WISCONSIN DEPARTMENT of HEALTH SERVICES

Clinical Laboratory Improvement Amendments (CLIA) Laboratory Provider Forum

Laboratory Survey Preparation and Process Part II

State of Wisconsin
CLIA Team

January 24, 2024

Welcome

Angela K. Mack, MLS(ASCP)
Licensing, Certification, and CLIA Section Manager
Division of Quality Assurance | Bureau of Health Services

Joann E. Amend, MSHA, MLS(ASCP)
Laboratory Certification Officer
Division of Quality Assurance | Bureau of Health Services

Tracy Moraine, MLS(ASCP)
Laboratory Certification Officer
Division of Quality Assurance | Bureau of Health Services

Anita Iwanski, MBA, MLS(ASCP)
Laboratory Certification Officer
Division of Quality Assurance | Bureau of Health Services

Ann Hansen
Bureau of Health Services Director
Division of Quality Assurance | Bureau of Health Services

Objectives

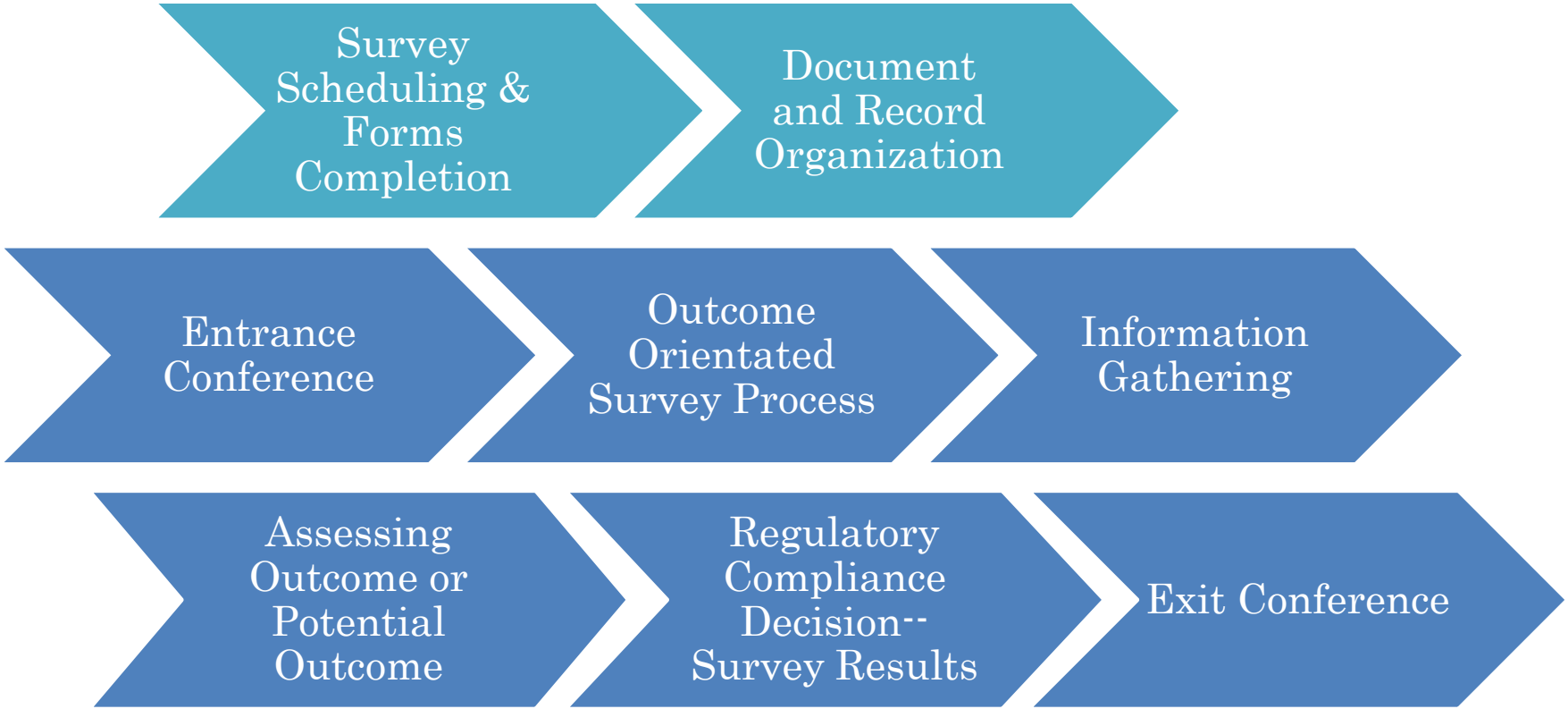
- Provide information so laboratories are well prepared and ready for a CLIA survey.
  - Review of CMS-2567 Statement of Deficiencies (SOD) and Response Requirements including Plan of Correction (POC) or Allegation of Compliance (AOC) and discuss Commonly Cited Deficiencies.
  - Provide an overview of Proficiency Testing (PT), PT Referral, and CLIA PT Changes.
  - Explain Competency Assessment and New Test Performance Verification Requirements.

Disclaimer: The information presented in this CLIA Provider Forum is for educational purposes only. Refer to Standards and Certification: Laboratory Requirements (42 CFR 493) for official CLIA Regulations.

