The Process of Surveying:

What You Need to Know for Your CLIA Survey

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ABOUT THE PRESENTER

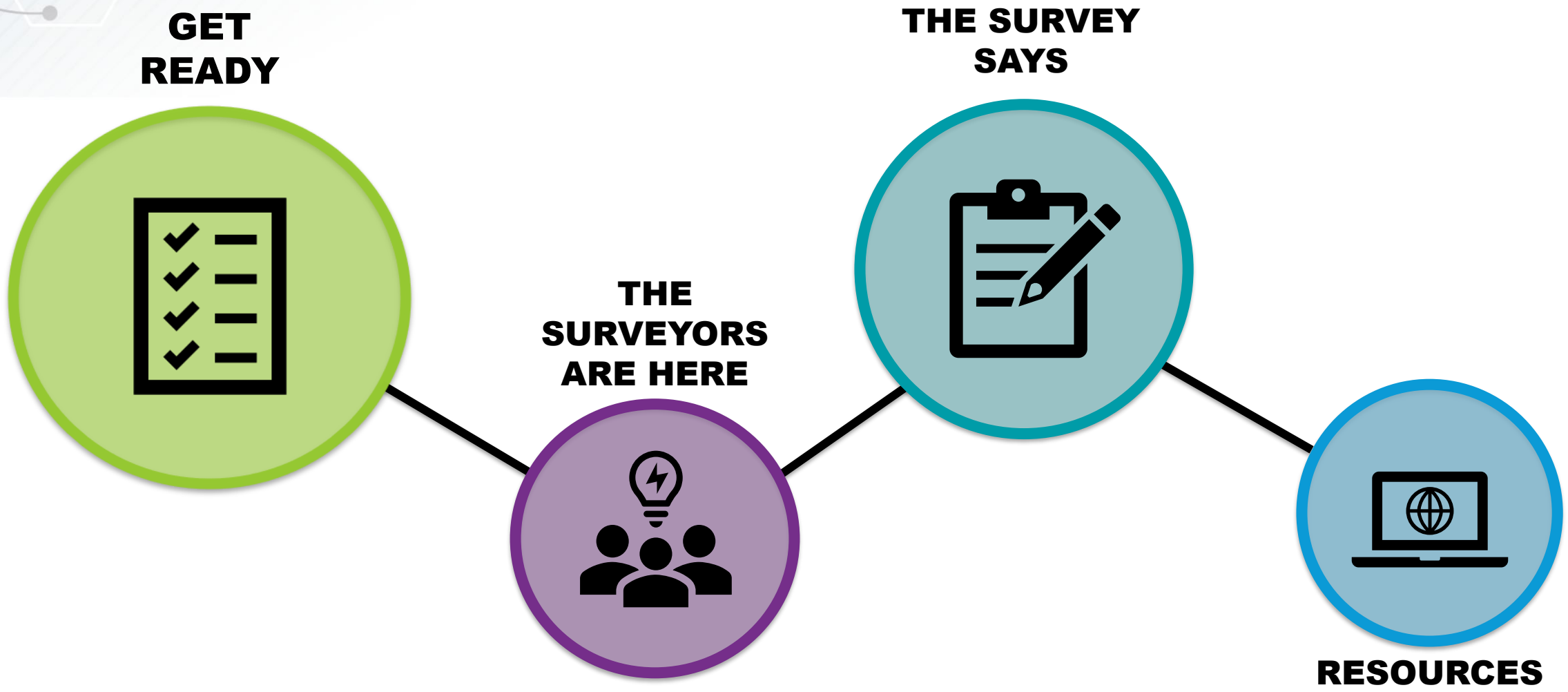
Mississippi State University (2007)

Biologist
FSAP Inspector (2010-2015)

Clinical Laboratory Scientist
CLIA Surveyor (2015-2021)

Clinical Laboratory Scientist
Division of Laboratory Systems

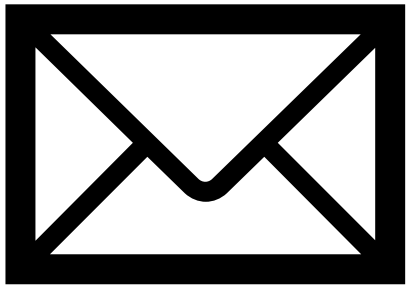
THE PROCESS OF SURVEYING



THE PROCESS OF SURVEYING

THE SURVEYOR

STATE AGENCY



COMPLAINTS

ENFORCEMENTS

SURVEYS

THE SURVEYOR

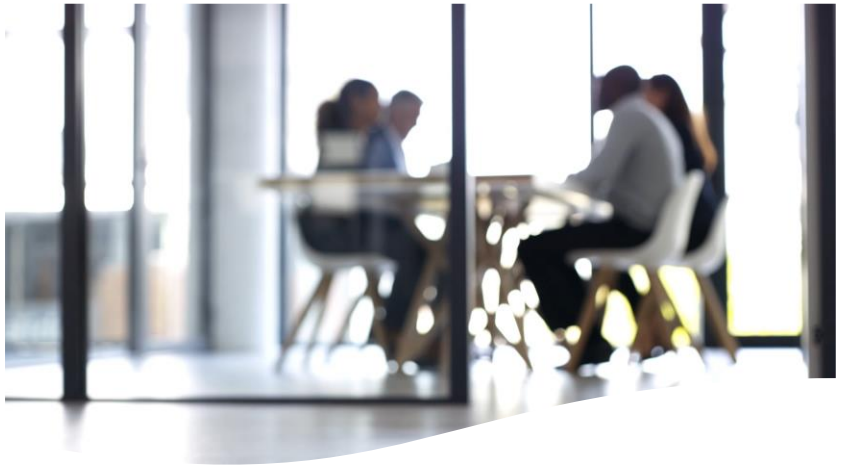
How Surveyors Prepare

Check Survey Fees Are Paid
Pull Information From Last Survey

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

Proficiency Testing Report
Open Enforcement Cases

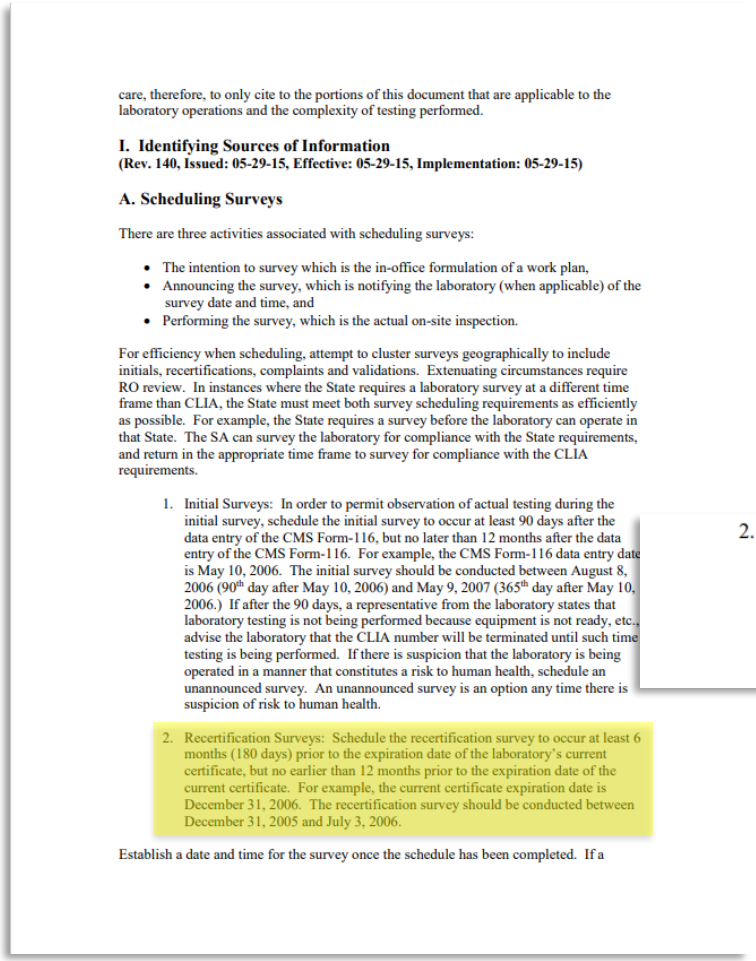
Planning Meeting
Contact Laboratory with Potential Date



THE LABORATORY

POLL QUESTION #1

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.

