  - Instrument maintenance and function checks
- Quality Assessment
  - Policies and procedures to monitor, assess, and correct problems
  - Documentation of ongoing assessment activities
- Patient Testing Records
  - Requisition
  - Testing Records (Direct Printouts)
  - Test Reports

THE LABORATORY

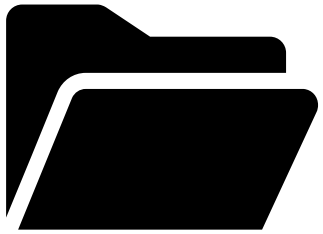
LABORATORY PERSONNEL



SHIPPING & RECEIVING



IT

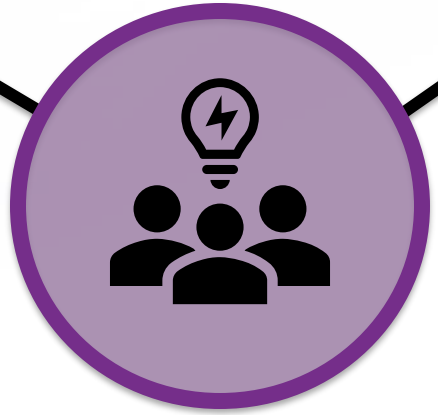


HUMAN RESOURCES

THE SURVEY PROCESS

GET READY

THE SURVEYORS ARE HERE



THE SURVEY SAYS

RESOURCES

THE SURVEYORS ARE HERE

Division of Laboratory Systems

THE OPENING MEETING

POLL QUESTION #2

How frequently does your laboratory conduct internal assessments to evaluate the effectiveness of your quality management system?

THE OPENING MEETING

Invite Laboratory Staff

Technical Supervisors

General Supervisors

Quality Manager(s)

Prepare To Give Updates

Any Facility Changes Since Last Survey

Added Specialties/New Test

New TS/GS

Allow Surveyors To Discuss Survey Flow

Length

Tour

Record Review/Interviews

THE TOUR

OBSERVATION & INFORMATION GATHERING

SPECIMEN COLLECTION/SPECIMEN PROCESSING

- Specimen Integrity

PREP AREAS/ STORAGE AREA

- Verify Reagents and Kits
- Temperature/Humidity

TESTING & REPORTING AREAS

- Quality Control Performance
- Testing Performance
- Evaluation of Test Results

THE REVIEW

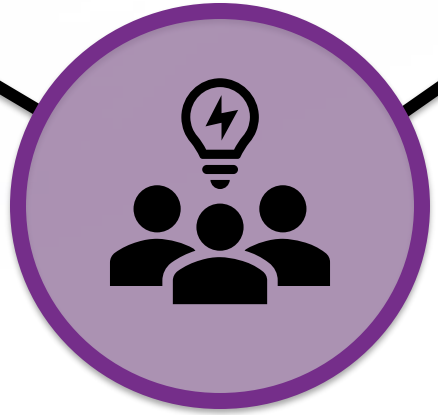
PT Subpart H	Facility Administration Subpart J	Quality Systems Subpart K	Personnel Subpart M
Test runs with PT results	Space	General Laboratory Systems	Board of Certification for Laboratory Director
Printouts	Safety	Preanalytic	Diplomas, Degrees, and Transcripts
Signed attestation sheets	Ventilation	Analytic	Training Records
Remedial action and review for unsatisfactory results	Contamination procedures	Postanalytic	Competency Assessment
Twice a year verification			

Records generated since the last survey

THE SURVEY PROCESS

GET READY

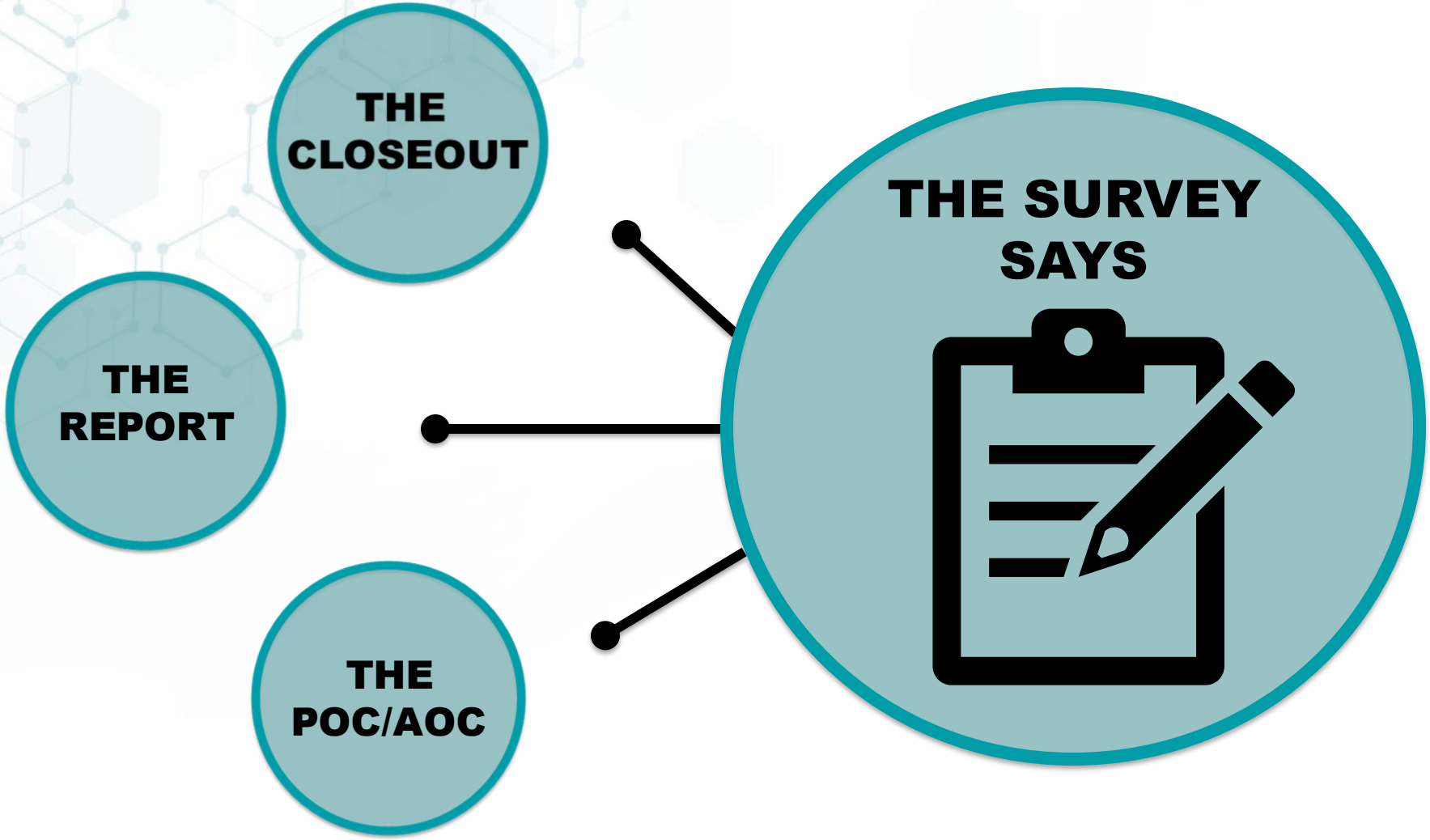
THE SURVEYORS ARE HERE



THE SURVEY SAYS

RESOURCES

THE SURVEY PROCESS



Division of Laboratory Systems

THE CLOSEOUT

POLL QUESTION #3

Do you attend closeout meetings following your survey?