To Ask a Question

- Click the Q&A button
- Type your question in the Q&A box and Submit
- Please DO NOT submit questions using the Chat Button

CLIA Survey Preparation and Process Summary



DHS Survey Guide for Clinical Laboratories

Survey Results

Tracy Moraine, Laboratory Certification Officer

Survey Results

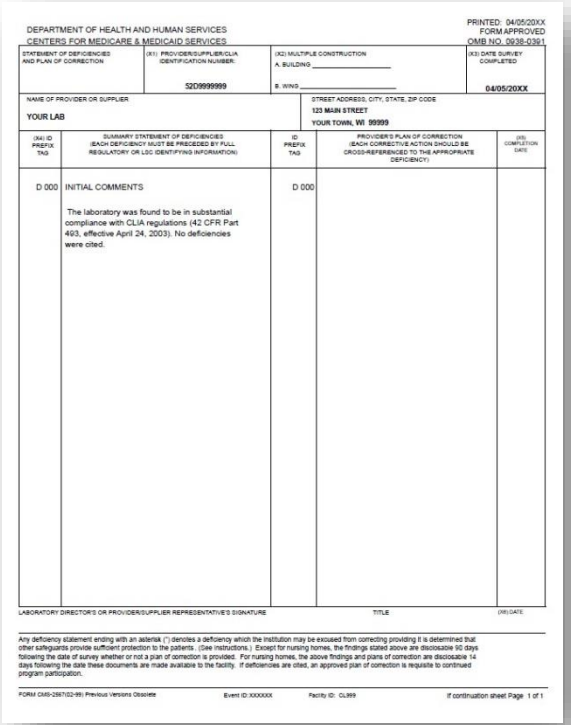
CMS-2567 Statement of Deficiencies (SOD)

No Deficiencies Cited

Electronic Plan of Correction (POC) Provider Agreement Form

The Exit Conference is an opportunity for the lab to present additional information in response to the survey findings.

Survey Results (cont.)
CMS-2567 SOD—No Deficiencies



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

PRINTED: 04/05/20XX
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
	52D9999999	A. BUILDING _____ B. WING _____	04/05/20XX

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
YOUR LAB	123 MAIN STREET YOUR TOWN, WI 99999

(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
D 000	INITIAL COMMENTS The laboratory was found to be in substantial compliance with CLIA regulations (42 CFR Part 493, effective April 24, 2003). No deficiencies were cited.	D 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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: XXXXXX Facility ID: CL999 If continuation sheet Page 1 of 1

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)
D 000	INITIAL COMMENTS The laboratory was found to be in substantial compliance with CLIA regulations (42 CFR Part 493, effective April 24, 2003). No deficiencies were cited.

Lab Director's or Representative's Signature

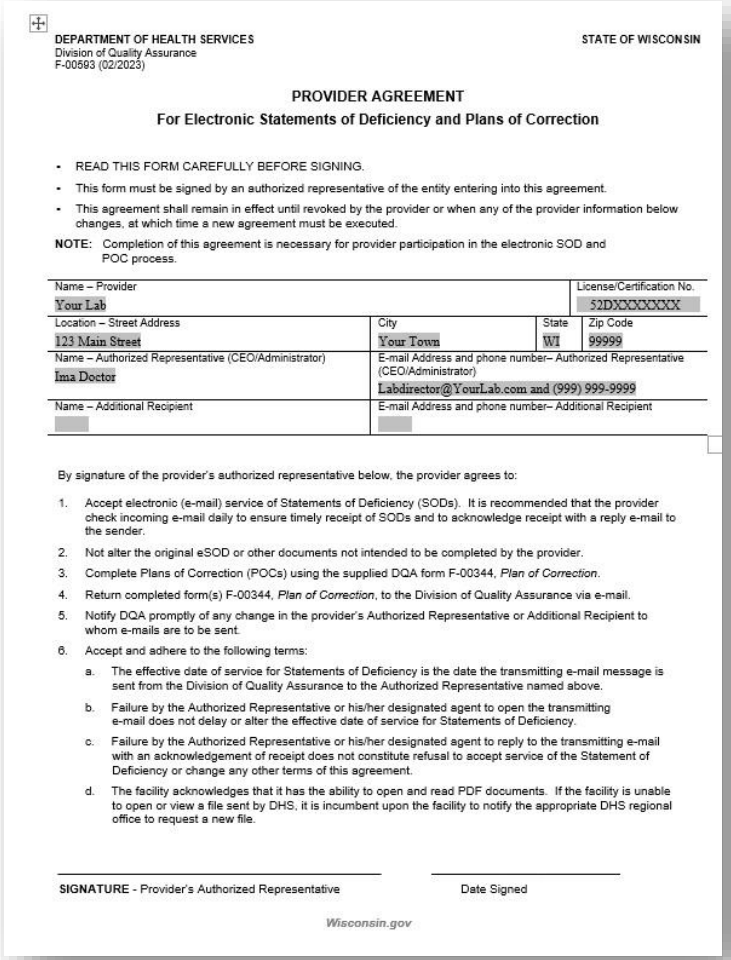
Survey Results (cont.)
No Deficiencies—Laboratory is Compliant

Confirmation Letter

Survey Results (cont.)
Deficiencies Present

- Types of Deficiencies
  - Standard Level
  - Condition Level
- Immediate Jeopardy Consideration
  - Non-Compliance
  - Injury, Harm, Impairment or Death
  - Need for Immediate Action

Survey Results (cont.) Electronic POC Provider Agreement



DEPARTMENT OF HEALTH SERVICES
Division of Quality Assurance
F-00593 (02/2023)

STATE OF WISCONSIN

PROVIDER AGREEMENT
For Electronic Statements of Deficiency and Plans of Correction

- READ THIS FORM CAREFULLY BEFORE SIGNING.
- This form must be signed by an authorized representative of the entity entering into this agreement.
- This agreement shall remain in effect until revoked by the provider or when any of the provider information below changes, at which time a new agreement must be executed.

NOTE: Completion of this agreement is necessary for provider participation in the electronic SOD and POC process.