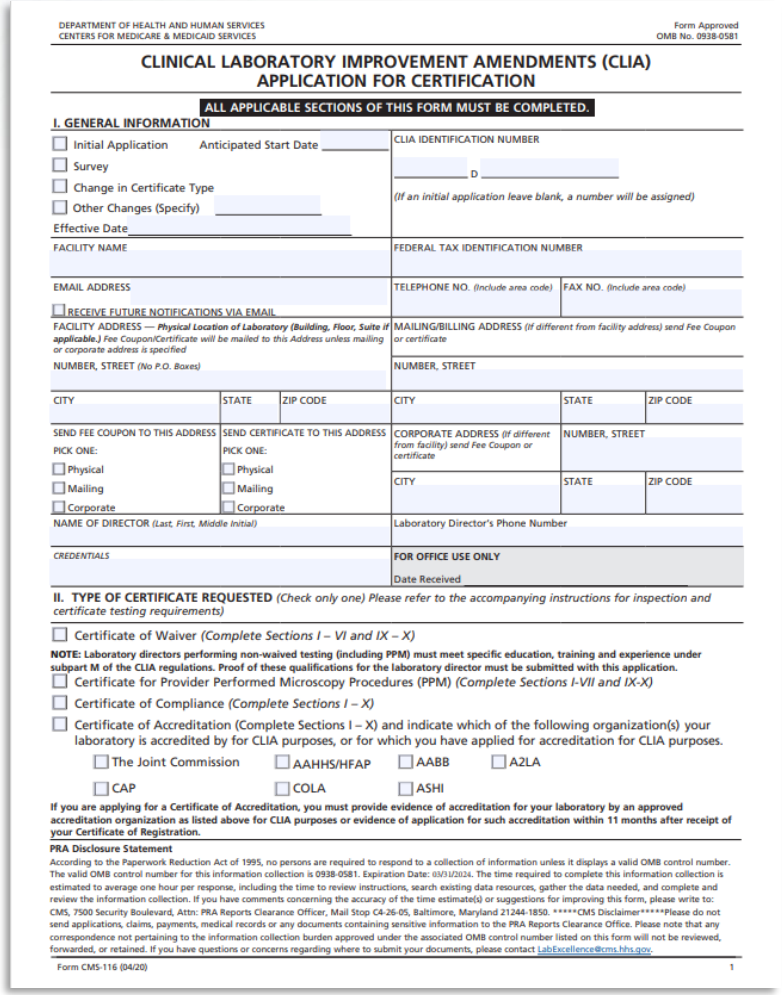
2. Recertification Surveys: Schedule the recertification survey to occur at least 6 months (180 days) prior to the expiration date of the laboratory's current certificate, but no earlier than 12 months prior to the expiration date of the current certificate. For example, the current certificate expiration 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.

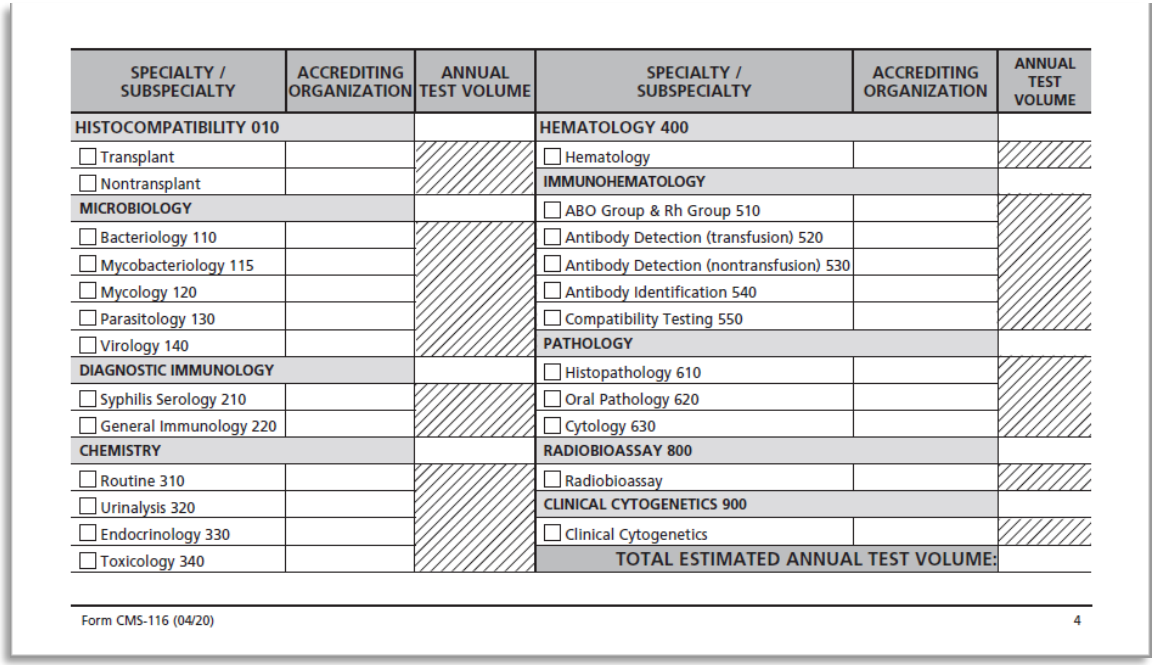
☐ The Joint Commission ☐ AAHHS/HFAP ☐ AABB ☐ A2LA
☐ CAP ☐ COLA ☐ ASHI

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: 03/31/2024. 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 LabExcellence@cms.hhs.gov.

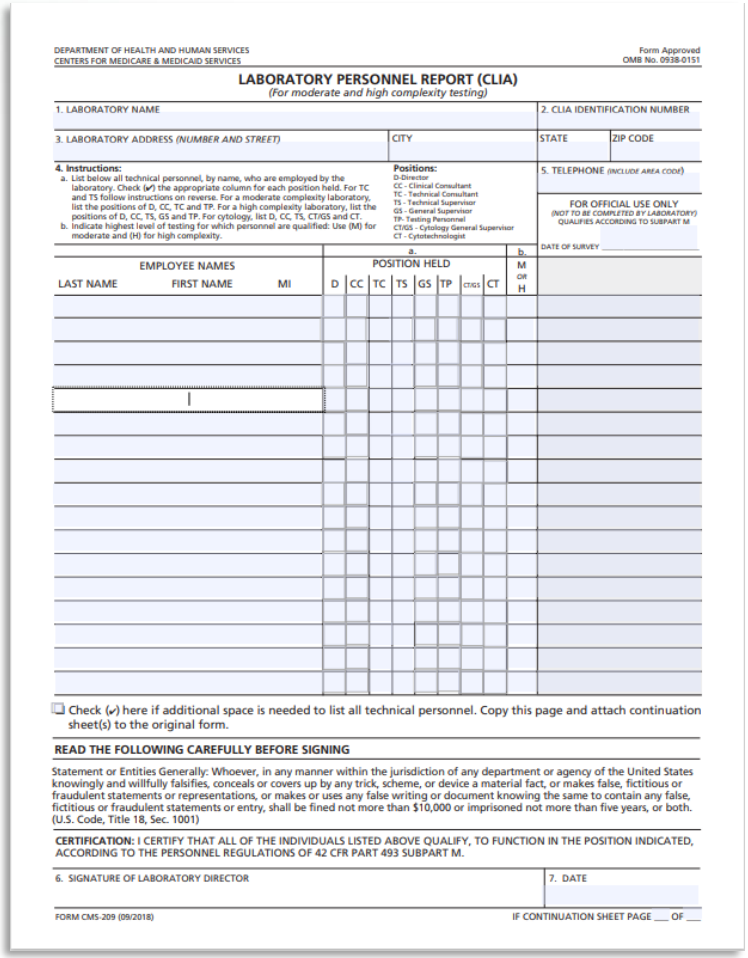
Form CMS-116 (04/20) 1



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 (04/20) 4

THE LABORATORY



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.

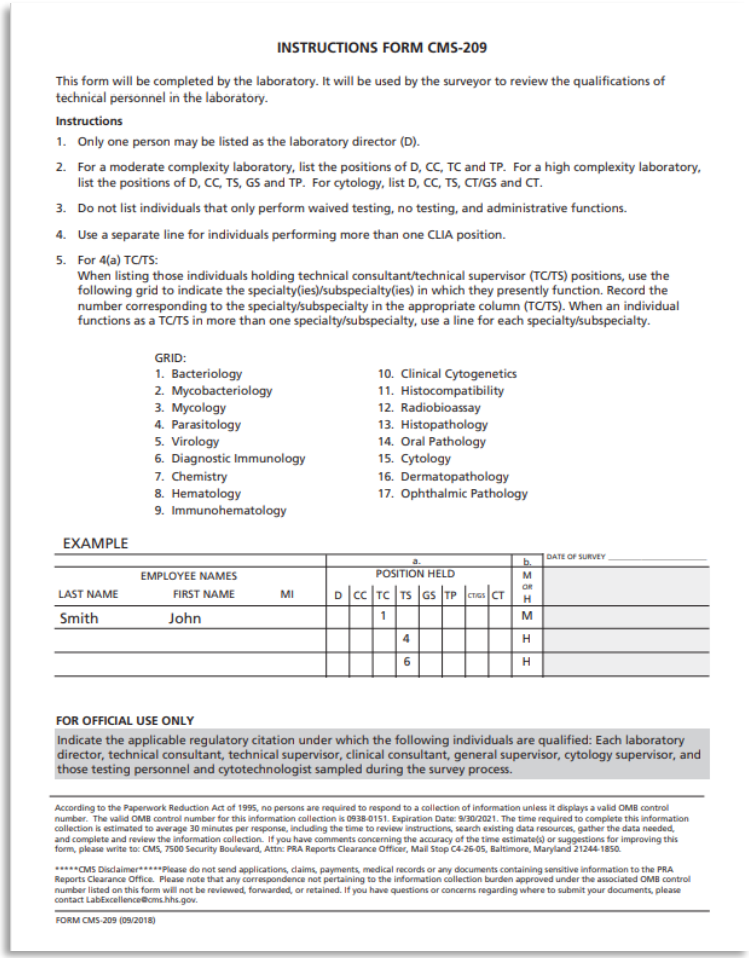
READ THE FOLLOWING CAREFULLY BEFORE SIGNING

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

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

DATE OF SURVEY _____

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.