THE CLOSEOUT

THE CLOSEOUT

- Invite the laboratory staff
- Listen to the findings and the recommendations from the survey
- Ask questions if you require clarification

THE REPORT

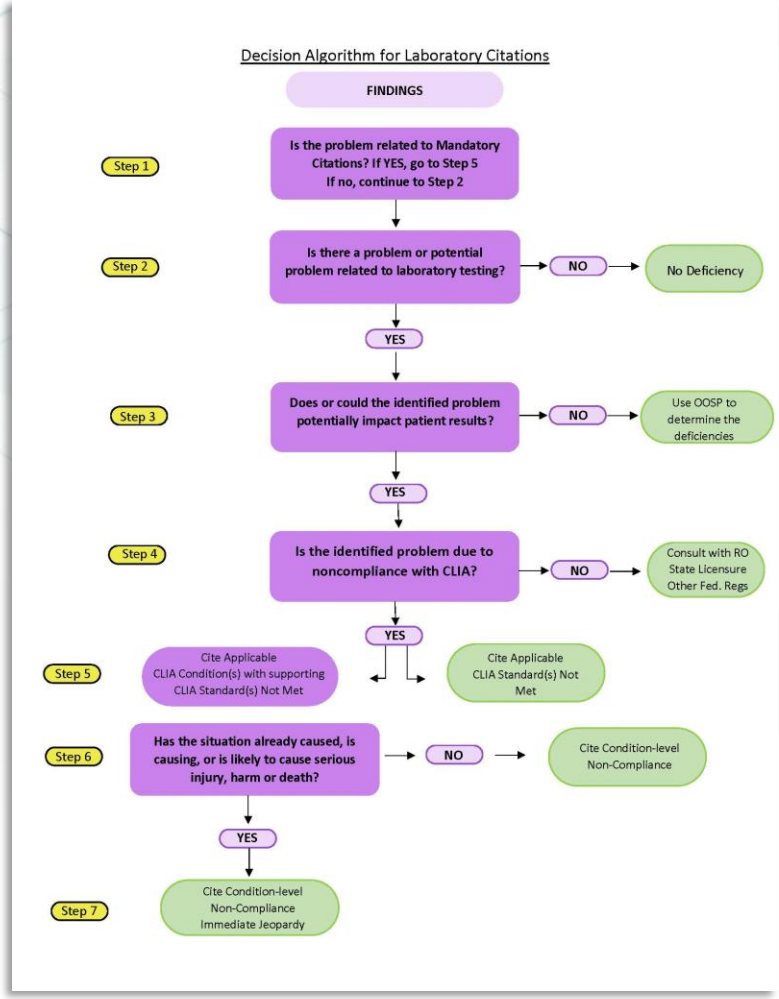


Table VII-1

MANDATORY CITATIONS

IF YOU FIND NON-COMPLIANCE WITH. . .		YOU MUST AT LEAST CITE THE *STANDARD* AT D-TAG. . .	YOU MUST AT LEAST CITE THE *CONDITION* AT D-TAG. . .
Non-enrollment in Proficiency Testing 42 CFR § 493.801			D2000
Proficiency Testing Referral 42 CFR § 493.801(b)(4)		D2013	D2000
Unsuccessful Participation in Proficiency Testing 42 CFR § 493.803		D2028, D2037, D2046, D2055, D2064, D2074, D2084, D2085, D2096, D2097, D2107, D2108, D2118, D2119, D2130, D2131, D2162, D2163, D2172, D2181, D2190, OR D2191	D2016
Personnel Qualifications - Subpart M	Laboratory Director PPMP	D5981	D5980
	Testing Personnel PPMP	D5991	D5990
	Laboratory Director Moderate Complexity Testing	D6003	D6000
	Technical Consultant Moderate Complexity Testing	D6035	D6033
	Clinical Consultant Moderate Complexity Testing	D6057	D6056
	Testing Personnel Moderate Complexity Testing	D6065	D6063
	Laboratory Director High Complexity Testing	D6078	D6076
	Technical Supervisor High Complexity Testing	D6111	D6108
	Clinical Consultant High Complexity Testing	D6135	D6134
	General Supervisor High Complexity Testing	D6143	D6141
	Cytology General Supervisor	D6155	D6153
	Cytotechnologist	D6164	D6162
	Testing Personnel High Complexity Testing	D6171	D6168

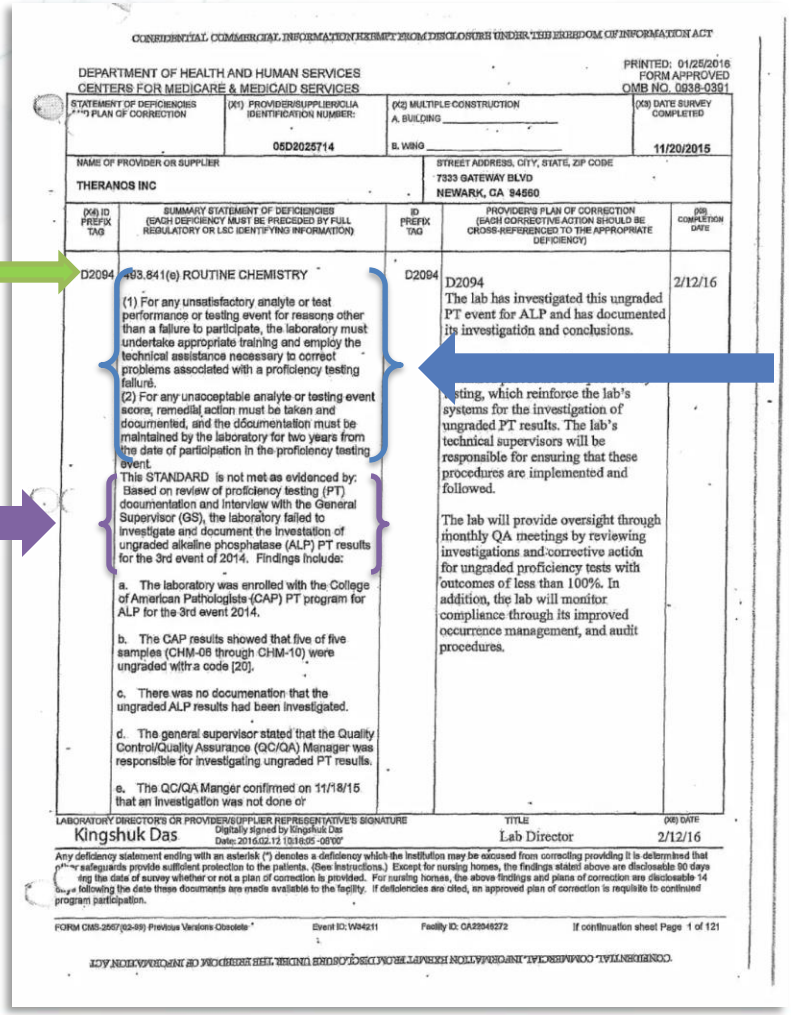
THE REPORT

CMS 2567

D-TAG

Deficient Practice Statement

CFR and Regulatory Language



CONFIDENTIAL COMMERCIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 01/25/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D2094	493.841(e) ROUTINE CHEMISTRY (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation and interview with the General Supervisor (GS), the laboratory failed to investigate and document the investation of ungraded alkaline phosphatase (ALP) PT results for the 3rd event of 2014. Findings include: a. The laboratory was enrolled with the College of American Pathologists (CAP) PT program for ALP for the 3rd event 2014. b. The CAP results showed that five of five samples (CHM-08 through CHM-10) were ungraded with a code [20]. c. There was no documenation that the ungraded ALP results had been investigated. d. The general supervisor stated that the Quality Control/Quality Assurance (QC/QA) Manager was responsible for investigating ungraded PT results. e. The QC/QA Manger confirmed on 11/18/15 that an investigation was not done or	D2094	D2094 The lab has investigated this ungraded PT event for ALP and has documented its investigation and conclusions. ...sting, which reinforce the lab's systems for the investigation of ungraded PT results. The lab's technical supervisors will be responsible for ensuring that these procedures are implemented and followed. The lab will provide oversight through monthly QA meetings by reviewing investigations and corrective action for ungraded proficiency tests with outcomes of less than 100%. In addition, the lab will monitor compliance through its improved occurrence management, and audit procedures.	2/12/16

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Kingshuk Das Digitally signed by Kingshuk Das Date: 2016.02.12 10:16:05 -08'00'	Lab Director	2/12/16

