

# **SURVEY GUIDE**

# **CLINICAL LABORATORIES**

**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)**



**STATE OF WISCONSIN**  
**DEPARTMENT OF HEALTH SERVICES**

Division of Quality Assurance  
Bureau of Health Services

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## DIVISION OF QUALITY ASSURANCE (DQA) CONTACT INFORMATION

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<b>Important Links</b>	
<ul style="list-style-type: none"> <li>• Stay up-to-date with regulatory changes by signing up for DQA Email Subscription Services at: <a href="https://www.dhs.wisconsin.gov/regulations/listserv-signup.htm">https://www.dhs.wisconsin.gov/regulations/listserv-signup.htm</a></li> <li>• Federal Clinical Laboratory Improvement Amendments (CLIA) and Interpretive Guidelines are available at: <a href="https://www.cms.gov/regulations-and-guidance/legislation/clia/index.html">https://www.cms.gov/regulations-and-guidance/legislation/clia/index.html</a></li> <li>• The publication, <i>Survey Guide – Clinical Laboratories</i> (DQA publication P-01227), is available online at: <a href="https://www.dhs.wisconsin.gov/publications/index.htm">https://www.dhs.wisconsin.gov/publications/index.htm</a></li> </ul>	

## **SURVEY GUIDE CLINICAL LABORATORIES**

This survey guide is a general reference for informational purposes. In the event of any conflict between information provided in this guide and the federal legal requirements for clinical laboratories, rely on the applicable legal requirements.

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### **I. INTRODUCTION**

The Division of Quality Assurance (DQA), Bureau of Health Services (BHS) is responsible for conducting announced or unannounced surveys of laboratories in Wisconsin to ensure that federal requirements are met as directed by Centers for Medicare and Medicaid Services (CMS). Types of surveys conducted may be recertification, initial, validation, complaint, federal monitoring, and educational surveys for labs with a certificate of waiver. The following information has been prepared to serve as a guide to the survey process for evaluating laboratories.

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### **II. OVERVIEW OF THE SURVEY PROCESS**

The purpose of the survey is to determine whether the entity meets federal Clinical Laboratory Improvement Amendments (CLIA) regulations. CMS' objective is not only to determine the laboratory's regulatory compliance but to also assist regulated laboratories in improving patient care by emphasizing those aspects of the regulatory provisions that have a direct impact on the laboratory's overall test performance.

Surveys are conducted by CLIA surveyors employed by DQA. State of Wisconsin surveyors perform recertification, initial, and complaint surveys on laboratories holding a Certificate of Compliance (CoC). DQA also performs validation and, when directed by CMS, complaint surveys on laboratories holding a Certificate of Accreditation (CoA). Laboratories holding a Provider Performed Microscopy (PPM) certificate or a Certificate of Waiver (CoW) are not routinely surveyed, but may be for complaint investigations. Under the direction of CMS, DQA performs educational surveys on approximately 2% of the CoW labs each year. On occasion, CMS staff may conduct federal monitoring or complaint surveys.

#### **A. Announced and/or Unannounced Surveys**

Section 353(g)(1) of the Public Health Service Act provides for either announced or unannounced surveys. Complaint or revisit surveys, and some validation surveys, must be conducted on an unannounced basis. Surveyors performing surveys of a laboratory with a CoC will schedule initial and recertification surveys. An unannounced survey may be performed after one appointment is cancelled by the laboratory. The laboratory must be informed of this when originally notified about the survey. Surveys are to be conducted during the laboratory's routine hours of operation. The laboratory should notify the State Agency (SA) if its laboratory operations are not conducted during usual hours of operation or only on specific days and times. The surveyor will confirm the laboratory's certificate type and advise the laboratory to notify the SA of any changes that would necessitate a different certificate.

## B. Scheduling of Surveys

The surveyor reviews the historical file of the laboratory. The surveyor will schedule the recertification survey at least six months prior, but no earlier than 12 months prior to the expiration of the laboratory's current certificate. In order to permit observation of actual testing during an initial survey, the surveyor will schedule the initial survey at least three months after the laboratory opens.

A date and time for the survey will be established with the laboratory. If a laboratory operates more than one shift or location, survey hours may be scheduled to include a representative cross-section of shifts or locations, as necessary. Note that, depending upon the extent of the findings and laboratory preparedness, the survey process may extend throughout the day and possibly into the next day(s).