Name – Provider			License/Certification No.
Your Lab			52DXXXXXXX
Location – Street Address	City	State	Zip Code
123 Main Street	Your Town	WI	99999
Name – Authorized Representative (CEO/Administrator)	E-mail Address and phone number– Authorized Representative (CEO/Administrator)		
Ima Doctor	Labdirector@YourLab.com and (999) 999-9999		
Name – Additional Recipient	E-mail Address and phone number– Additional Recipient		

By signature of the provider's authorized representative below, the provider agrees to:

1. Accept electronic (e-mail) service of Statements of Deficiency (SODs). It is recommended that the provider check incoming e-mail daily to ensure timely receipt of SODs and to acknowledge receipt with a reply e-mail to the sender.
2. Not alter the original eSOD or other documents not intended to be completed by the provider.
3. Complete Plans of Correction (POCs) using the supplied DQA form F-00344, *Plan of Correction*.
4. Return completed form(s) F-00344, *Plan of Correction*, to the Division of Quality Assurance via e-mail.
5. Notify DQA promptly of any change in the provider's Authorized Representative or Additional Recipient to whom e-mails are to be sent.
6. Accept and adhere to the following terms:
   a. The effective date of service for Statements of Deficiency is the date the transmitting e-mail message is sent from the Division of Quality Assurance to the Authorized Representative named above.
   b. Failure by the Authorized Representative or his/her designated agent to open the transmitting e-mail does not delay or alter the effective date of service for Statements of Deficiency.
   c. Failure by the Authorized Representative or his/her designated agent to reply to the transmitting e-mail with an acknowledgement of receipt does not constitute refusal to accept service of the Statement of Deficiency or change any other terms of this agreement.
   d. The facility acknowledges that it has the ability to open and read PDF documents. If the facility is unable to open or view a file sent by DHS, it is incumbent upon the facility to notify the appropriate DHS regional office to request a new file.

SIGNATURE - Provider's Authorized Representative _____ Date Signed _____

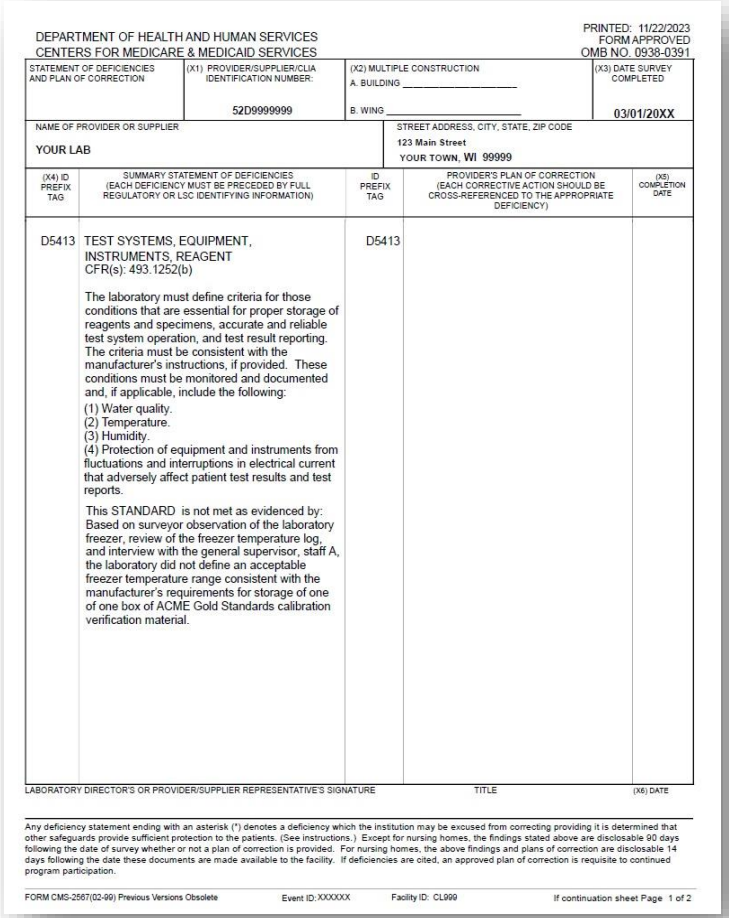
Wisconsin.gov

Deficiencies Present (cont.)
Laboratory is Non-Compliant

- CMS-2567 Statement of Deficiencies (SOD)
- Letter to Request Plan of Correction (POC) or Allegation of Compliance (AOC)
- Personnel Identifier Form
- Plan of Correction (POC) Form

All correspondence sent securely via email with attachments.

CMS-2567 Statement of Deficiencies



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

PRINTED: 11/22/2023
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
	52D9999999	A. BUILDING _____ B. WING _____	03/01/20XX

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
YOUR LAB	123 Main Street YOUR TOWN, WI 99999

(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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory freezer, review of the freezer temperature log, and interview with the general supervisor, staff A, the laboratory did not define an acceptable freezer temperature range consistent with the manufacturer's requirements for storage of one of one box of ACME Gold Standards calibration verification material.	D5413		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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: XXXXXX Facility ID: CL999 If continuation sheet Page 1 of 2

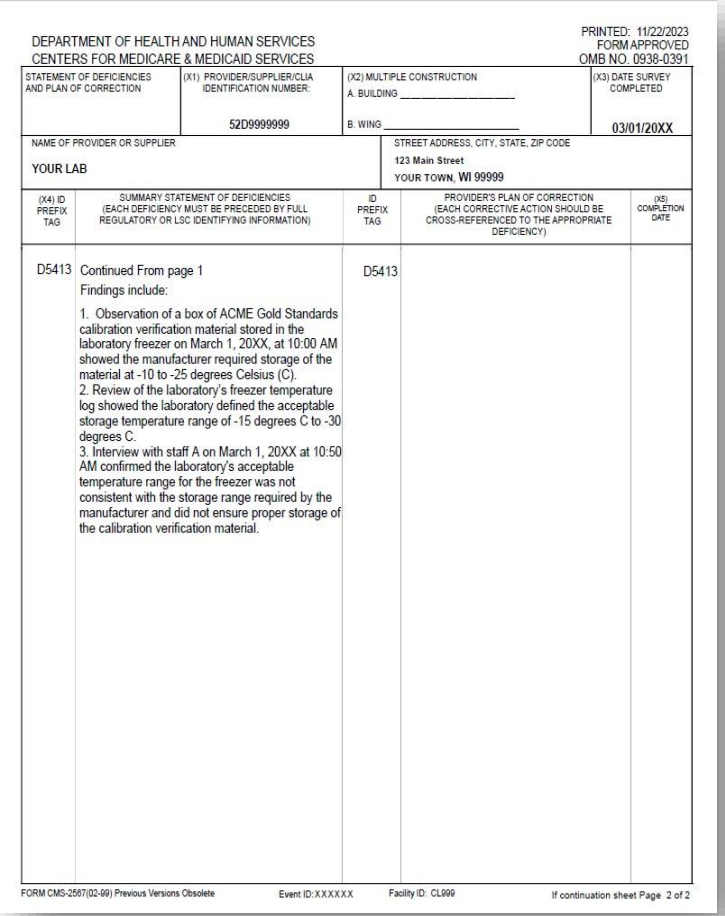
D-Tag

Code of Federal Regulations (CFR) Reference

Deficient Practice Statement

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory freezer, review of the freezer temperature log, and interview with the general supervisor, staff A, the laboratory did not define an acceptable freezer temperature range consistent with the manufacturer's requirements for storage of one of one box of ACME Gold Standards calibration verification material.