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

FORM CMS-2567(02-99) Previous Versions Obsolete * Event ID: W94211 Facility ID: CA2354272 If continuation sheet Page 1 of 121

CONFIDENTIAL COMMERCIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

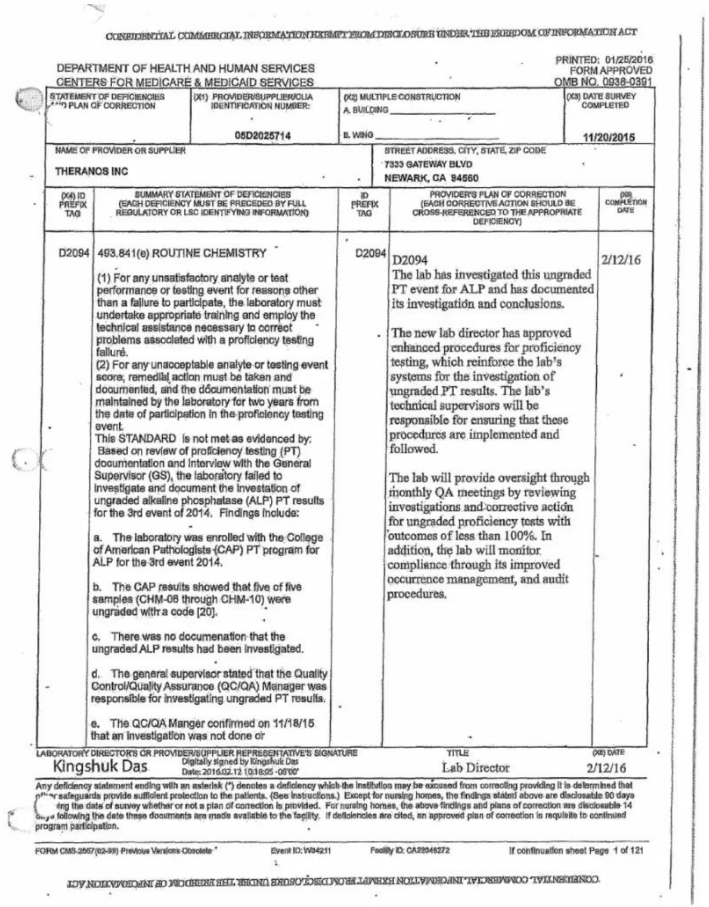
PLAN OF CORRECTION (PoC)
ALLEGATION OF COMPLIANCE (AoC)

1. Documentation describing the corrective actions that have been taken for patients that were identified by the survey and subsequent analysis as having been affected by the deficient practice(s);

2. An explanation as to how the laboratory has identified other patients who may have been affected by the deficient practice(s);

3. A description of the correction(s) that have been put into place and/or the systemic changes that have been made to ensure that the deficient practice does not recur; and

4. How the corrective actions are being monitored to ensure the deficient practice does not recur.



CONFIDENTIAL COMMERCIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 01/25/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D2094	493.841(e) ROUTINE CHEMISTRY (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation and interview with the General Supervisor (GS), the laboratory failed to investigate and document the investation of ungraded alkaline phosphatase (ALP) PT results for the 3rd event of 2014. Findings include: a. The laboratory was enrolled with the College of American Pathologists (CAP) PT program for ALP for the 3rd event 2014. b. The CAP results showed that five of five samples (CHM-06 through CHM-10) were ungraded with a code [20]. c. There was no documenation that the ungraded ALP results had been investigated. d. The general supervisor stated that the Quality Control/Quality Assurance (QC/QA) Manager was responsible for investigating ungraded PT results. e. The QC/QA Manger confirmed on 11/18/15 that an investigation was not done cir	D2094	D2094 The lab has investigated this ungraded PT event for ALP and has documented its investigation and conclusions. The new lab director has approved enhanced procedures for proficiency testing, which reinforce the lab's systems for the investigation of ungraded PT results. The lab's technical supervisors will be responsible for ensuring that these procedures are implemented and followed. The lab will provide oversight through monthly QA meetings by reviewing investigations and corrective action for ungraded proficiency tests with outcomes of less than 100%. In addition, the lab will monitor compliance through its improved occurrence management, and audit procedures.	2/12/16

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Kingshuk Das Digitally signed by Kingshuk Das Date: 2016.02.12 13:16:05 -08'00'	Lab Director	2/12/16

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

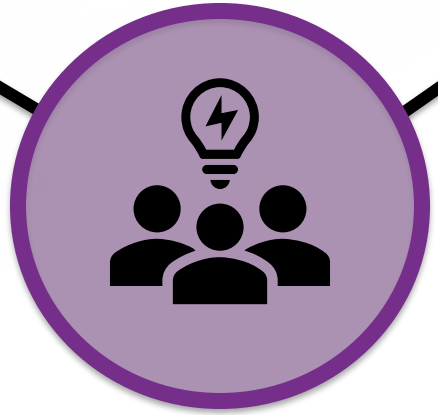
FORM CMS-2567(02-99) Previous Versions Obsolete * Event ID: WR4211 Facility ID: CA2254272 If continuation sheet Page 1 of 121