## C. Survey Announcement Letter and Documents Required for Survey

To enhance survey effectiveness and efficiency, except in the case of complaints, the following forms and the survey announcement letter will be provided to the laboratory before the scheduled survey date. The laboratory must complete the forms and hold them for review during the onsite survey.

The following forms and laboratory records must be available during the survey:

1. *Laboratory Personnel Report (CLIA)*, form CMS-209 (required), with directions for completing or updating information, adding new personnel, or changes in positions or status, with signature of current lab director
2. *Clinical Laboratory Improvement Amendments (CLIA) Application for Certification*, form CMS-116 (required), with signature of current owner/operator/director
3. The following **must** be accessible and retrievable at the time of survey:
  - a. Standard operating procedure manual with all laboratory policies and procedures, showing initial date of use and approval by lab director. (Include package inserts and supplemental information, as necessary.)
  - b. Reference laboratory's client services manual, if applicable
  - c. Records of tests referred to other laboratories
  - d. Personnel records, including:
    - 1) Diplomas, certificates, degrees
    - 2) Training and experience
    - 3) Continuing education
    - 4) Competency assessment (initial, semi-annual, annual)
    - 5) Duties and responsibilities
    - 6) Personnel changes
  - e. Quality records, including:
    - 1) Remedial corrective action information
    - 2) Calibration and calibration verification records
    - 3) Maintenance and function checks records, etc.
    - 4) Individualized quality control plans

- f. Performance verification records for all test systems introduced or revised within the last two years
- g. Proficiency testing (PT) reports, including:
  - 1) Test runs with PT results
  - 2) Direct printouts (e.g., analyzer, test system printouts)
  - 3) Records showing review and assessment of results, corrective action, and quality assessment for ungraded or unscored and unsatisfactory results
  - 4) Attestation documentation
- h. Quality system assessment plan and documentation for each of the analytic systems
  - 1) Policies and procedures to monitor, assess, and correct identified problems
  - 2) Documentation of ongoing assessment activities, including review of the effectiveness of corrective actions, including revision of policies and procedures to prevent recurrence of problems
  - 3) Discussion of assessment reviews with staff
    - a) Safety and environment information
    - b) Patient testing records
      - (1) Requisition (Patient charts may be used.)
      - (2) Work records (direct printouts)
      - (3) Patient test reports (Patient charts may be used.)
    - c) List of tests currently performed in the laboratory

#### **D. Entrance Conference**

Upon entering the facility, the surveyor will present appropriate identification and introduce him/herself. They will ask to meet the administrator, director, or supervisor. The surveyor will request a working area.

The surveyor will inform the laboratory about the survey process. The laboratory will be informed that the survey will include a tour of the facility, record review, observation, and interviews with personnel involved in the pre-analytic, analytic, and post-analytic phases of the testing process. There will also be establishment of personnel availability and discussion of approximate time frames for survey completion.

The surveyor will request that the laboratory collect any documents, records, or information that may be needed to complete the survey, and solicit and answer any questions the laboratory may have concerning the survey process.

#### **E. Outcome Oriented Survey Process**

The primary objective of the survey process is to determine whether or not the laboratory meets the CLIA requirements. The surveyor meets this objective by employing an outcome-oriented survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory and the way it monitors itself, rather than on a methodical evaluation of each standard level regulatory requirement.

The principal focus of the outcome-oriented survey is the effect (outcome) of the laboratory's practices on patient test results and/or patient care. The outcome-oriented survey process is

intended to direct the surveyor to those requirements that will most effectively and efficiently assess the laboratory's ability to provide accurate, reliable, and timely test results.

In the outcome-oriented survey process, the surveyor reviews and assesses the overall functioning of the laboratory and evaluates the laboratory's ability to perform quality testing; that is, the surveyor evaluates the laboratory's quality system. The quality system requirements in the Introduction to Subpart K and the General Laboratory, Preanalytic, Analytic, and Postanalytic Quality Assessment requirements are appropriate guides which the surveyor will use in their review of the laboratory. "Subpart K – Quality System for Nonwaived Testing": <http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5%20-%20sp42.5.493.k>

In the outcome-oriented survey process, emphasis is placed on the laboratory's quality system as well as the structures and processes throughout the entire testing process that contribute to quality test results. The surveyor selects a cross-section of information from all aspects of the laboratory's operation for review to assess the laboratory's ability to produce quality results. The surveyor reviews the cross-section of information to verify that the laboratory has established and implemented appropriate ongoing mechanisms for monitoring its practices, and identifying and resolving problems effectively.