CMS-2567 Statement of Deficiencies (cont.)



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

PRINTED: 11/22/2023
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
	52D9999999	A. BUILDING _____ B. WING _____	03/01/20XX

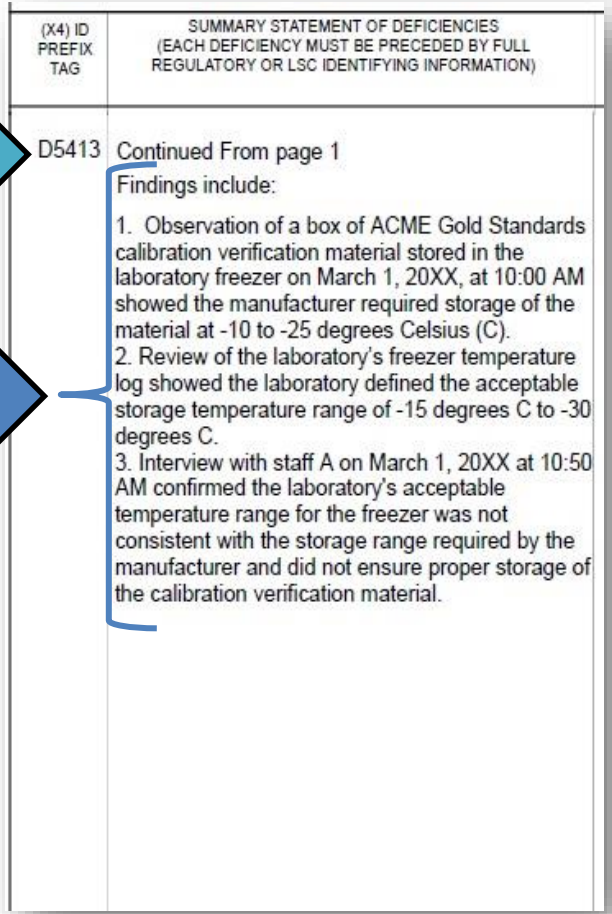
NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
YOUR LAB	123 Main Street YOUR TOWN, WI 99999

(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
D5413	Continued From page 1 Findings include: 1. Observation of a box of ACME Gold Standards calibration verification material stored in the laboratory freezer on March 1, 20XX, at 10:00 AM showed the manufacturer required storage of the material at -10 to -25 degrees Celsius (C). 2. Review of the laboratory's freezer temperature log showed the laboratory defined the acceptable storage temperature range of -15 degrees C to -30 degrees C. 3. Interview with staff A on March 1, 20XX at 10:50 AM confirmed the laboratory's acceptable temperature range for the freezer was not consistent with the storage range required by the manufacturer and did not ensure proper storage of the calibration verification material.	D5413		

FORM CMS-2567(02-99) Previous Versions Obsolete Event ID: XXXXXX Facility ID: CL999 If continuation sheet Page 2 of 2

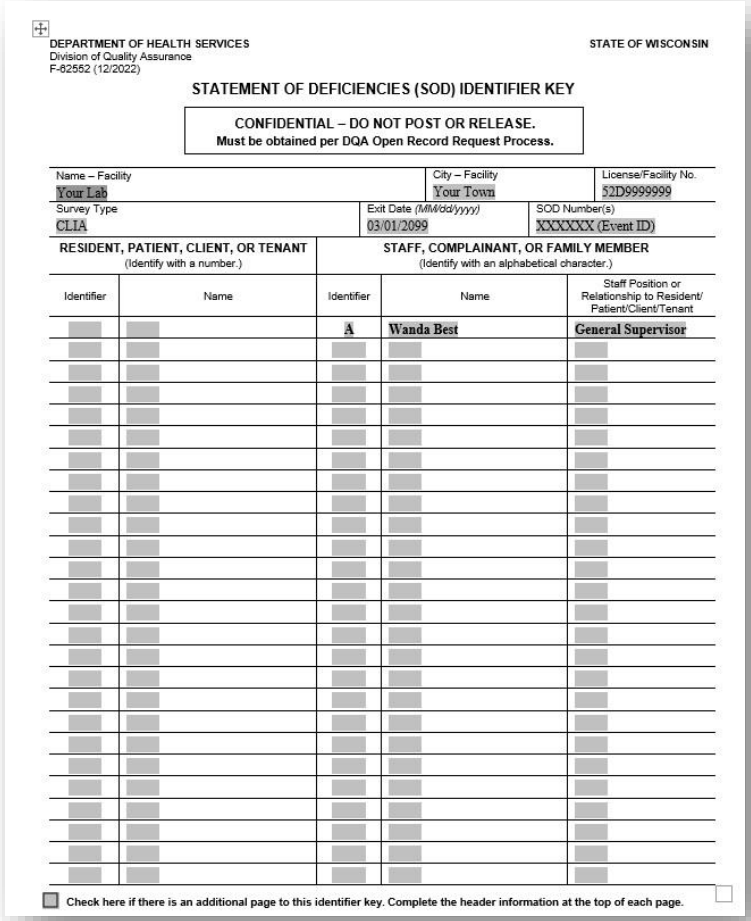
D-Tag

Findings



(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)
D5413	Continued From page 1 Findings include: 1. Observation of a box of ACME Gold Standards calibration verification material stored in the laboratory freezer on March 1, 20XX, at 10:00 AM showed the manufacturer required storage of the material at -10 to -25 degrees Celsius (C). 2. Review of the laboratory's freezer temperature log showed the laboratory defined the acceptable storage temperature range of -15 degrees C to -30 degrees C. 3. Interview with staff A on March 1, 20XX at 10:50 AM confirmed the laboratory's acceptable temperature range for the freezer was not consistent with the storage range required by the manufacturer and did not ensure proper storage of the calibration verification material.