CONFIDENTIAL COMMERCIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

THE SURVEY PROCESS

GET READY

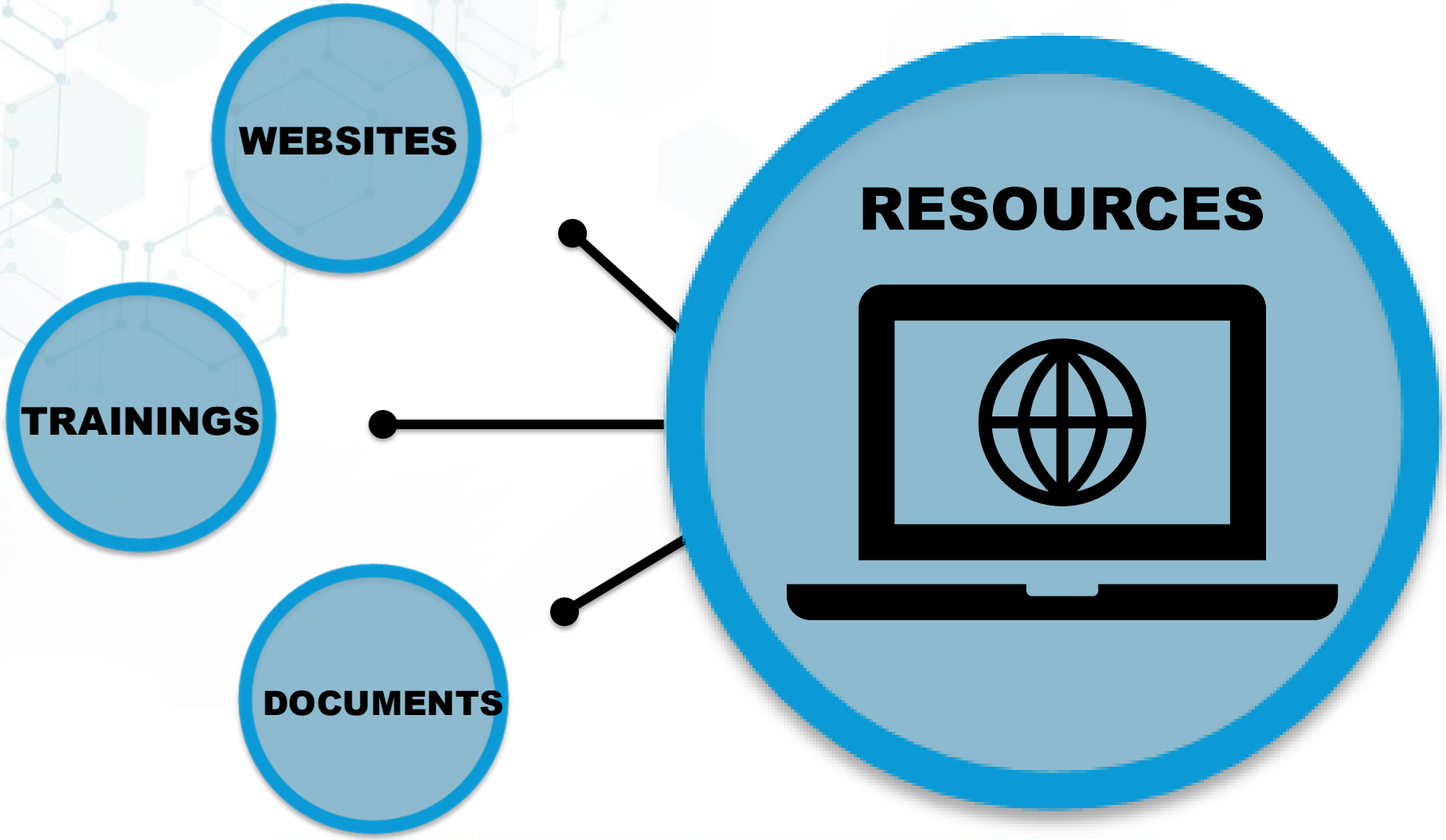
THE SURVEYORS ARE HERE



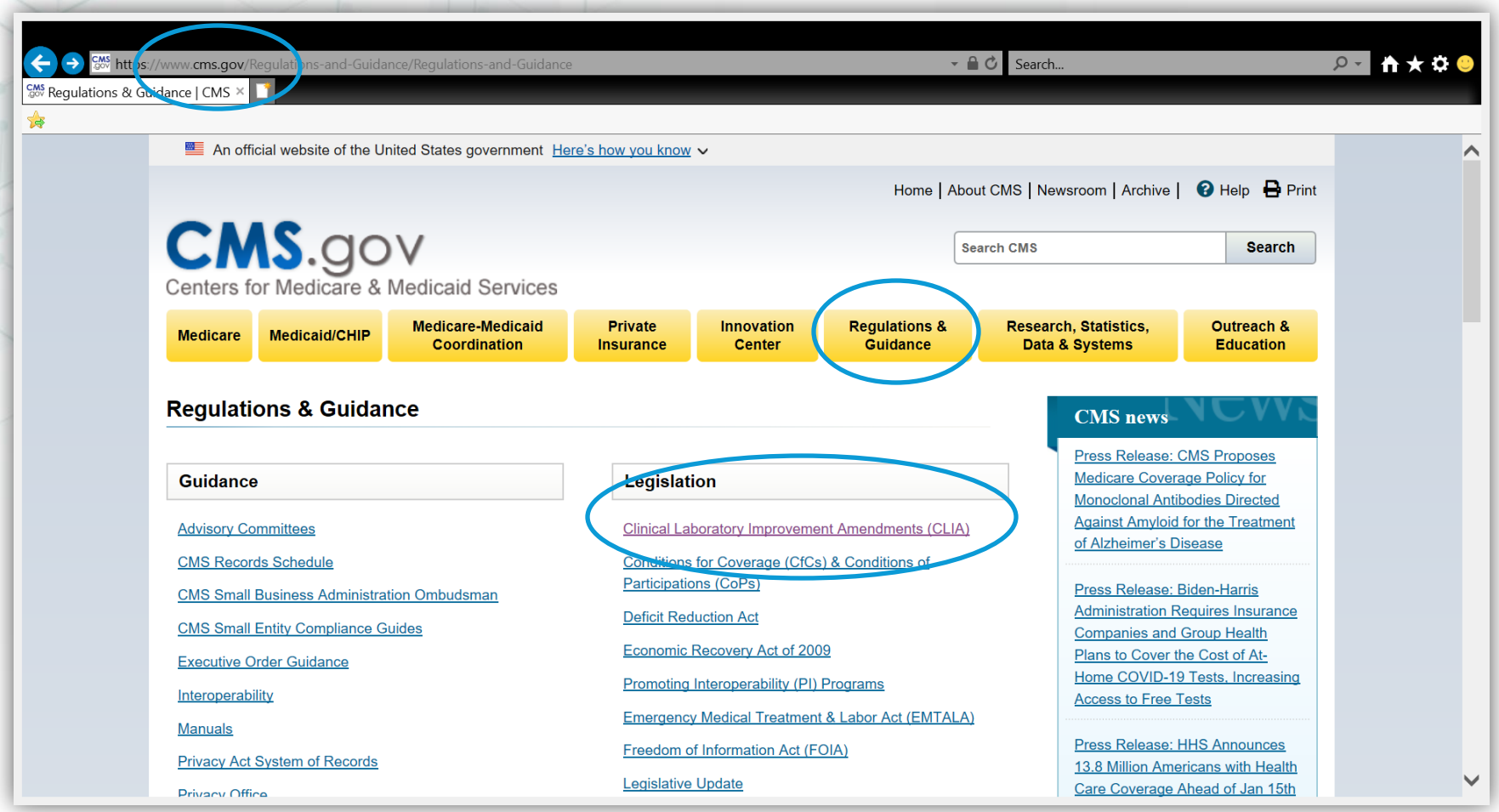
THE SURVEY SAYS

RESOURCES

THE SURVEY PROCESS

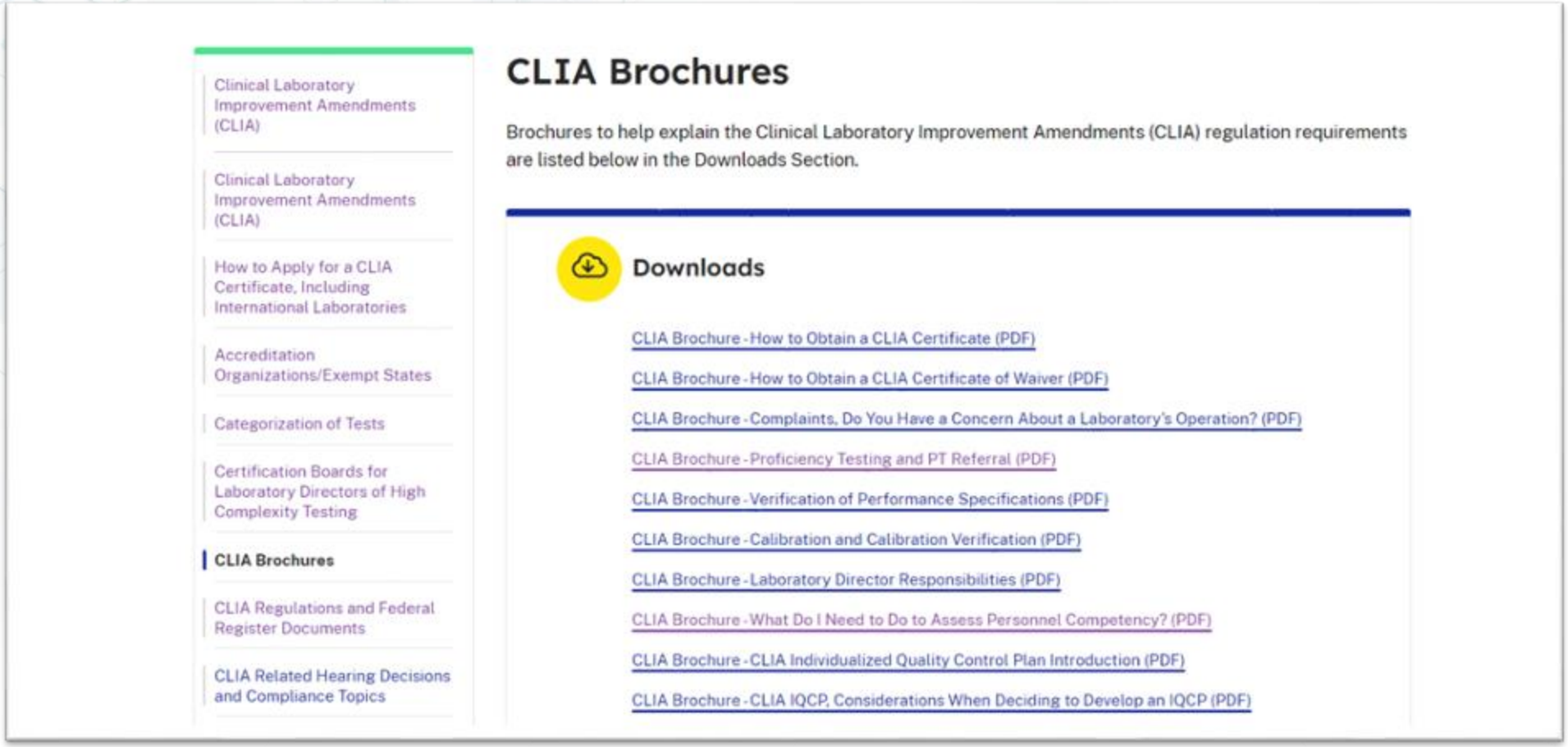


WEBSITES, TRAININGS, AND DOCUMENTS



WEBSITES, TRAININGS, AND DOCUMENTS

WEBSITES, TRAININGS, AND DOCUMENTS



Clinical Laboratory Improvement Amendments (CLIA)