FORM CMS-209 (09/2018)

CMS 209

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

SOPs

- Test Procedures
- Package Inserts

Personnel Records

- Degrees
- Transcripts
- Training
- Competency Assessments

Quality Control Records

- Remedial Action
- Instrument Maintenance
- Function Checks

THE LABORATORY

Quality System Assessment Plan

- Policies and Procedures
- Documentation of Ongoing Assessments

Patient Records

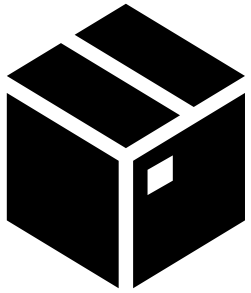
- Requisitions
- Work Records
- Patient Test Reports

Proficiency Testing Records

- Test Runs with PT results
- Printouts
- Signed Attestation
- Remedial Action

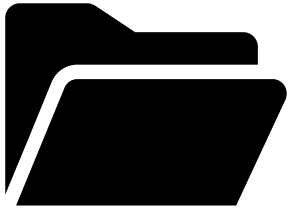
WHO IS RESPONSIBLE

DON'T FORGET ABOUT…



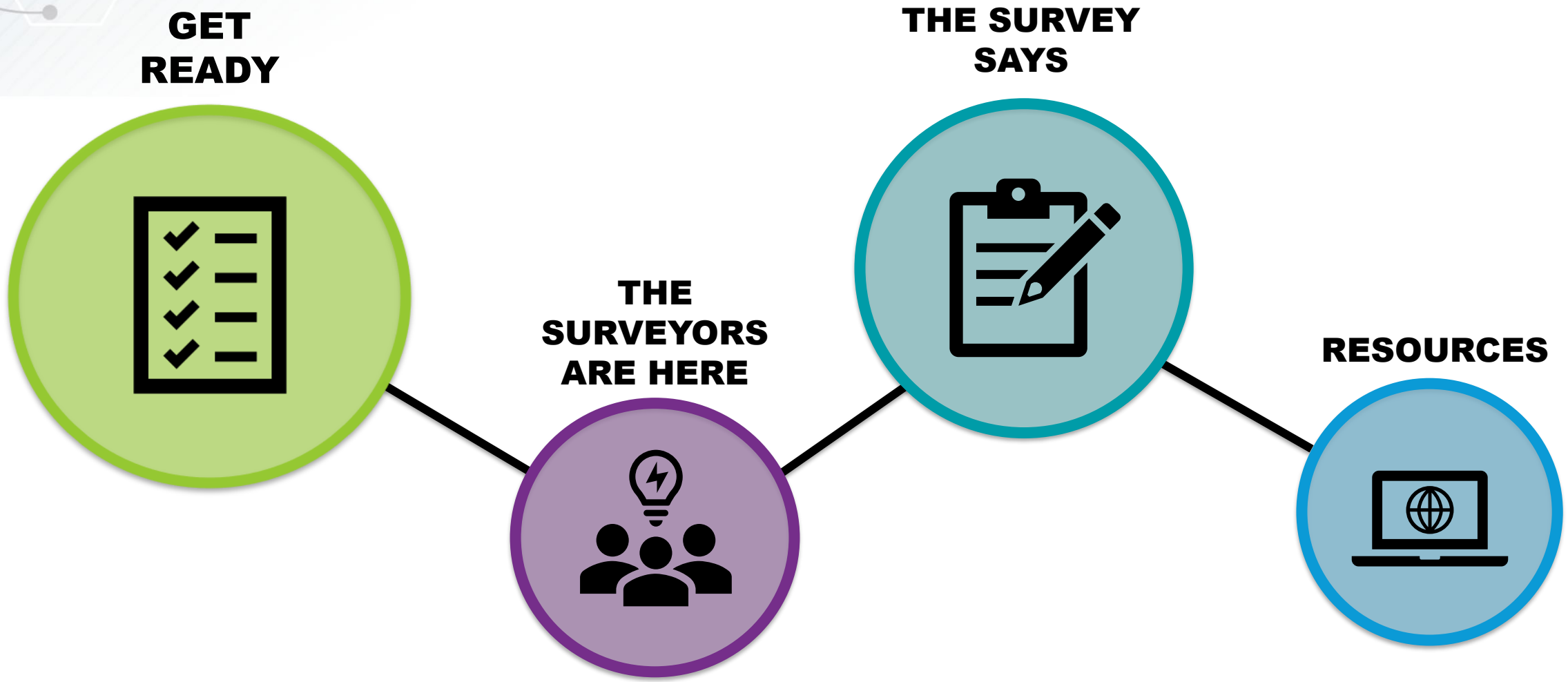
SPECIMEN RECEIVING & PROCESSING

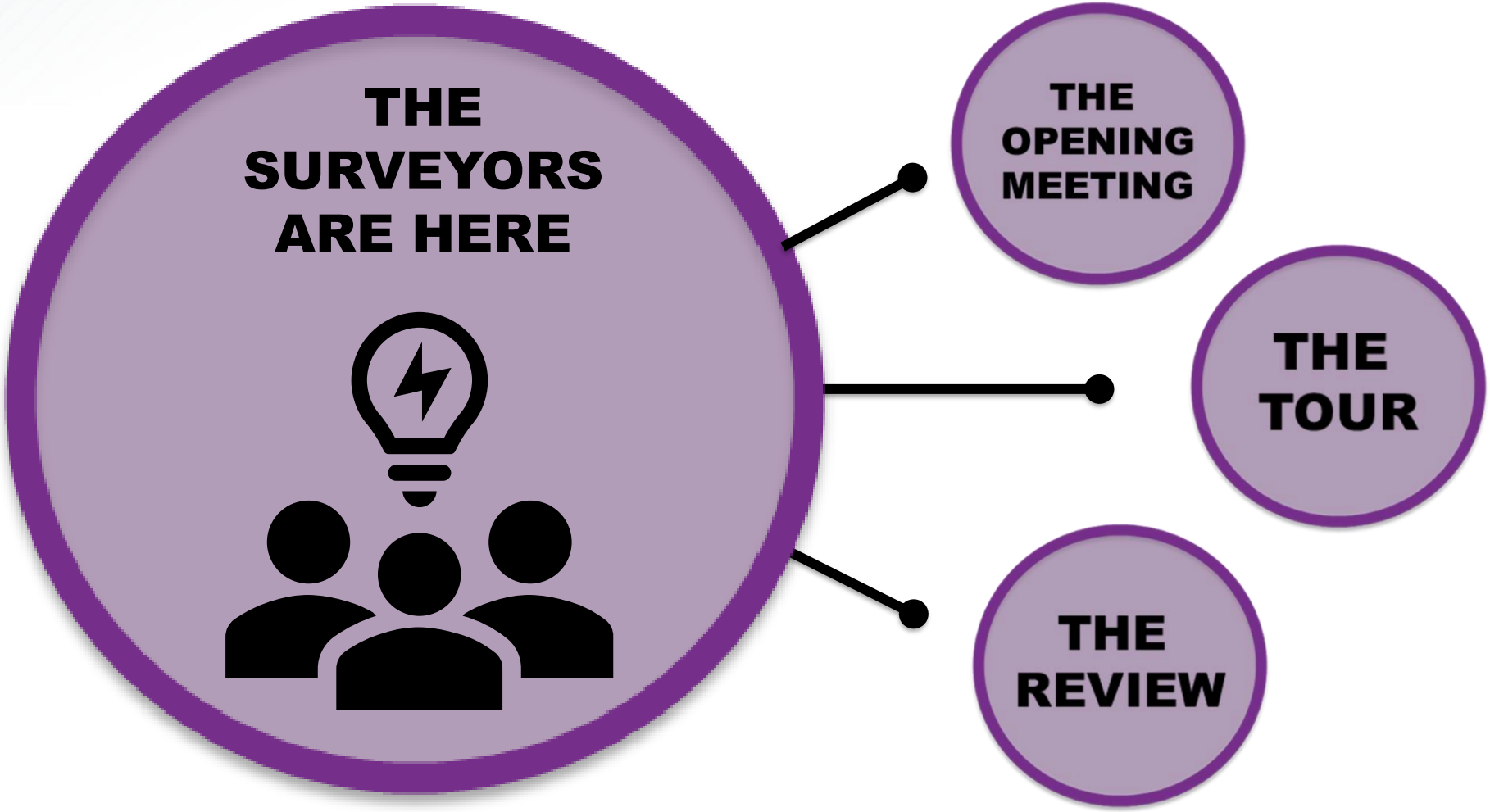
IT



HUMAN RESOURCES

THE PROCESS OF SURVEYING




THE SURVEYORS ARE HERE
THE OPENING MEETING
THE TOUR
THE REVIEW

THE OPENING MEETING

THE OPENING MEETING

Invite Laboratory Staff

Technical Consultant/Technical Supervisor

General Supervisor

Quality Manager

Prepare To Give Updates

Any Facility Changes Since Last Survey

Added Specialties/New Test

Personnel Promoted (ex. TP to TC or TS)

Allow Surveyors To Discuss Survey Flow

Length

Tour

Record Review/Interviews

THE TOUR

Facility Tour/Surveyor Section Tour

THE REVIEW

What Do Surveyors Want To See?