Personnel Identifier Form



DEPARTMENT OF HEALTH SERVICES
Division of Quality Assurance
F-62552 (12/2022)

STATE OF WISCONSIN

STATEMENT OF DEFICIENCIES (SOD) IDENTIFIER KEY

CONFIDENTIAL – DO NOT POST OR RELEASE.
Must be obtained per DQA Open Record Request Process.

Name – Facility	City – Facility	License/Facility No.
Your Lab	Your Town	52D9999999

Survey Type	Exit Date *(MM/dd/yyyy)*	SOD Number(s)
CLIA	03/01/2099	XXXXXX (Event ID)

RESIDENT, PATIENT, CLIENT, OR TENANT (Identify with a number.)		STAFF, COMPLAINANT, OR FAMILY MEMBER (Identify with an alphabetical character.)		
Identifier	Name	Identifier	Name	Staff Position or Relationship to Resident/ Patient/Client/Tenant
		A	Wanda Best	General Supervisor

☐ Check here if there is an additional page to this identifier key. Complete the header information at the top of each page.

Letter to Request Plan of Correction (POC) or Allegation of Compliance (AOC)

Four Points to Address in POC or AOC:

1. Who (by position title) will be responsible for the plan of correction?
2. Exactly what will be done to correct the deficiency?
3. Has the deficient practice affected or potentially affected any patient results and if so, what corrective actions will be taken for these patients?
4. What systemic changes will you make to ensure that the deficient practice does not recur and how will this be monitored?

Plan of Correction (POC)/Allegation of Compliance (AOC)

DEPARTMENT OF HEALTH SERVICES
Division of Quality Assurance
F-00344 (07/17)

STATE OF WISCONSIN

PLAN OF CORRECTION

The individual signing the first page of the CMS-2567, *Statement of Deficiencies (SOD)*, is indicating their approval of the plan of correction being submitted on this form.

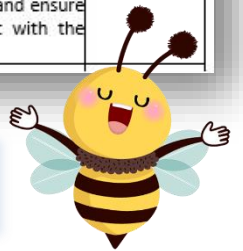
Name - Provider/Supplier:	
Your Lab	
Street Address/City/Zip Code:	
123 Main Street, Your Town, WI 99999	
License/Certification/ID Number (X1):	52D9999999
Survey Date (X3):	03/01/20XX
Survey Event ID Number:	XXXXXX

ID Prefix Tag (X4)	Provider's Plan of Correction (Each corrective action must be cross-referenced to the appropriate deficiency.)	Completion Date (X5)
D5413	**1. Who (by position title) will be responsible for the plan of correction?** General Supervisor **2. Exactly what will be done to correct the deficiency?** The manufacturer's storage requirements for all products stored in the laboratory freezer will be reviewed. A freezer temperature range that is consistent with the manufacturers' storage requirements for all products stored in this freezer will be defined. **3. Has the deficient practice affected or potentially affected any patient results and if so, what corrective actions will be taken for these patients?** No, the deficient practice did not affect any patient results as actual laboratory freezer temperatures were within the manufacturer's required temperature range for the ACME Gold calibration verification material. **4. What systemic changes will you make to ensure that the deficient practice does not recur and how will this be monitored?** • Similar reviews of manufacturer's storage requirements will be done for all products stored in the laboratory's refrigerators. Defined temperature ranges for each unit will be adjusted as needed to be consistent with manufacturers' storage requirements for all products stored in the unit. • The General Supervisor will review storage requirements for new laboratory products requiring refrigerator or freezer storage and ensure that the required storage temperature range is consistent with the defined temperature range for the refrigerator or freezer.	03/02/20XX

D-Tag

Completion Date

ID Prefix Tag (X4)	Provider's Plan of Correction (Each corrective action must be cross-referenced to the appropriate deficiency.)	Completion Date (X5)
D5413	**1. Who (by position title) will be responsible for the plan of correction?** General Supervisor **2. Exactly what will be done to correct the deficiency?** The manufacturer's storage requirements for all products stored in the laboratory freezer will be reviewed. A freezer temperature range that is consistent with the manufacturers' storage requirements for all products stored in this freezer will be defined. **3. Has the deficient practice affected or potentially affected any patient results and if so, what corrective actions will be taken for these patients?** No, the deficient practice did not affect any patient results as actual laboratory freezer temperatures were within the manufacturer's required temperature range for the ACME Gold calibration verification material. **4. What systemic changes will you make to ensure that the deficient practice does not recur and how will this be monitored?** • Similar reviews of manufacturer's storage requirements will be done for all products stored in the laboratory's refrigerators. Defined temperature ranges for each unit will be adjusted as needed to be consistent with manufacturers' storage requirements for all products stored in the unit. • The General Supervisor will review storage requirements for new laboratory products requiring refrigerator or freezer storage and ensure that the required storage temperature range is consistent with the defined temperature range for the refrigerator or freezer.	03/02/20XX



The POC/AOC is the lab's opportunity to demonstrate their commitment to providing quality lab services through their efforts in becoming and maintaining CLIA compliance.

Laboratory's Expected Response

- Acknowledge receipt of email and attachments.
  - Confirm that you can open all attachments.
  - Contact the surveyor with any questions or concerns.
- Within 10 calendar days, return the following:
  - CMS-2567 SOD signed and dated by the Laboratory Director.
  - POC/AOC with responses to all 4 questions for each deficiency.
  - For AOCs, must include documentation of corrective action.