Clinical Laboratory Improvement Amendments (CLIA)

How to Apply for a CLIA Certificate, Including International Laboratories

Accreditation Organizations/Exempt States

Categorization of Tests

Certification Boards for Laboratory Directors of High Complexity Testing

CLIA Brochures

CLIA Regulations and Federal Register Documents

CLIA Related Hearing Decisions and Compliance Topics

CLIA Brochures

Brochures to help explain the Clinical Laboratory Improvement Amendments (CLIA) regulation requirements are listed below in the Downloads Section.

Downloads

CLIA Brochure - How to Obtain a CLIA Certificate (PDF)

CLIA Brochure - How to Obtain a CLIA Certificate of Waiver (PDF)

CLIA Brochure - Complaints, Do You Have a Concern About a Laboratory's Operation? (PDF)

CLIA Brochure - Proficiency Testing and PT Referral (PDF)

CLIA Brochure - Verification of Performance Specifications (PDF)

CLIA Brochure - Calibration and Calibration Verification (PDF)

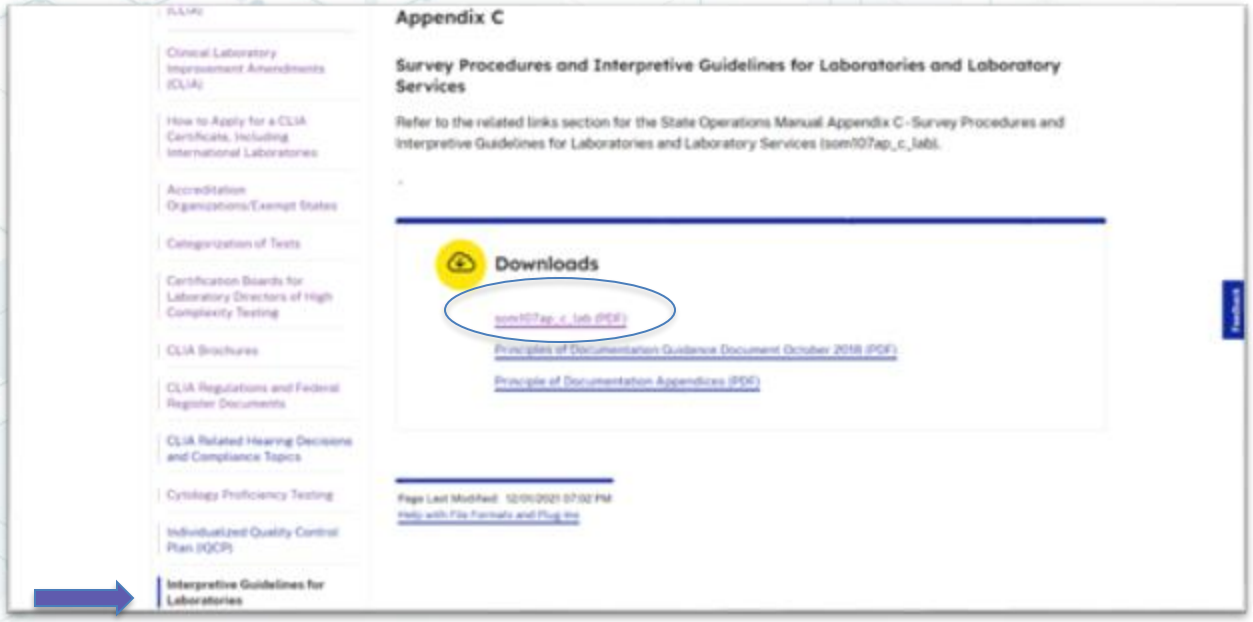
CLIA Brochure - Laboratory Director Responsibilities (PDF)

CLIA Brochure - What Do I Need to Do to Assess Personnel Competency? (PDF)

CLIA Brochure - CLIA Individualized Quality Control Plan Introduction (PDF)

CLIA Brochure - CLIA IQCP, Considerations When Deciding to Develop an IQCP (PDF)

WEBSITES, TRAININGS, AND DOCUMENTS



Appendix C

Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

Refer to the related links section for the State Operations Manual Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (som107ap_c_labs).

Downloads

som107ap_c_labs (PDF)

Principles of Documentation Guidance Document October 2018 (PDF)

Principle of Documentation Appendices (PDF)

Page Last Modified: 12/01/2021 07:02 PM

Help with File Formats and Plug-ins

Clinical Laboratory Improvement Amendments (CLIA)

How to Apply for a CLIA Certificate, Including International Laboratories

Accreditation Organizations/Exempt States

Categorization of Tests

Certification Boards for Laboratory Directors of High Complexity Testing

CLIA Brochures

CLIA Regulations and Federal Register Documents

CLIA Related Hearing Decisions and Compliance Topics

Cytology Proficiency Testing

Individualized Quality Control Plan (IQCP)

Interpretive Guidelines for Laboratories

D5419

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies

(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

Interpretive Guidelines §493.1252(e)

"Kit" means all components of a test that are packaged together.

§493.1253 Standard: Establishment and verification of performance specifications

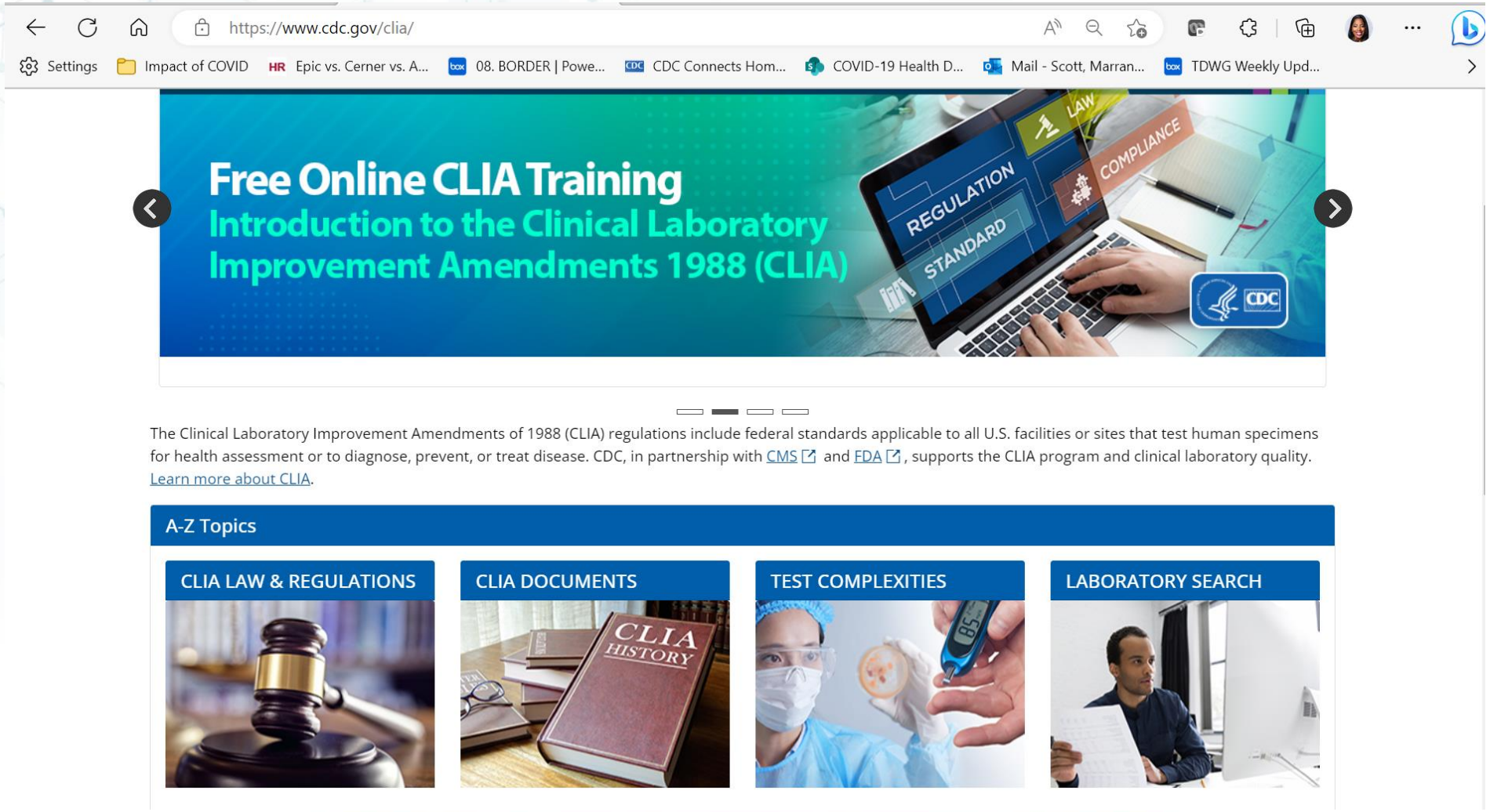
(a) Applicability. Laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