If the findings from the review of the laboratory's ongoing mechanisms for ensuring quality test results are sufficient to make the determination of compliance and if the evaluation does not warrant a more in-depth review, the surveyor concludes the survey and asks if the laboratory has any questions about CLIA requirements.

## **F. Information Gathering**

Information gathering includes observation, interviews, and record review and these are usually performed concurrently. The information gathering process is critical in the determination of quality laboratory testing. As each laboratory is unique in the services offered, the order of gathering information may be different for each survey. The timing for observing testing and the availability of staff for interview may determine the sequence of the survey.

The surveyor will verify the correction and continued compliance with previously cited deficiencies. Particular attention to deficiencies that the laboratory has failed to correct will be made.

1. *Organization of the Survey.* The surveyor will consider the following variables when making determinations for organizing the survey and the areas to be reviewed:
  - a. Purpose of the Survey
    - 1) Initial or recertification
    - 2) Complaint
    - 3) Follow-up and/or
    - 4) Validation
  - b. Pre-survey Information gathered
    - 1) Problematic PT
    - 2) Previous survey deficiencies

- 3) Complaints and/or
- 4) Enforcement actions
- c. Size and Organization of the Laboratory
  - 1) Type of instruments/test procedures
  - 2) Type of information system(s)
  - 3) Number of supervisors and testing personnel
  - 4) Number of testing sites
  - 5) Scheduling of testing (e.g., Stat, daily, weekly shifts)
  - 6) Number of specialties/subspecialties
  - 7) Test volume
  - 8) Record availability and/or
  - 9) Type of patients/clients served
2. *Observation of Facilities and Processes*
  - a. The surveyor will observe the laboratory's physical layout. These observations should include specimen collection and processing, "prep", and clean-up areas, testing and reporting areas, and storage areas.
  - b. Specimen integrity
  - c. Quality control performance
  - d. Skills and knowledge of personnel regarding:
    - 1) Performance of testing
    - 2) Evaluation of test results
    - 3) Identification and resolution of problems
  - e. Interactions of personnel regarding:
    - 1) Availability of supervisor to staff
    - 2) Communication among personnel
3. *Interviews.* Surveyor will interview staff to confirm observations and obtain additional information, as necessary.
4. *Record Review*
  - a. Surveyor will gather relevant information that will reflect the laboratory's ability to provide quality testing from all areas of the laboratory, including records encompassing the time period since the last certification survey. There will be a review of all new tests, new test methods, and new equipment added since the prior survey and a review of documentation relevant to as many of these factors as possible when reviewing laboratory records.
  - b. Surveyor reviews a cross-section of information selected from records of quality system assessment activities within each of the four systems. Surveyor reviews a cross-section of information, simultaneously assessing the laboratory's ability to provide quality test results as well as its ability to identify and correct problems. The surveyor will further investigate any problems identified but not addressed by the laboratory's quality system assessment. If the laboratory is failing to monitor (or



effectively monitor) its own system and correct its problems, the laboratory will be directed to the requirements and the relevant sections for its particular setting.

5. *Proficiency Testing Review*

- a. Surveyor will review PT forms that the lab has retained with required signatures.
- b. Surveyor will verify the laboratory is appropriately enrolled and participates in a CMS-approved PT program(s) for each specialty, subspecialty, analyte, and/or test for the entire period of time the laboratory has been performing testing for each regulated test.
- c. If the laboratory has unacceptable analyte/test results or unsatisfactory performance in specialties or subspecialties since the last survey, review the specific record, corrective action, and any other data, such as education and training of staff associated with PT remediation. Include both patient test results and quality control (QC) records in the review.
- d. Surveyor will verify that the laboratory has reported results under the appropriate methodology/instrumentation used for test performance, e.g., automated vs. manual hematology.
- e. Surveyor will verify that the laboratory did not engage in inter-laboratory communications and/or refer its PT samples for testing prior to reporting results to the PT provider.
- f. Surveyor will verify that PT samples were handled, prepared, processed, examined, tested, and reported, to the extent practical, in the same manner as patient samples.
- g. For tests where there is no PT available and/or those tests performed by the laboratory that are not included in Subpart I, surveyor will determine that the laboratory verifies the accuracy of each test at least twice a year.