Surveyor's Review of POC/AOC

- Acknowledge receipt of POC/AOC.
- Evaluate POC/AOC and corrective action documentation for AOC.
- Accept or reject POC/AOC.
  - If accepted, send letter confirming laboratory's compliance.
  - If rejected, provide analysis of rejected response(s). Send new CMS-2567 SOD, letter requesting POC/AOC, and POC Form to complete.
    - The laboratory has 10 calendar day to respond and should follow steps in "Laboratory's Expected Response."

If the initial POC/AOC is rejected, please submit the new CMS-2567 (signed and dated) and POC Form. It is acceptable to cut and paste from the initial POC Form.

Common Deficiencies

Common Deficiencies

- Procedure Manuals--including IQCPs
- Retention Requirements
- Personnel Qualifications and Responsibilities
- Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies
- Quality Assessment and Corrective Action
- Proficiency Testing

Common Deficiencies (cont.)

Procedure Manuals--including IQCPs

- Control Procedures
- Step-by-Step Directions
- Initiation and Discontinuation Dates
- Lab Director Approval
- IQCPs

Retention Requirements

- Records for Discontinued Methods
- Verification Records
- Reagent Records
- Maintenance Records

Common Deficiencies (cont.)

Personnel Qualifications and Responsibilities

- Lab Director
- Technical Consultant/Supervisor
- Testing Personnel

Test Systems, Equipment, Instruments, Reagents, Materials and Supplies

- Calibration and Calibration Verification
- Maintenance and Function Checks
- Environmental Monitoring

Common Deficiencies (cont.)

Quality Assessment and Corrective Action

- Having a Plan
- Documenting Corrective Action for Problem Resolution

Proficiency Testing

- Pt Referral and Communication
- Signatures
- Review of Unacceptable and Not Scored/Non-Consensus Results
- Twice Annual Accuracy

Proficiency Testing

Joann Amend, Laboratory Certification Officer

Proficiency Testing

See § 493 Subpart H, § 493 Subpart I and § 493.1236 for Details

- **What is Proficiency Testing (PT)?**
  - The testing of unknown samples sent by an HHS-approved PT program.
  - Required for regulated, non-waived analytes.
  - The PT program grades the results using the CLIA grading criteria and sends the scores back to the lab.
  - CMS (State Agency) and accreditation organizations routinely monitor their labs' PT performance for regulated analytes.

✓ *Can't assay PT samples on two analyzers or methods.*
✓ *Some PT programs offer verification samples.*

Proficiency Testing (cont.)

- **Are there CLIA requirements for non-regulated analytes?**
  - Yes, accuracy must be verified for these methods twice a year.
- **How can accuracy be verified for non-regulated analytes?**
  - Enroll in a PT program that offers samples for the analyte.
  - Split patient samples with a peer lab.
  - Re-test previously tested samples.

Lab needs to establish acceptability criteria for non-regulated analytes and evaluate against these established criteria.

Proficiency Testing (cont.)

- **What PT records do I need to maintain?***
  - Proficiency Testing Instructions
  - Instrument Testing Records & Printouts
  - PT Program Results Forms
    - If results submitted electronically, print out a record of the submitted results.
  - Attestation Statements
  - PT program Evaluation of Survey Results
  - Documentation of Survey Result Review and Corrective Action as needed

**Records must be maintained for a minimum of 2 years from the date of the PT survey.*

Proficiency Testing (cont.)

- **What are surveyors looking for when reviewing PT records?**
  - Enrollment in PT for all regulated, non-waived analytes
  - Wet or electronic attestation signatures of the laboratory director/designee and testing personnel
  - Documented review and sign-off of survey results in both formats
  - PT samples tested like patient samples
    - For example: same number of runs, primary testing method, clerical process
  - PT testing rotated among all testing personnel

Proficiency Testing (cont.)

- **What steps should I take when I receive PT results?**
  - Review PT results with testing personnel and lab director.
  - Evaluate PT results against scores published by the PT program.
  - Investigate any unacceptable/unsatisfactory PT results—even those with passing event scores.
  - Document review and any investigation and/or corrective action taken.

Look for bias in results. Document and follow-up even if results are acceptable.

Proficiency Testing (cont.)

- **What about Not scored/Not graded including non-consensus or educational challenges?**
  - These scores may indicate that the lab scored 100% and passed. Lab needs to take a closer look and review all not scored results.
  - Compare/calculate with expected results provided by PT provider.
  - Evaluate and follow-up as necessary if lab review shows results to be unacceptable.

Don't forget to look at ungraded results.

Proficiency Testing (cont.)

- **What must I do if I get an unsatisfactory/unacceptable score for an analyte?**
  - Review submitted results and check for clerical and transcription errors.
  - Compare PT results with the inter-laboratory comparison evaluations that are provided by the PT provider.
  - Investigate the cause of the error(s), take corrective action, document the investigation and steps taken.
  - Review patient results reported when PT was unacceptable. If patient results were affected or potentially affected, address the patient results and document actions taken.

Proficiency Testing (cont.)

- **What does unsuccessful performance in PT mean?**
  - Unacceptable/unsatisfactory results for an analyte, specialty or subspecialty in two consecutive or two out of three PT events
  - Mandatory condition level deficiency

Analyte #	Current Program #	------- 2020 ------- Event 1 Score	Event 2 Score	Event 3 Score	------- Event 1 Score
0245 ROUTINE CHEMISTRY	9	100	100	96	0*
	9	100	100	100	0*
0345 CA, TOTAL	9	100	100	100	0*
0355 CL	9	100	100	100	0*
0365 CHOLESTEROL, TOTAL	9	100	100	100	0*
0375 CHOLESTEROL, HDL	9	100	100	100	0*
0495 TRIGL	9	100	100	60*	0*
0505 BUN	9	100	100	100	0*
0515 URIC ACID	9	100	100	100	0*

* Unsatisfactory Scores

✓ *Review unacceptable PT result follow-up. Why didn't the corrective action work the first time?*

Proficiency Testing (cont.)