Interpretive Guidelines §493.1253(a)

The requirements of §493.1253 apply to each nonwaived test system (i.e., moderate and high complexity) introduced into the laboratory on or after April 24, 2003. This includes the following:

- A test system that is introduced into the laboratory for the first time to measure an analyte that the laboratory has not previously measured;
- A test system introduced for the first time into the laboratory for a test that the laboratory currently performs on an alternative test system (e.g., instrument A has been used to perform cholesterol testing, now instrument B will be used);
- An analyte added to a test system that can measure multiple analytes which the laboratory has been using for patient testing but has not previously reported patient results for this particular analyte; and
- A modification to a test system that the laboratory has been using for patient testing (e.g., the laboratory reduces the specimen and/or reagent volumes).

WEBSITES, TRAININGS, AND DOCUMENTS

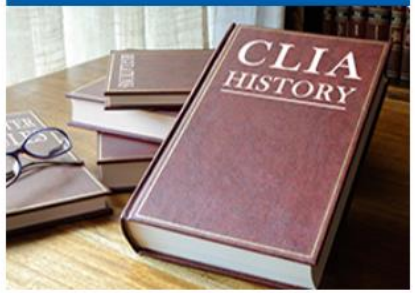


WEBSITES, TRAININGS, AND DOCUMENTS

A-Z Topics

CLIA LAW & REGULATIONS

CLIA DOCUMENTS



TEST COMPLEXITIES

LABORATORY SEARCH

Clinical Laboratory Improvement Advisory Committee (CLIAC)

Find information about the Clinical Laboratory Improvement Advisory Committee (CLIAC), which is managed by the Centers for Disease Control and Prevention (CDC), provides scientific and technical advice and guidance to the Department of Health and Human Services (HHS).

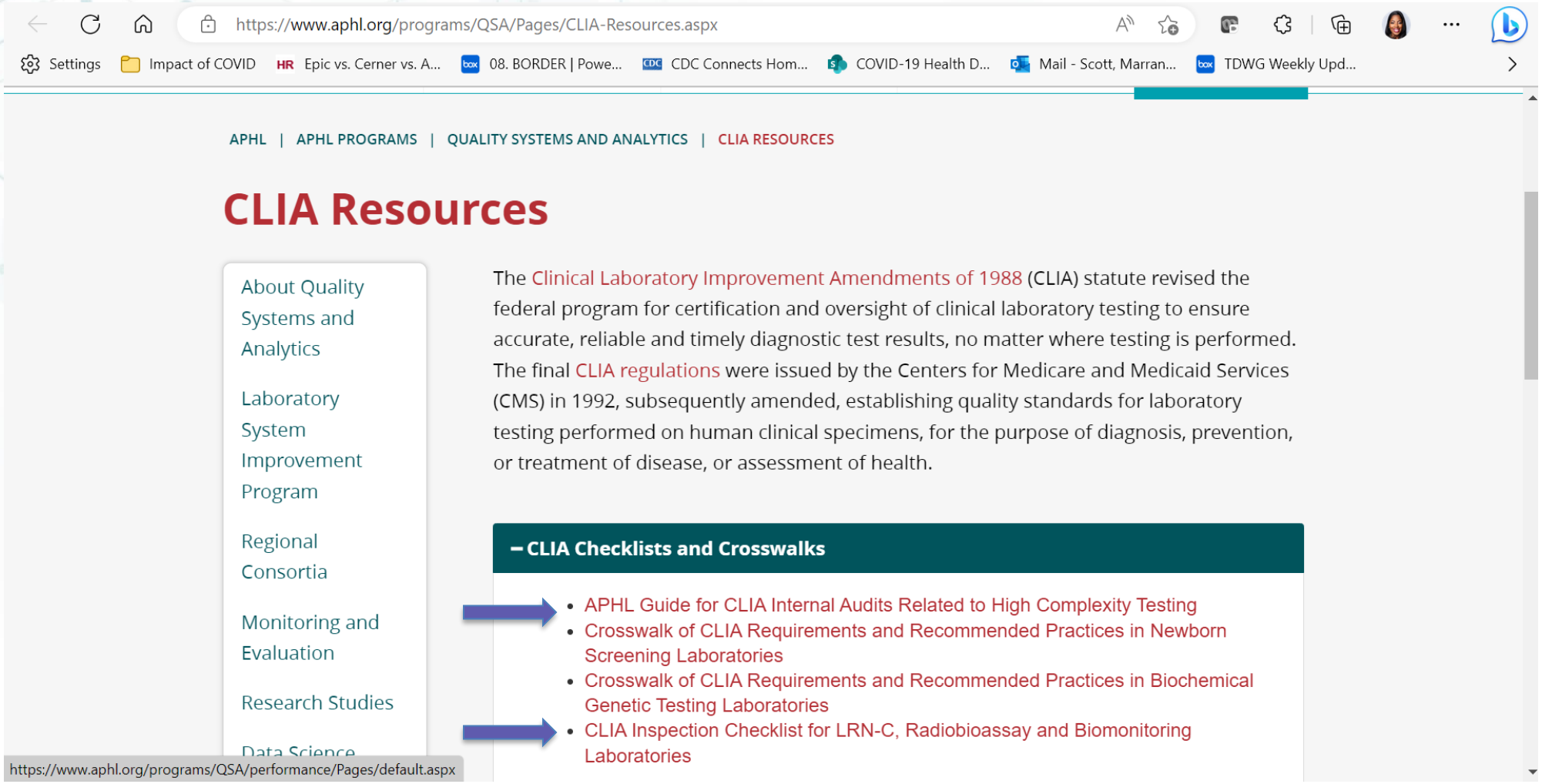
Get Answers to CLIA Related Questions

Find links for answers to frequently asked questions on the CLIA Quick Tips page or email CMS directly.