Records Generated Since the Last Survey
Provide Requested Records in a Timely Manner

SOPs
- Test Procedures
- Package Inserts

Personnel Records
- Degrees
- Transcripts
- Training
- Competency Assessments

Quality Control Records
- Remedial Action
- Instrument Maintenance
- Function Checks

Quality System Assessment Plan
- Policies and Procedures
- Documentation of Ongoing Assessments

Patient Records
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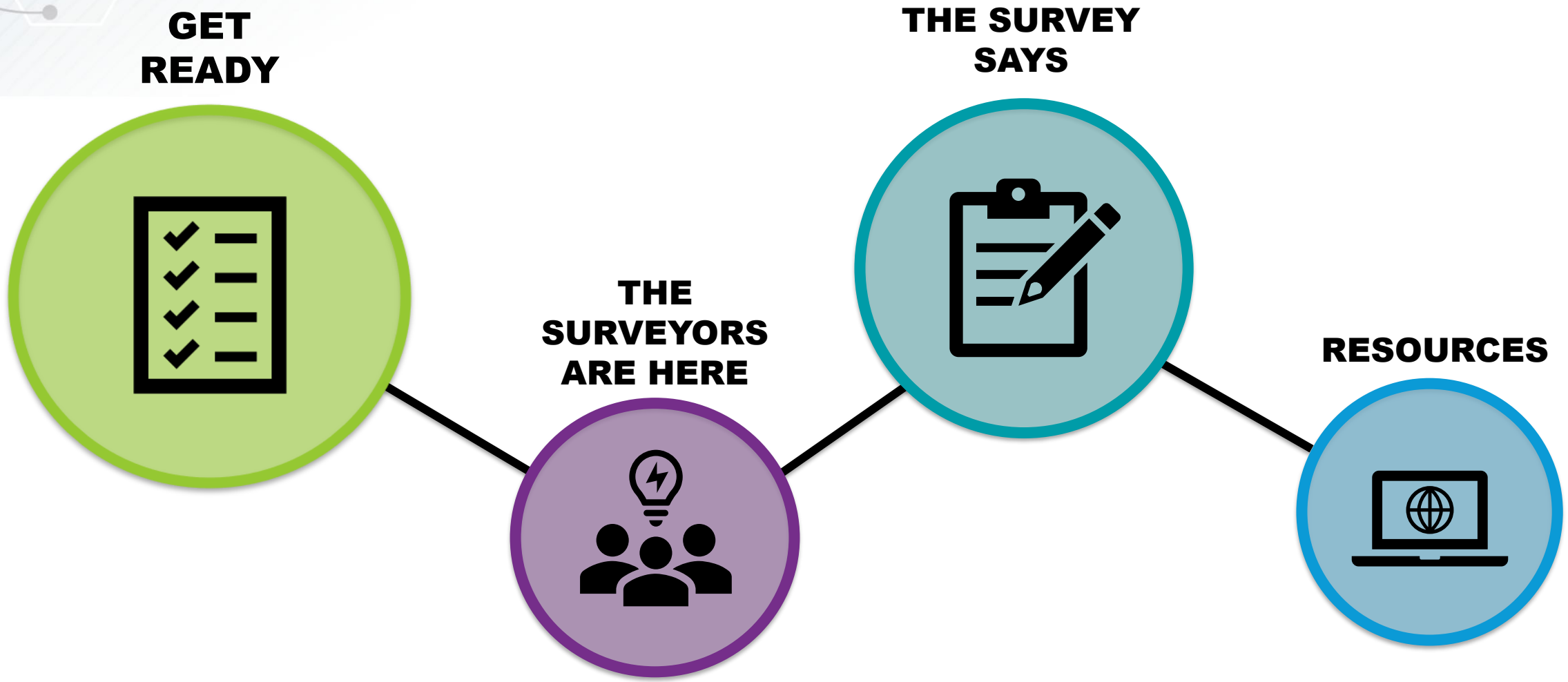
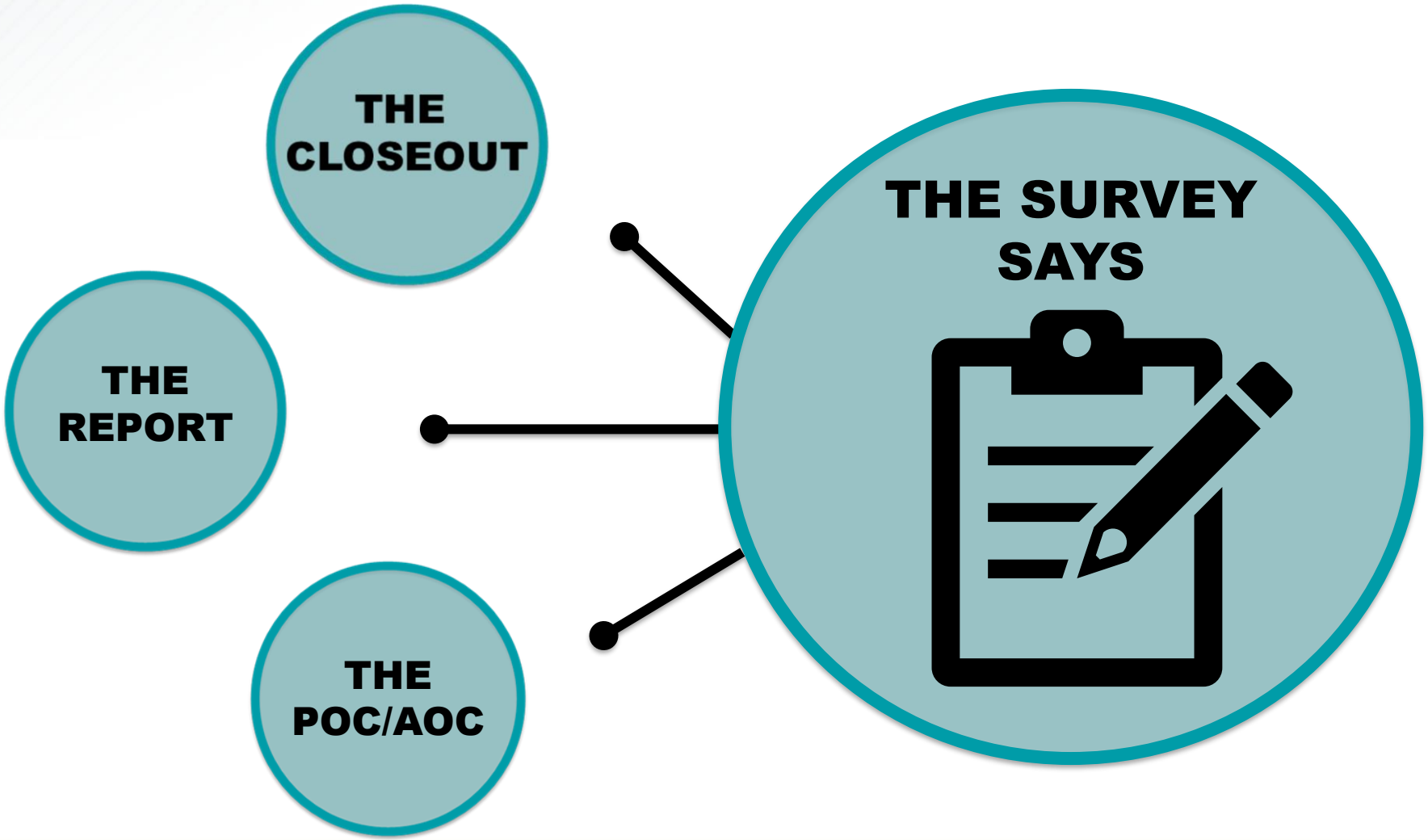
THE PROCESS OF SURVEYING