- **What does "subsequent" unsuccessful performance in PT mean?**
  - A repeat of unsucessful PT performance
  - For subsequent unsuccessful PT performance in the same analyte, specialty, or subspecialty— CMS may impose more stringent sanctions including testing limitations and possible cancellation of a laboratory's Medicaid/Medicare payments
  - A lab may voluntarily cease testing prior to CMS imposing sanctions

		-------	2020	-------	-------	2021	-------	-------	2022	-------
Analyte #	Current Program #	Event 1 Score	Event 2 Score	Event 3 Score	Event 1 Score	Event 2 Score	Event 3 Score	Event 1 Score	Event 2 Score	Event 3 Score
0495 TRIGL	9	100	100	60*	0*	100	100	0*	100	40*
0505 BUN	9	100	100	100	0*	100	100	0*	100	100
0515 URIC ACID	9	100	100	100	0*	100	100	0*	100	100

* Unsatisfactory Scores

Proficiency Testing (cont.)

- **How else can I use the PT materials (after PT event cut-off date only)?**
  - Testing personnel competency
  - Calibration verification
  - Training for new hires
  - Accuracy assessment of 2nd analyzer

Proficiency Testing (cont.)

- **What about PT Referral?**
  - PT Referral is when PT samples are sent to another lab for testing.
  - This includes sending a PT sample to another lab even in cases when a patient sample would be forwarded for reflex, confirmatory, or distributive testing.
  - PT Referral applies to any PT sample regardless of whether the analyte is regulated, non-regulated, or a waived test.
  - PT Referral can result in significant fines and CLIA certificate testing limitations.

Proficiency Testing (cont.)

- **What are best practices for avoiding PT Referral?**
  - Develop a laboratory PT procedure that addresses PT Referral including:
    - Prohibits staff from forwarding PT samples to other laboratories even when they would normally forward a patient specimen for testing.
    - Prevents staff from splitting PT samples with any lab including other labs within the same lab system.
    - Prohibits staff from discussing PT results with another lab prior to the event cut-off date.
    - Addresses staffing situations in which Testing Personnel may have the opportunity to test the same PT event samples for multiple labs.
      - This includes staff that work at multiple lab sites within the lab system or have a second job at an external lab.

Proficiency Testing (cont.)

- **What should I do if I receive PT samples from another lab for testing?**
  - Immediately notify your inspecting agency (accreditation organization or State Agency) that you have received PT samples from another lab.
  - Tell the inspecting agency the name of the other lab and the test(s) requested.
  - **Do not** test the samples.

Proficiency Testing (cont.)

- **What about PT Changes?**
  - Current requirements for moderate and high complexity testing labs that also perform waived testing:
    - Not required to enroll in PT for waived tests
    - Are held to requirements for testing of PT samples if enrolled for waived tests
    - Can be subject to PT referral for waived testing PT
  - Changes seen with enrollment in 2025 PT
    - Overall, an increase in regulated analytes
    - Changes to grading and determination of acceptable performance
  - For details, see CLIA Proficiency Testing - Analytes and Acceptable Performance Final Rule (QSO-22-21-CLIA).

Competency Assessment

Competency Assessment

See § 493.1235, § 493.1413(b)(8) & (b)(9) (moderate complexity) and § 493.1451(b)(8) &(b)(9) (high complexity) for Details

Six Required Procedures for Competency Assessment of Testing Personnel
1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing
2. Monitoring the recording and reporting of test results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observations of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
6. Assessment of problem solving skills

Competency Assessment (cont.)

- **Who is required to have a competency assessment?**
  - All Testing Personnel (TP), including Clinical Consultants (CC),Technical Consultants (TC),Technical Supervisors (TS), and General Supervisors (GS) who perform testing on patient specimens are required to have the six required procedures in their competency assessment.
  - CCs, TCs, TSs, and GSs are required to have their competency assessed based on their federal regulatory responsibilities.

Competency Assessment (cont.)

- **Who is responsible for performing the competency assessment of Testing Personnel?**
  - For Moderate Complexity Testing
    - The Technical Consultant (TC) or other personnel who meet the regulatory qualification requirements for a TC for moderate complexity testing.
  - For High Complexity Testing
    - The Technical Supervisor (TS) but annual competency can be delegated to the General Supervisor (GS) in writing if the GS meets the regulatory qualifications as a GS for high complexity testing.

✓ *Peer testing personnel who meet the regulatory qualification of a TC, TS, or GS, can be designated to perform competency assessments.*

✓ *The Laboratory Director is ultimately responsible to ensure that all testing personnel are competent.*

Competency Assessment (cont.)

- **How often should competency assessment be performed?**
  - At least semiannually during the first year the individual tests patient specimens
  - At least annually after the individual's first year of testing patient specimens
  - When test methodology or instrumentation changes, an individual's competency must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

Competency assessment can be done throughout the entire year by coordinating it with routine practices and procedures to minimize impact on workload.

Competency Assessment (cont.)

- **What are the competency assessment requirements for testing personnel that work at multiple lab locations?**
  - When testing personnel are new to a laboratory site (different CLIA number) but not the laboratory system, their competency must be assessed semiannually the first year at the new laboratory site.
  - Even though test methodology or instrumentation may be the same at the lab sites, Direct Observation (DO) competency assessment procedures must be performed annually at each lab site.

Consider having staff collect and document their own relevant competency assessment records.

Competency Assessment (cont.)

- **May I combine for competency purposes, all tests performed simultaneously on the same testing platform?**
  - Yes, procedures associated with any test on the testing platform and all tests performed simultaneously on the same testing platform may be combined.
  - Any test with unique aspects, problems or procedures within the same testing platform should be assessed separately to ensure that staff maintain their competency to report test results promptly, accurately and proficiently.

Don't forget to perform competency assessment of special specimen handling such as pre-treatment steps or dilution of specimens.

Competency Assessment (cont.)

- **May I use training and personnel evaluations to assess competency?**
  - No, training and personnel evaluation are not the same as competency assessment.
  - Competency is the application of the knowledge, skills and behaviors for performance and is developed during training to meet established requirements.
  - Training happens before someone begins testing independently and competency assessment confirms that they are performing the test correctly.*
  - Personnel evaluations evaluate other behaviors and attributes as they relate to the position or job (such as customer service or teamwork).