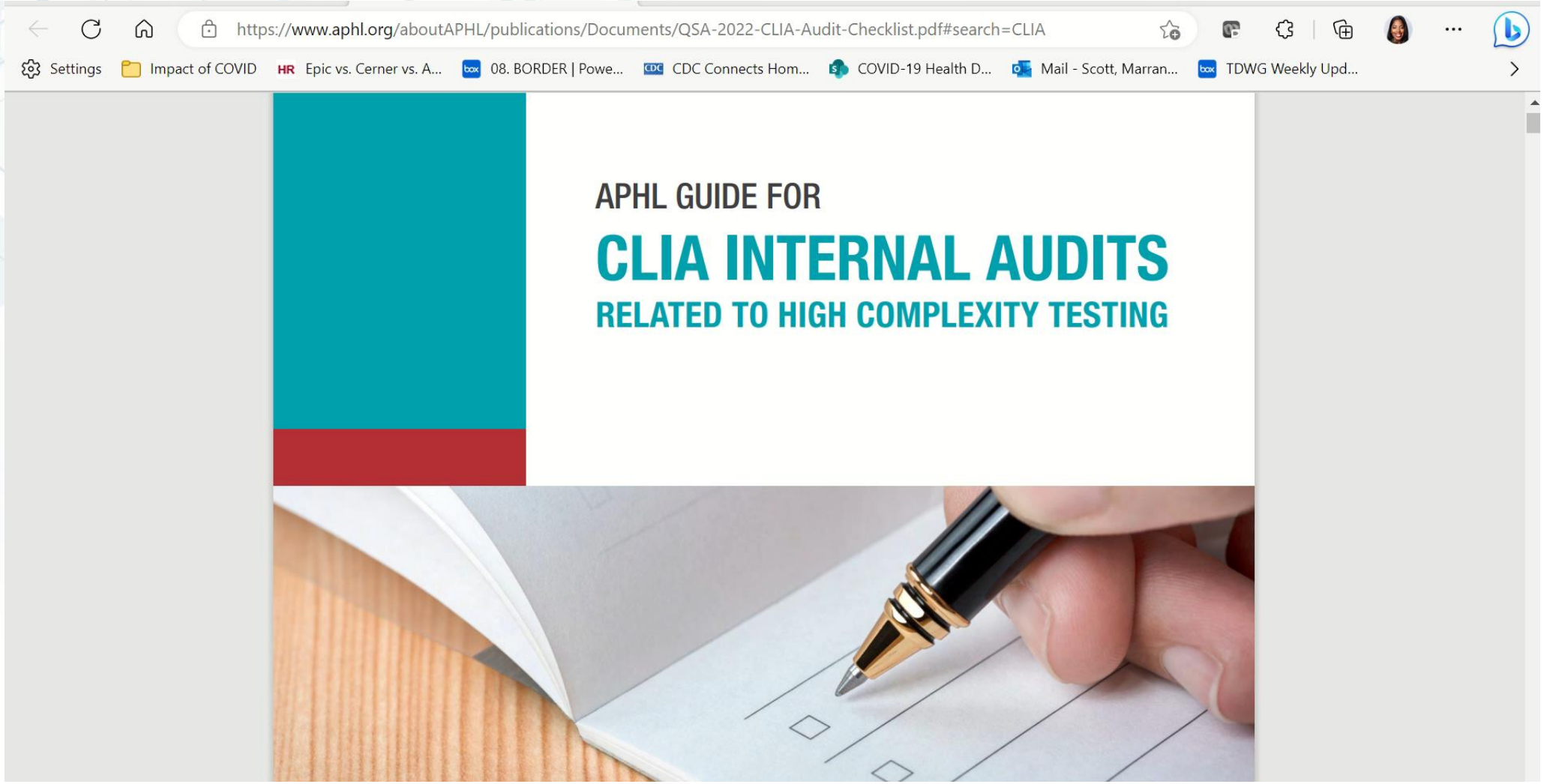
Find the Laboratory Quality Portal

Laboratories are on the frontline for protecting our communities' health. CDC provides clinical and public health laboratories with training and technical assistance to help them achieve the highest-quality laboratory science while ensuring the safety of laboratory professionals and the communities where they work. Learn more about CDC's laboratory quality efforts.

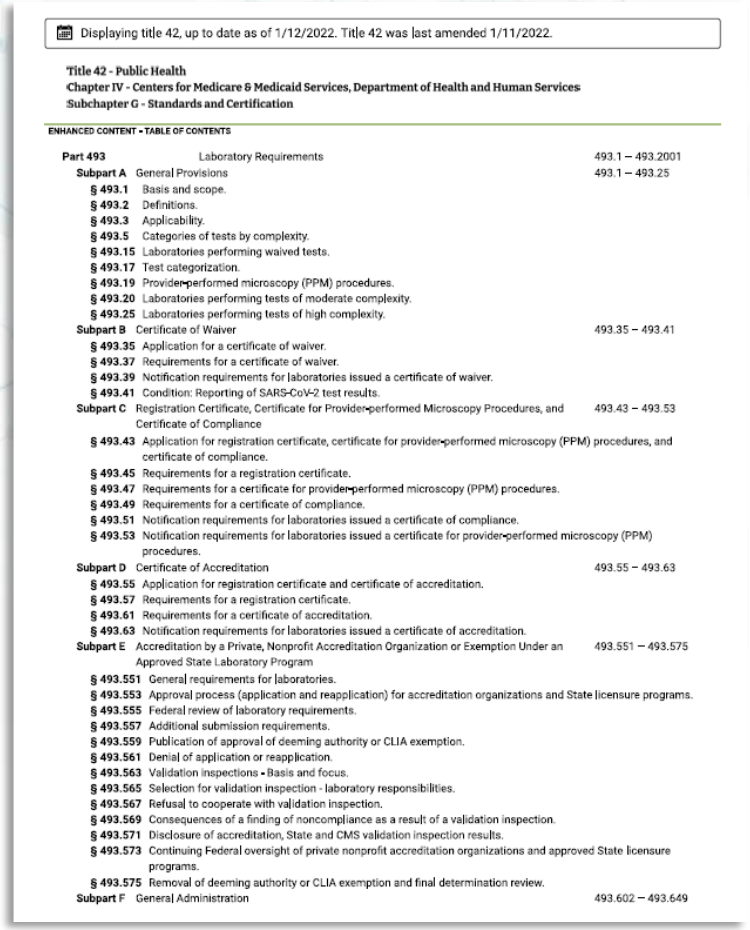
WEBSITES, TRAININGS, AND DOCUMENTS



WEBSITES, TRAININGS, AND DOCUMENTS



WEBSITES, TRAININGS, AND DOCUMENTS

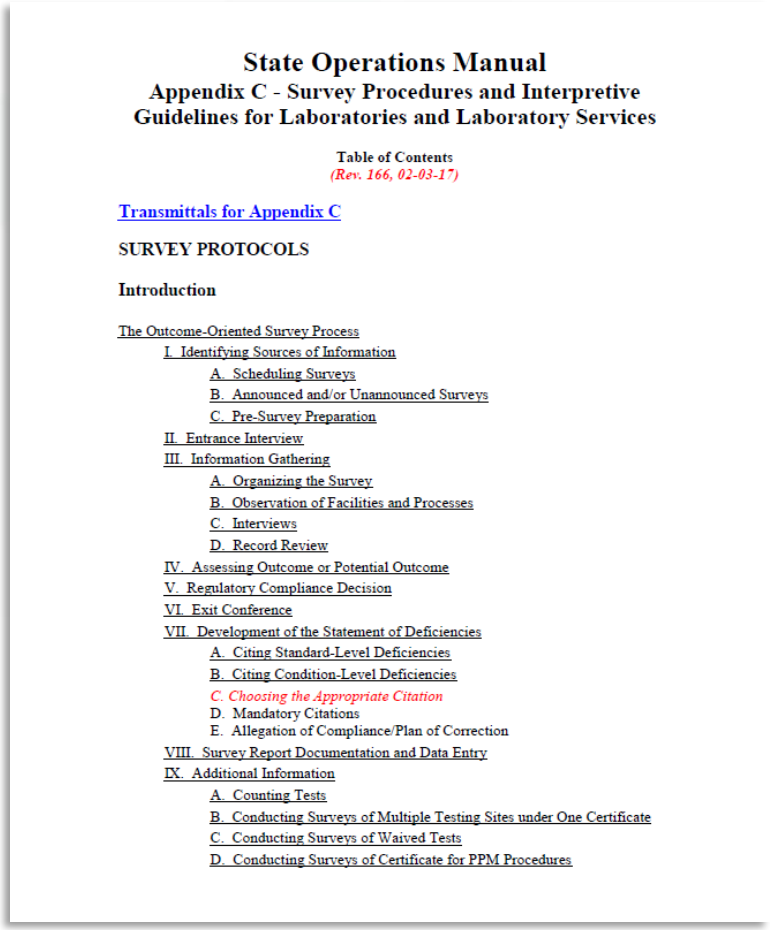


Displaying title 42, up to date as of 1/12/2022. Title 42 was last amended 1/11/2022.