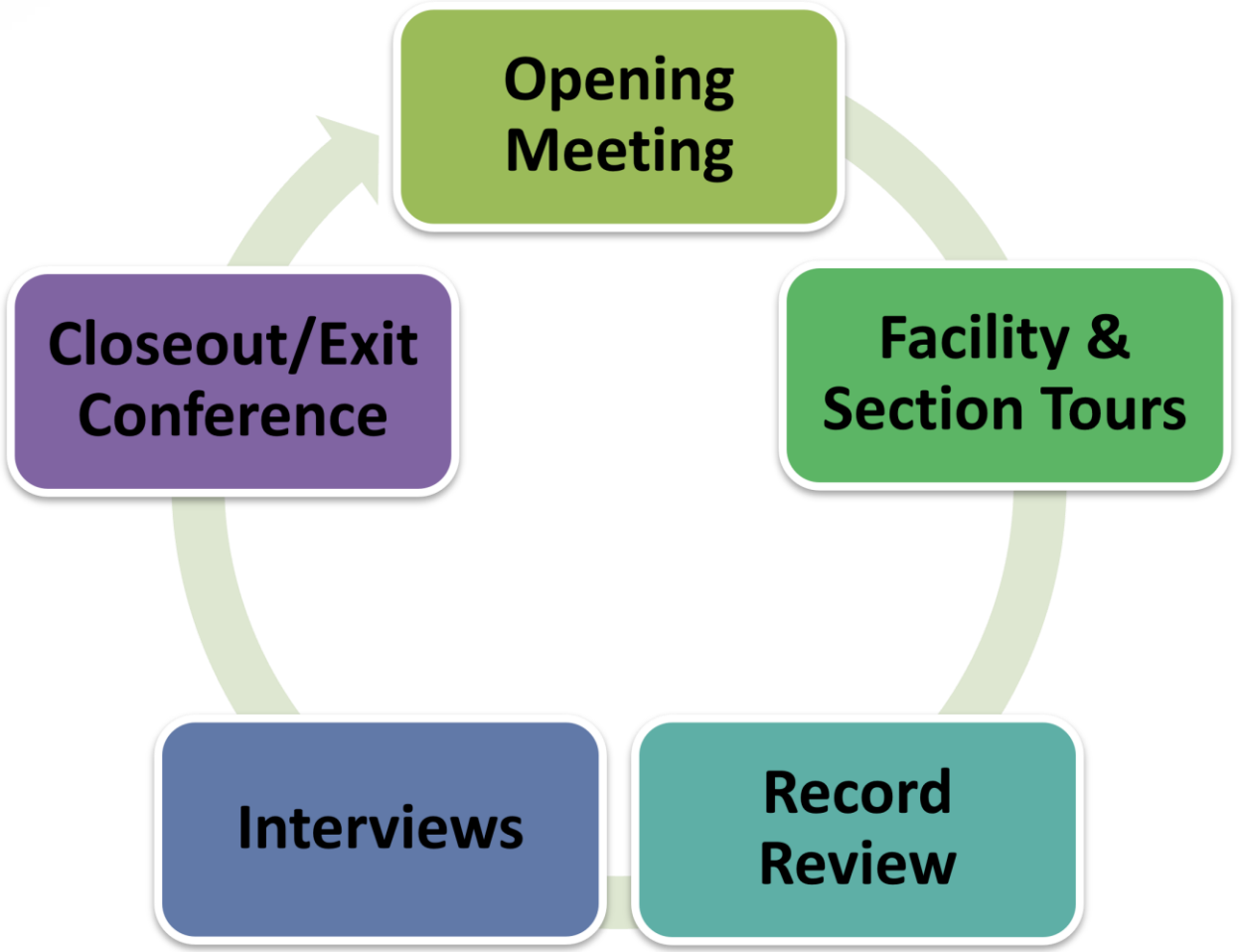


THE PROCESS OF CMS SURVEYING



THE CLOSEOUT

THE CLOSEOUT

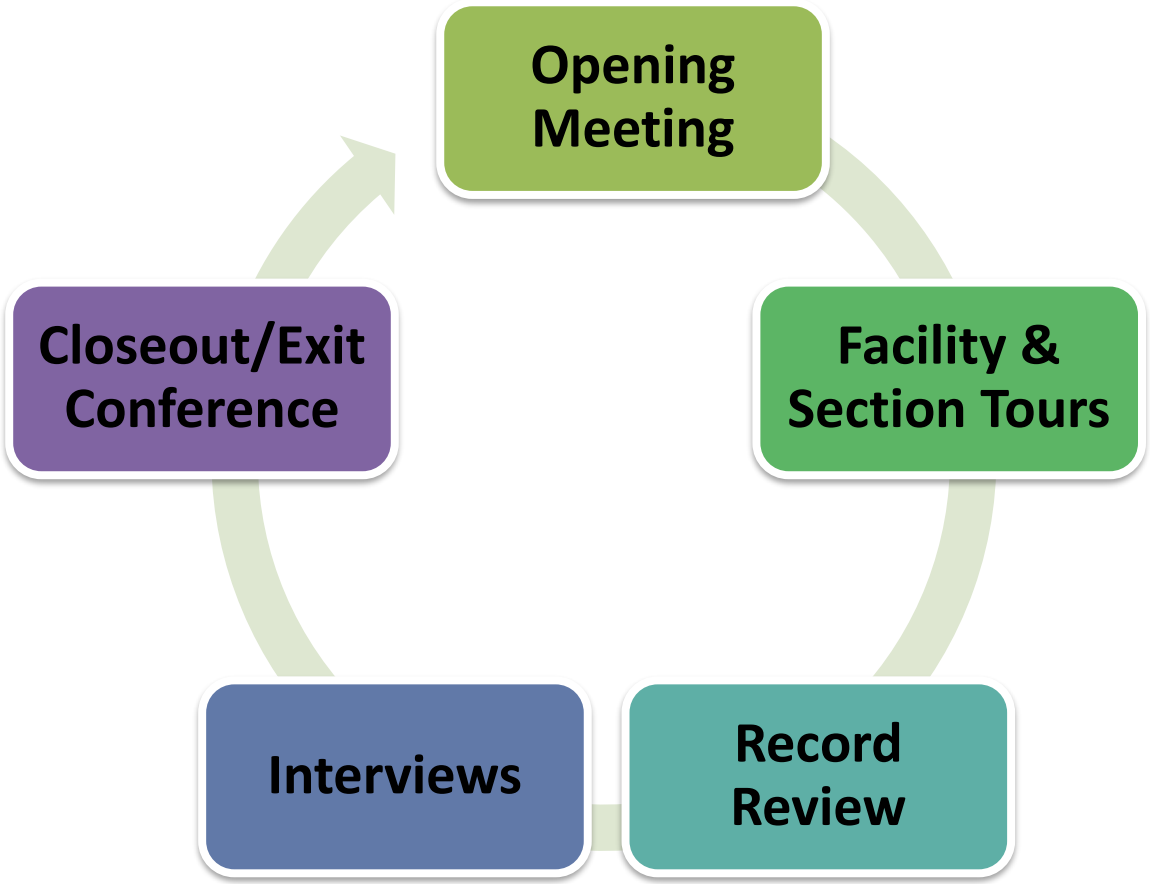


THE CLOSEOUT

Invite the Laboratory Staff

Overview of the Survey

Ask Questions



THE REPORT

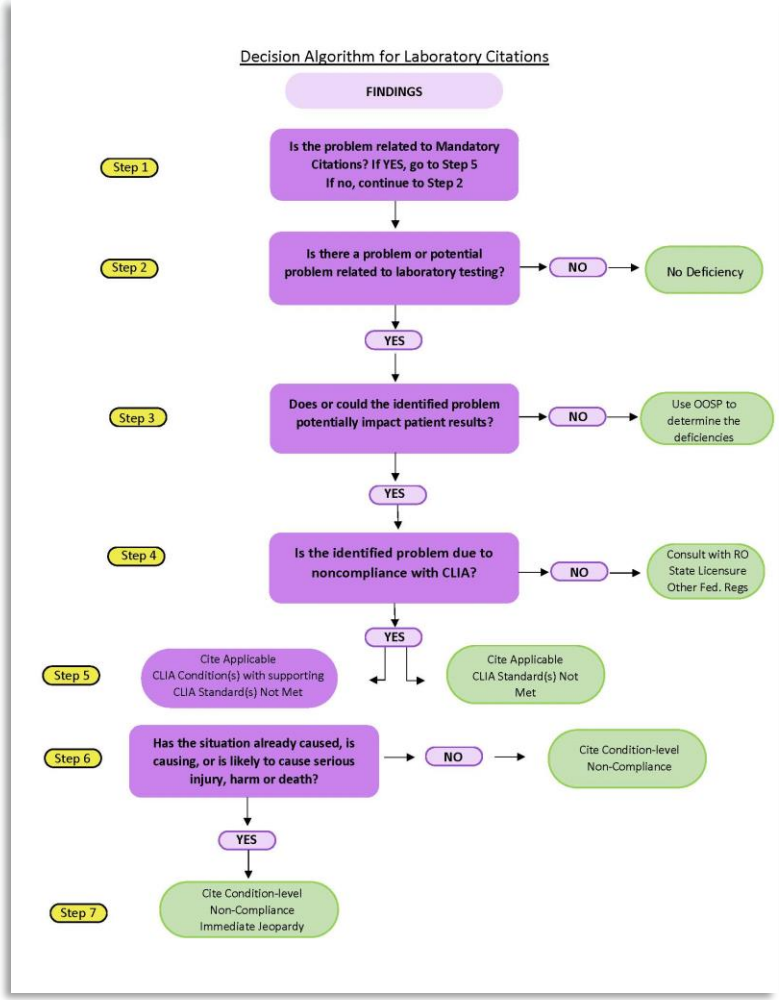


Table VII-1

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

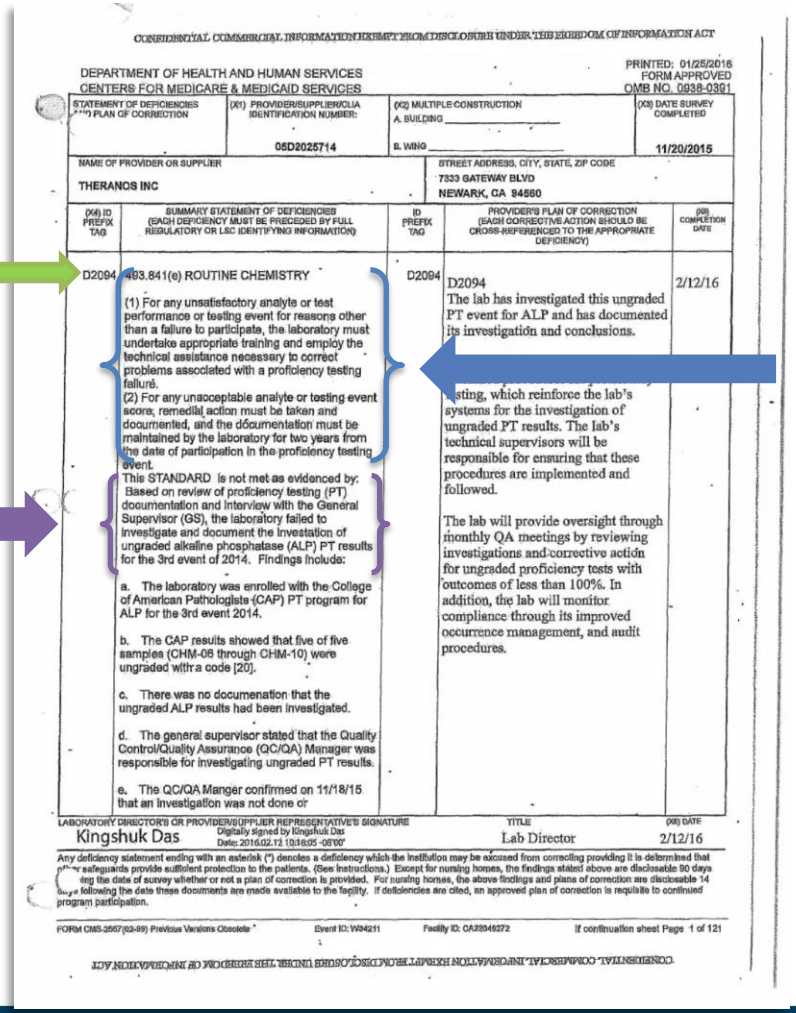
THE REPORT

CMS 2567

D-TAG

Deficient Practice Statement

CFR and Regulatory Language



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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.