**When documenting training, make sure to assess the ability to perform testing independently.*

Competency Assessment (cont.)

- **I have personnel in my laboratory that only draw blood and label samples. Does CLIA require that I perform competency assessments on them?**
  - Competency assessment is not required by CLIA for non-testing personnel such as phlebotomists, accessioning personnel, or specimen processors.
  - The Laboratory Director is responsible for the entire testing process and needs to ensure that preparation is done correctly--competency assessment of such non-testing personnel would be considered good laboratory practice and a good quality assurance measure.

Competency assessment of all 6 elements is not required for non-testing personnel or for waived testing.

New Test Performance Verification and Establishment

Tracy Moraine, Laboratory Certification Officer

Verification of Performance Specifications

See § 493.1253 and SOM, App. C § 493.1253 for Details

- Applies to FDA-approved methods
- Verification must be completed and approved by the Laboratory Director or designee prior to reporting patient test results.
- Develop a plan to compare the performance of the test system in your lab to the performance specifications established by the manufacturer.
  - Consider test type—Qualitative vs Quantitative
  - Define the minimum number of specimens to test for each verification study.
  - Define acceptability criteria for each performance characteristic. At minimum, should meet manufacturer's performance specifications.
- Document all verification of performance specification activities.

Verification of Performance Specifications (cont.)

- Performance Characteristics to be verified are:

1. Accuracy – getting the correct result
   - Compare split samples with a verified in-house or reference lab method and/or use reference materials.
   - For qualitative methods, lab must verify that method will correctly identify the presence/absence of the analyte. Specimens of known quantitative value may be used to verify the accuracy of a qualitative test.
2. Precision – getting the same result time after time
   - Consider day-to-day, run-to-run, and within-run precision, as well as Testing Personnel variance if applicable.

It is a good practice to verify that within-run precision is acceptable prior to performing other verification studies.

Verification of Performance Specifications (cont.)

- Performance Characteristics to be verified continued:
  3. Reportable Range
     - Must verify manufacturer's range and may only report patient test results that fall within the verified range.
     - To verify very low or very high samples, use previously reported patient samples, PT samples, QC, or calibration materials.
  4. Reference Interval
     - Manufacturer's range is acceptable if verified as appropriate for the lab's patient population.
  - Other studies as needed depending on the test method
- Determine calibration and control procedures based on verification of performance specifications—May not be less frequent than manufacturer's instructions.

Establishment of Performance Specifications

See § 493.1253 and SOM, App. C § 493.1253 for Details

- Applies to laboratory modified FDA-approved methods and laboratory developed methods (LDTs)
  - Modifications include but are not limited to changes to specimen matrix tested (serum vs plasma vs fluids), specimen handling, dilution protocol, reagents or calibration materials.
  - Note: Modifications of an FDA approved moderate complexity test changes the test to high complexity.
- Prior to reporting patient results, the lab must establish the performance specifications of the method.
  - The Laboratory Director and Clinical Consultant determine and approve that the performance specifications meet the needs of the clients.

Establishment of Performance Specifications (cont.)

- Develop a plan to establish the performance specifications of the test method.
  - Define the minimum number of specimens to test for each study and acceptability criteria for each performance characteristic.
- Performance Characteristics to be established are:
  - Accuracy, Precision, Reportable Range, and Reference Interval
  - Analytical Sensitivity
  - Analytical Specificity--including interfering substances
  - Other performance characteristic required for test performance
- Determine calibration, quality control, maintenance and function check procedures based on established performance characteristics.
- Document all establishment of performance specification activities.

CLIA Resources

Anita Iwanski, Laboratory Certification Officer

CLIA Resources

- CLIA Regulations, CMS Survey Guide, & FDA CLIA Database
  - Standards and Certification: Laboratory Requirements (42 CFR 493)
  - Survey Procedures and Interpretive Guidelines for Laboratories
    - Also know as the State Operations Manual (SOM), Appendix C
    - Interpretive guidelines are listed by the regulation.
  - FDA CLIA Database—Test Complexity Look-up

CLIA Resources

- CLIA Brochures
  - Personnel Competency
  - Proficiency Testing and PT Referral
  - Verification of Performance Specifications
  - Calibration and Calibration Verification
  - Individualized Quality Control Plan (IQCP)
    - IQCP Workbook

CLIA Resources (cont.)

- DHS Survey Guide for Clinical Laboratories
- Association of Public Health Laboratories (APHL) CLIA Resources
  - Clinical Consultant Competency Assessment Form
  - Technical Supervisor Competency Assessment Form
  - General Supervisor Competency Assessment Form
  - How to Write a Lab Quality Manual

APHL recently launched their Learning Center. Sign up for a free account to access on-demand laboratory related training and resources.

CLIA Resources

- Department of Health Services (DHS) CLIA Webpage
  - The "Memos, Publications, & Resources" tab has links to many of the CLIA Survey Resources and additional federal resources.

Just type "CLIA" in the DHS Search box to get to the CLIA pages.

CLIA Educational Resources

- CDC Division of Laboratory Systems (DLS)

- Next Generation Sequencing (NGS) Quality Initiative

CLIA Educational Resources (cont.)

- CDC OneLab™

OneLab™
A Unified Response to Training Needs

CLIA Updates and Correspondence

- DHS GovD CLIA Message
  - Sign up to receive email notices about DQA and CMS CLIA memos, DQA Quarterly Information Updates, and health care policy-related information.
  - Join our email list *Look for the sign-up on the DHS CLIA Webpage.*
- DHS CLIA Mailbox
  - Email for all of your CLIA questions and correspondence.
  - DHSDQACLIA@WI.GOV

Questions and Answers

Angela Mack, LCCS Section Manager

Future Forum

February 21, 2024

12-1:15 pm

- ***Certificate of Waiver (CoW) and Provider Performed Microscopy (PPM)***
  - CLIA Application Updates, Fees & Certificates
  - PPM Overview, Personnel Competency Assessment, and Resources
  - CoW CLIA Requirements, Best Practices & Resources

Thank You!