Title 42 - Public Health
Chapter IV - Centers for Medicare & Medicaid Services, Department of Health and Human Services
Subchapter G - Standards and Certification

ENHANCED CONTENT • TABLE OF CONTENTS

Part 493 Laboratory Requirements 493.1 – 493.2001
Subpart A General Provisions 493.1 – 493.25
§ 493.1 Basis and scope.
§ 493.2 Definitions.
§ 493.3 Applicability.
§ 493.5 Categories of tests by complexity.
§ 493.15 Laboratories performing waived tests.
§ 493.17 Test categorization.
§ 493.19 Provider-performed microscopy (PPM) procedures.
§ 493.20 Laboratories performing tests of moderate complexity.
§ 493.25 Laboratories performing tests of high complexity.
Subpart B Certificate of Waiver 493.35 – 493.41
§ 493.35 Application for a certificate of waiver.
§ 493.37 Requirements for a certificate of waiver.
§ 493.39 Notification requirements for laboratories issued a certificate of waiver.
§ 493.41 Condition: Reporting of SARS-CoV-2 test results.
Subpart C Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance 493.43 – 493.53
§ 493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance.
§ 493.45 Requirements for a registration certificate.
§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.
§ 493.49 Requirements for a certificate of compliance.
§ 493.51 Notification requirements for laboratories issued a certificate of compliance.
§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.
Subpart D Certificate of Accreditation 493.55 – 493.63
§ 493.55 Application for registration certificate and certificate of accreditation.
§ 493.57 Requirements for a registration certificate.
§ 493.61 Requirements for a certificate of accreditation.
§ 493.63 Notification requirements for laboratories issued a certificate of accreditation.
Subpart E Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program 493.551 – 493.575
§ 493.551 General requirements for laboratories.
§ 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.
§ 493.555 Federal review of laboratory requirements.
§ 493.557 Additional submission requirements.
§ 493.559 Publication of approval of deeming authority or CLIA exemption.
§ 493.561 Denial of application or reapplication.
§ 493.563 Validation inspections - Basis and focus.
§ 493.565 Selection for validation inspection - laboratory responsibilities.
§ 493.567 Refusal to cooperate with validation inspection.
§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.
§ 493.571 Disclosure of accreditation, State and CMS validation inspection results.
§ 493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.
§ 493.575 Removal of deeming authority or CLIA exemption and final determination review.
Subpart F General Administration 493.602 – 493.649



State Operations Manual
Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

Table of Contents
(Rev. 166, 02-03-17)

Transmittals for Appendix C

SURVEY PROTOCOLS

Introduction

The Outcome-Oriented Survey Process
I. Identifying Sources of Information
A. Scheduling Surveys
B. Announced and/or Unannounced Surveys
C. Pre-Survey Preparation
II. Entrance Interview
III. Information Gathering
A. Organizing the Survey
B. Observation of Facilities and Processes
C. Interviews
D. Record Review
IV. Assessing Outcome or Potential Outcome
V. Regulatory Compliance Decision
VI. Exit Conference
VII. Development of the Statement of Deficiencies
A. Citing Standard-Level Deficiencies
B. Citing Condition-Level Deficiencies
C. Choosing the Appropriate Citation
D. Mandatory Citations
E. Allegation of Compliance/Plan of Correction
VIII. Survey Report Documentation and Data Entry
IX. Additional Information
A. Counting Tests
B. Conducting Surveys of Multiple Testing Sites under One Certificate
C. Conducting Surveys of Waived Tests
D. Conducting Surveys of Certificate for PPM Procedures

Questions?

THANK YOU!

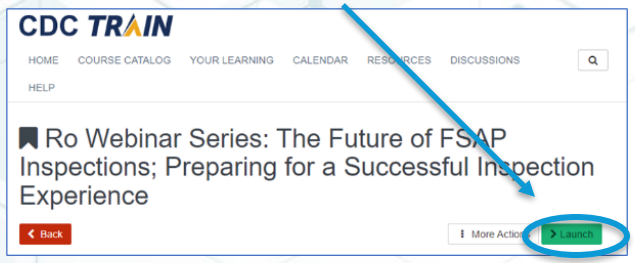
CONTACT INFORMATION: JUZ2@CDC.GOV

Continuing Education

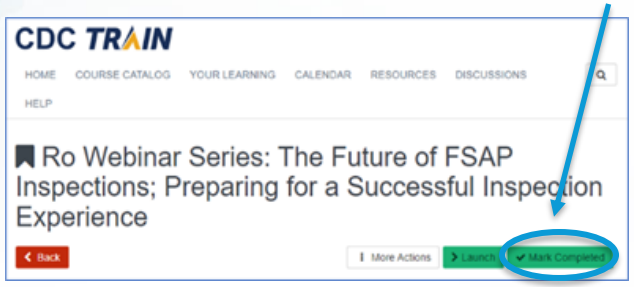
In order to receive continuing education credits, you must:

1. **Attend** entire webinar/**register** for course on TRAIN
   - Register for the course in TRAIN
   - Registration passcode: ***W874***
   - Select **"PACE"** credit type

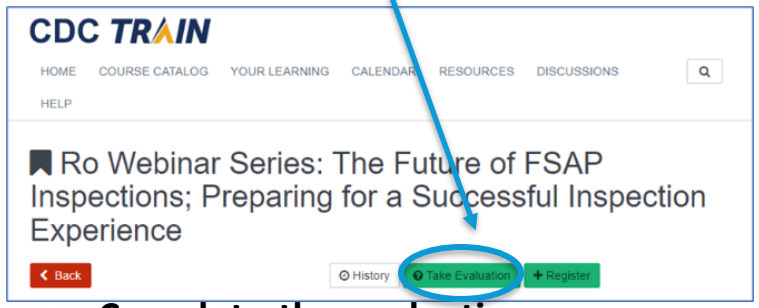
   - Click "**Launch**"



   - Click on green **"Mark Complete"**

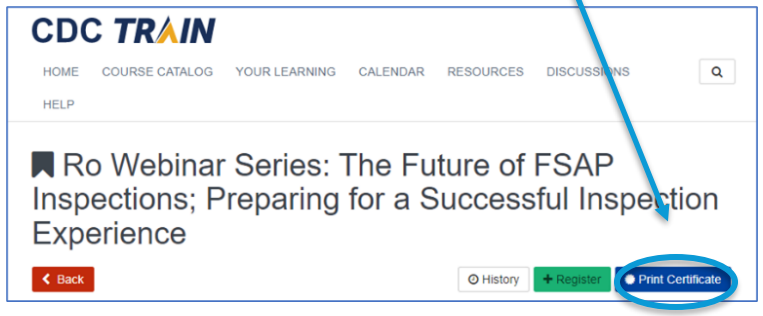


2. **Complete** webinar evaluation
   - Click green **"Take Evaluation"** button



   - **Complete the evaluation**

3. **Obtain** P.A.C.E Certificate
   - Click on the blue **"Print Certificate"** button to download



Upcoming OneLab Network Events

OneLab™
A Unified Response to Training Needs

Identifying and Recognizing Select Agents or Toxins

April 26, 2023

1:00-2:00 PM ET

Register Now!

https://cdc.zoomgov.com/webinar/register/WN_PyRXH6oMQiqKNXU7G69a3A

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