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

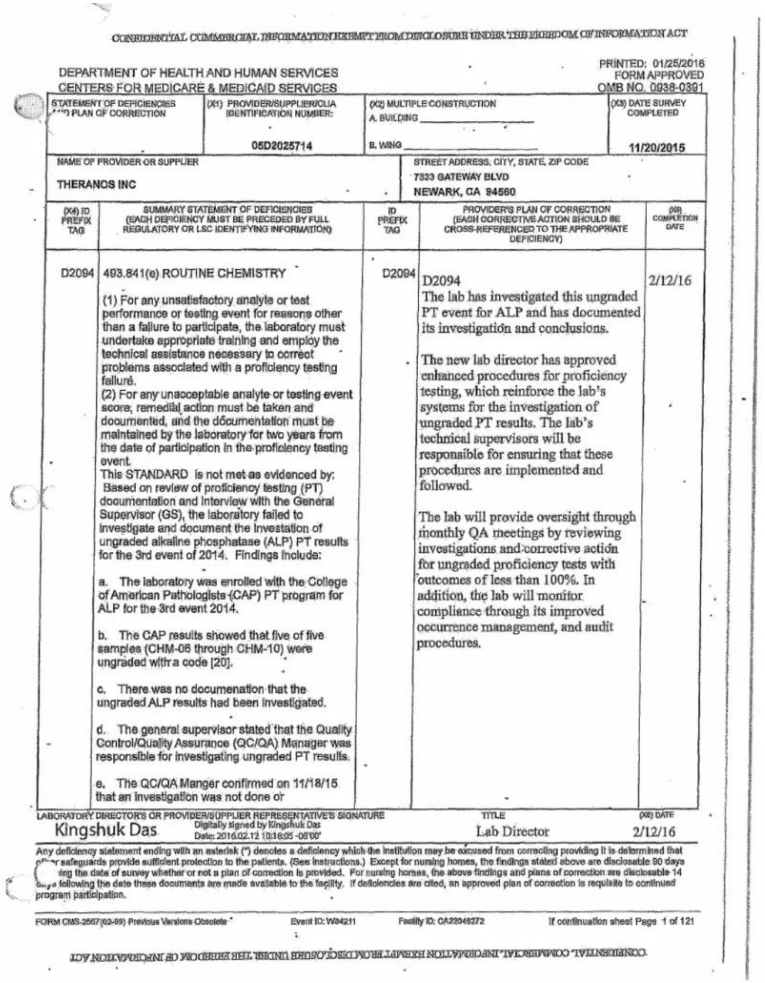
PLAN OF CORRECTION (PoC)
ALLEGATION OF COMPLIANCE (AoC)

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
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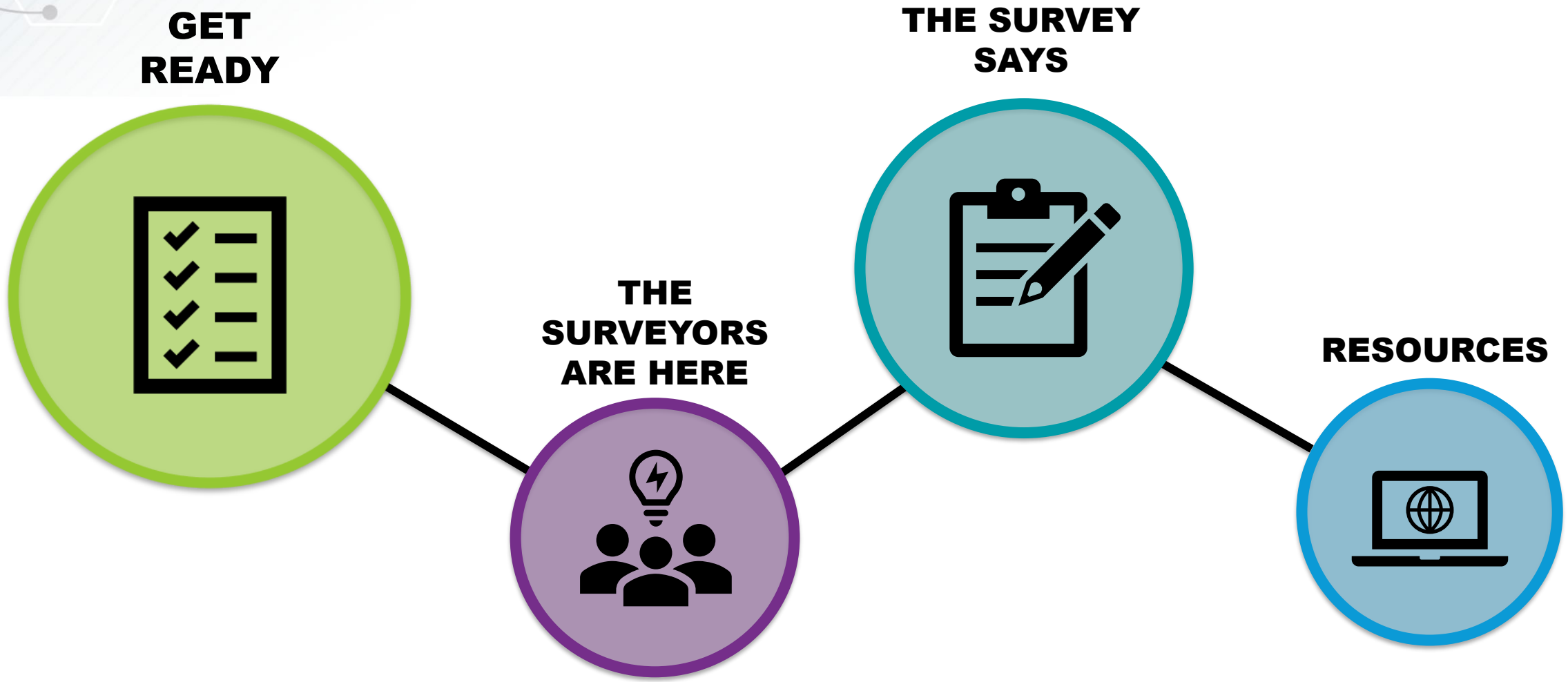
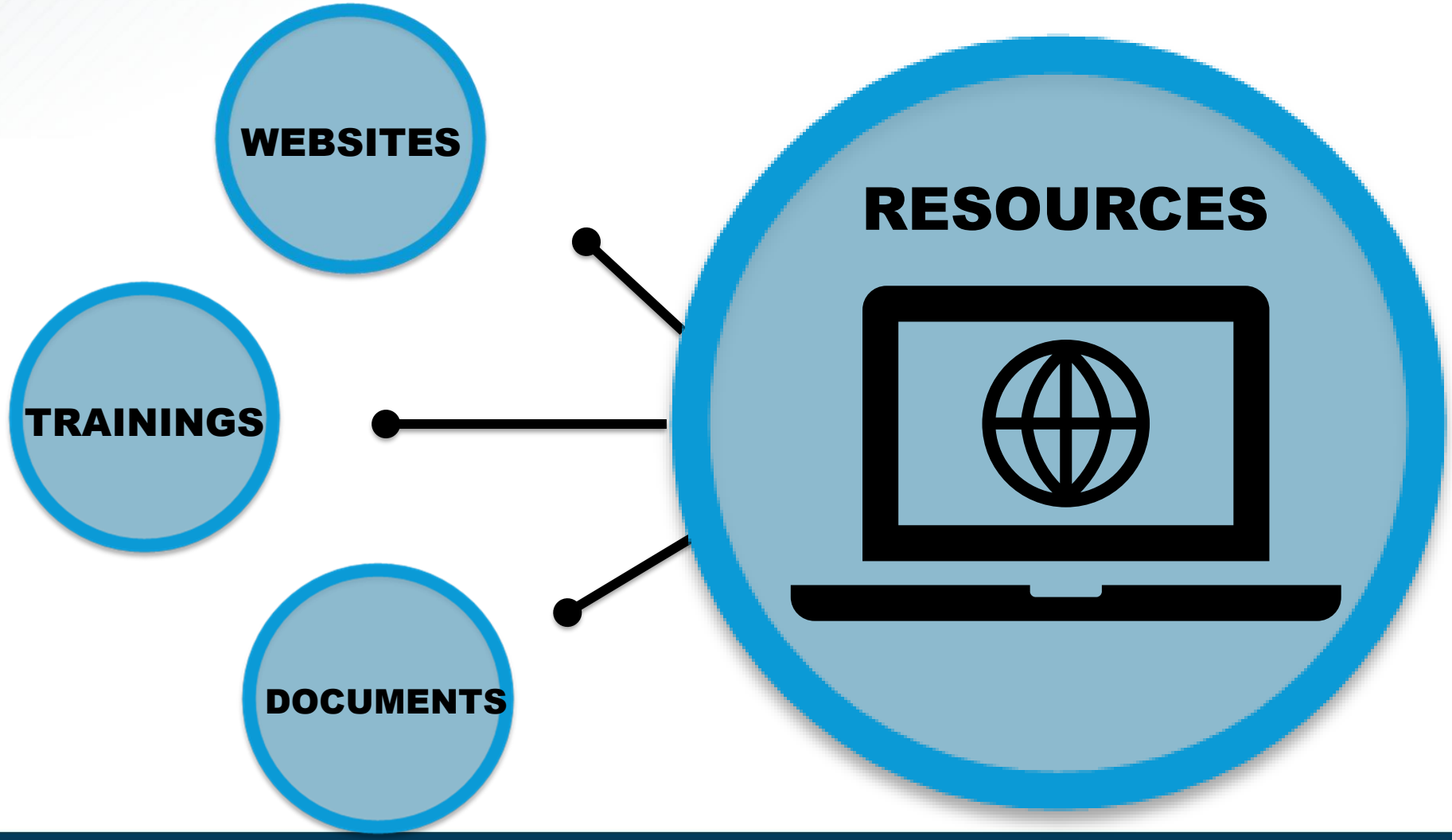
THE PROCESS OF SURVEYING



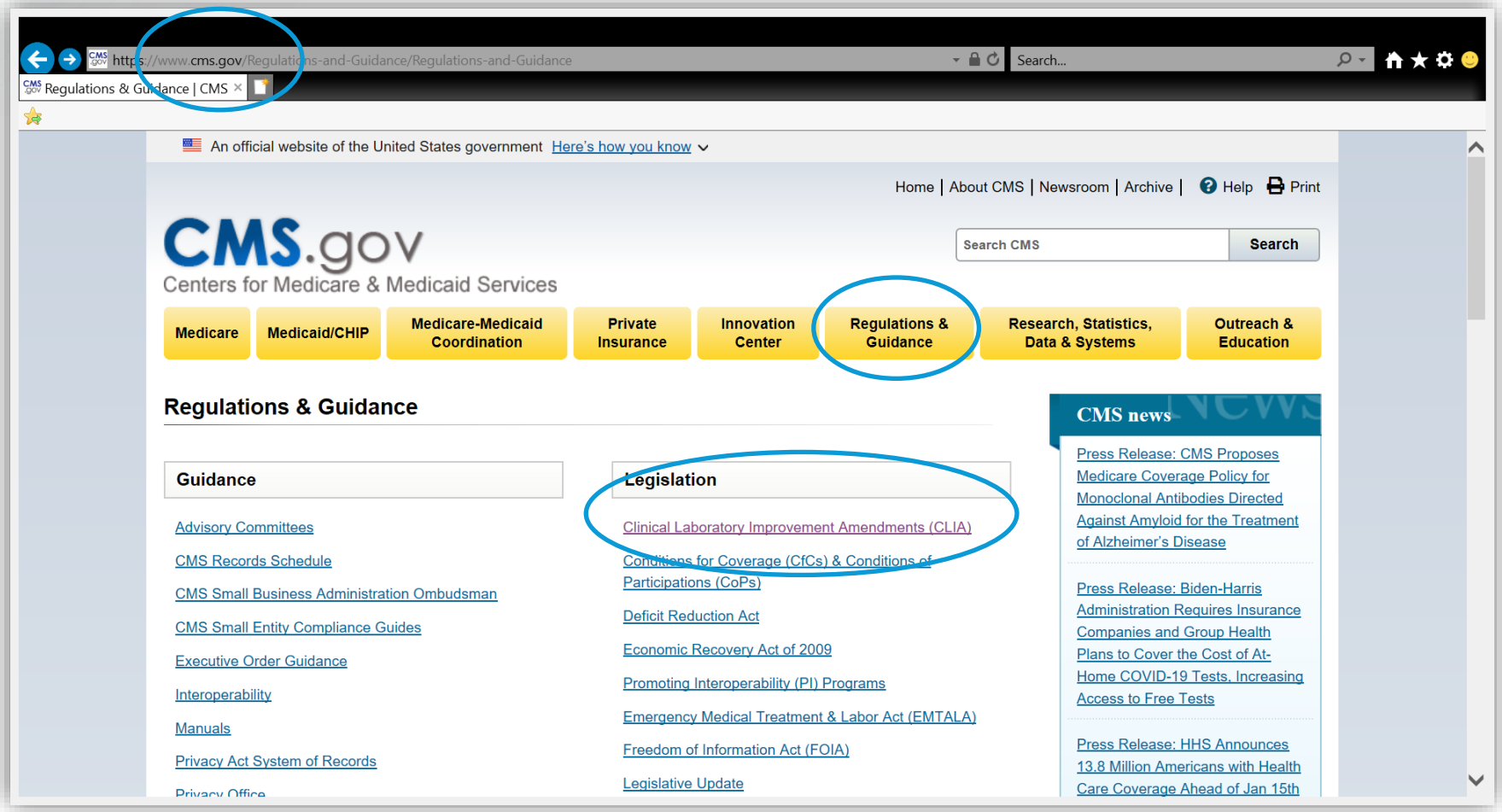
THE PROCESS OF SURVEYING



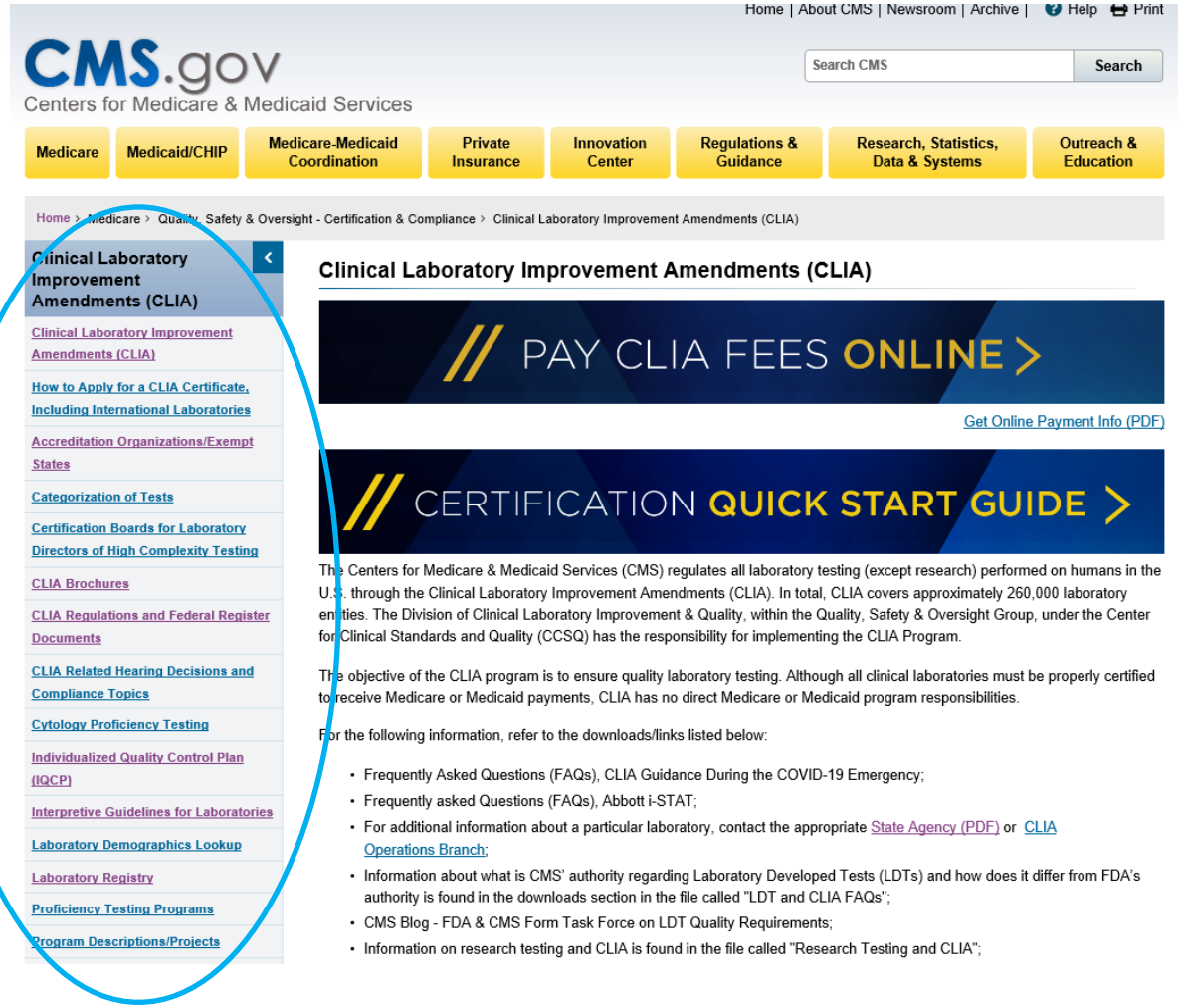
WEBSITES, TRAININGS, AND DOCUMENTS

POLL QUESTION #4

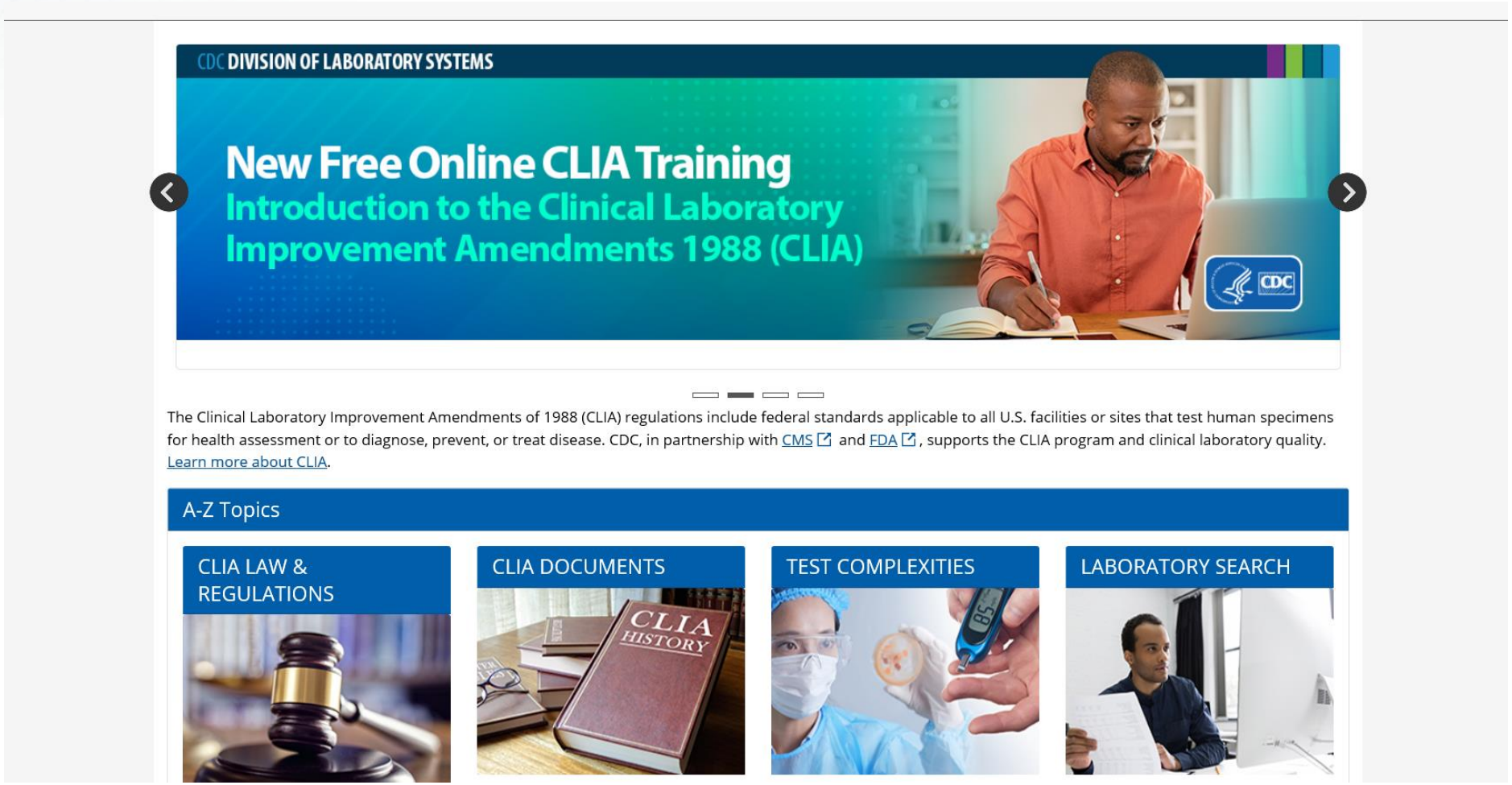
WEBSITES, TRAININGS, AND DOCUMENTS



WEBSITES, TRAININGS, AND DOCUMENTS



WEBSITES, TRAININGS, AND DOCUMENTS

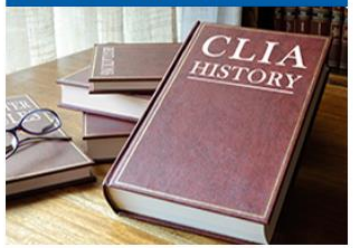


WEBSITES, TRAININGS, AND DOCUMENTS

A-Z Topics

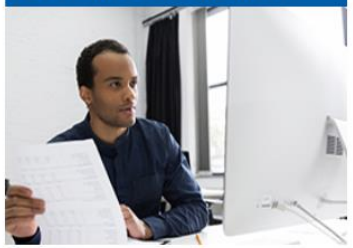
CLIA LAW & REGULATIONS

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).

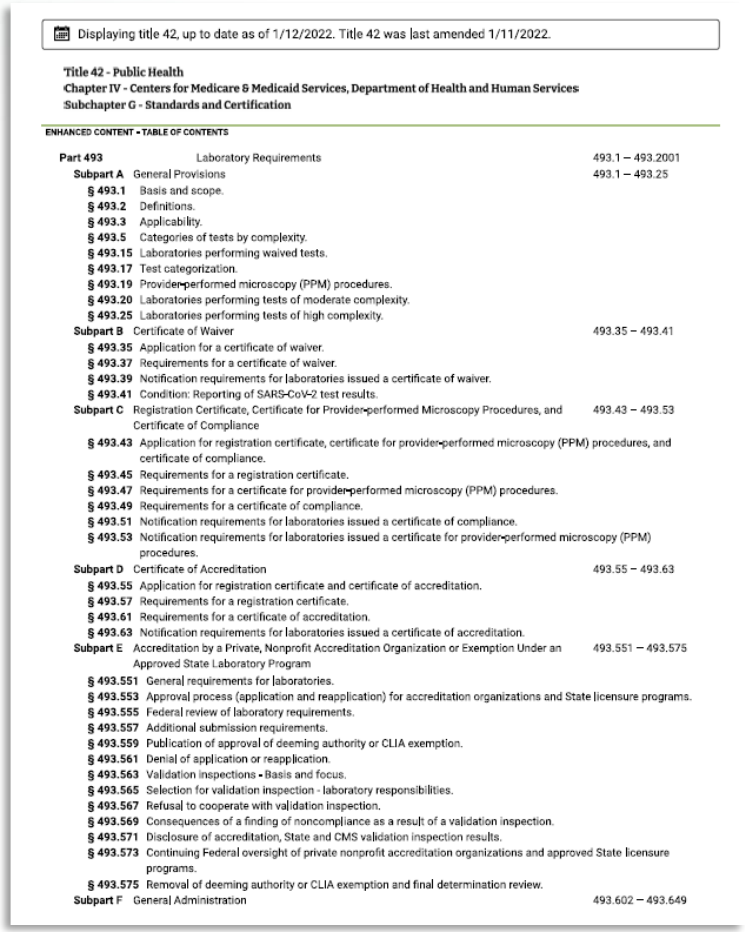
Get Answers to CLIA Related Questions

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.

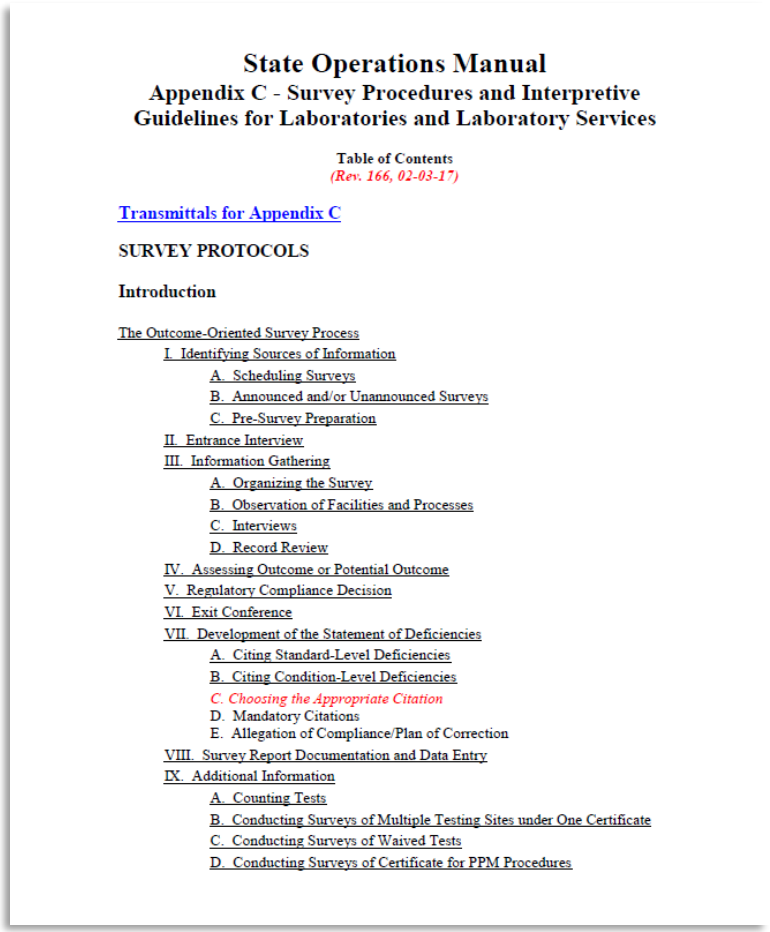
WEBSITES, TRAININGS, AND DOCUMENTS



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



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

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(Rev. 166, 02-03-17)

WEBSITES, TRAININGS, AND DOCUMENTS

CLIA REGULATIONS eCFR :: 42 CFR Part 493 -- Laboratory Requirements

CLIA INTERPRETIVE GUIDELINES SOM- Appendix C (cms.gov)

CMS CLIA WEBSITE Clinical Laboratory Improvement Amendments (CLIA) | CMS

CDC CLIA WEBSITE Clinical Laboratory Improvement Amendments (CLIA) | CDC

INTRODUCTION TO CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) - WB4497 - CDC TRAIN - an affiliate of the TRAIN Learning Network powered by the Public Health Foundation

STATE SURVEY AGENCIES (CLIA CONTACT LIST) (cms.gov)

CMS OPERATIONS BRANCH (CLIA CONTACT LIST)

CMS 116 LabExcellence@cms.hhs.gov CMS 209

THANK YOU

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

Marranda Scott (404)498-4552 or juz2@cdc.gov

Use of trade names is for identification only and does not imply endorsement by U.S. Centers for Disease Control and Prevention.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of Centers for Disease Control and Prevention.