6. *Facility Administration*

- a. Surveyor will review records for the appropriate retention times and assure the laboratory adheres to appropriate safety, arrangement, and space, ventilation, and contamination procedures.
- b. If the facility provides transfusion services, verify that the arrangement is current, the blood products are stored appropriately, and transfusion reactions are investigated and reported to the appropriate authorities in a timely manner.

7. *Quality Systems*

- a. *General Laboratory, Pre analytic, Analytic, and Post analytic System Quality Assessment.* Using the patient test requisitions, test records, test results, and test reports or, as applicable, patient charts, surveyor will review all phases of the laboratory testing processes, including instructions for specimen storage. After determining the patient population serviced by the laboratory (e.g., geriatrics, public health clinics, dialysis units, health fairs, and hospitals), review the following:
  - 1) A cross-section of patient test results encompassing all specialties and subspecialties of testing performed in the laboratory in sufficient numbers to determine if results vary significantly from expected population norms

- 2) Worksheets or instrument printouts, looking for outliers, trends, etc. for testing performed in batches and random
  - 3) Test results that are disproportionately abnormal or normal
  - 4) The correlation of initial test results and/or test result of various analytes of a patient over time
- b. Review QC practices and evaluate whether the laboratory is following its own QC protocols or those procedures specified by the manufacturer. Surveyor reviews QC results, including outliers, shifts, trends, and corrective actions taken, when necessary.
  - c. Refer to the establishment and verification of performance specifications at the Code of Federal Regulations, 42 CFR 493.1253, for guidance in reviewing the laboratory's method, test system, or analyte to its test menu.
  - d. Correlate reported patient test data with QC data and/or quality systems assessment records to ensure proper performance and documentation of controls. Review original test data (instrument printouts or computer files). Surveyor will verify that patient results have not been reported when QC data was unacceptable according to the laboratory's protocol.

The following will be considered in relation to the laboratory's patient population:

- 1) New methodologies and equipment
- 2) QC and calibration materials used
- 3) Source and availability of QC limits
- 4) Evaluation and monitoring of QC data
- 5) Corrective action for QC failures

#### 8. *Personnel*

- a. The scope of the review of personnel records (qualifications, training, and competency) will be related to the type of survey, type and complexity of testing performed, and the observations and findings of the survey. For **initial CLIA** certification surveys, evaluate the qualifications and experience of the laboratory director and each technical consultant, technical supervisor, clinical consultant, general and cytology supervisor, and cytotechnologist. Evaluate the qualification and experience of a cross-section of testing personnel.
- b. For CLIA **recertification** surveys, it is not necessary to review personnel records of individuals previously evaluated unless there have been changes in the individual's position and/or the laboratory's test menu since the last survey.

### G. **Assessing Outcome or Potential Outcome**

The surveyor will review and analyze all collected information to determine whether the laboratory has complied with applicable federal regulations. Analysis and outcome assessment is an ongoing process throughout the survey. The surveyor maintains ongoing, informal communication with the laboratory's liaison as questions arise. Surveyors will conduct a daily report of findings if survey is more than one day in length.

If the information gathered indicates that the laboratory has established, implemented, and maintained appropriate ongoing mechanisms for ensuring quality test results by monitoring, evaluating, and resolving any problems in its practices, and the surveyor's findings do not

warrant a more in-depth review, the survey will be concluded. However, if an outcome assessment of the laboratory's performance based on the cross-section of information collected can't be determined, it may be necessary to expand the cross-section (e.g., number of sites, observations, number of records).

The survey process allows the surveyor freedom to increase or decrease the number and types of records reviewed, the personnel interviewed, and the observations made as individual needs are identified.

## **H. Regulatory Compliance Decision**

After all necessary information has been collected and the outcome or potential outcome has been evaluated to determine if a preliminary finding constitutes a deficiency, determination will be made if it is a standard or condition level deficiency.

CLIA regulations are condition and standard level requirements as mandated by CLIA statute that must be met by laboratories, as applicable. The CLIA standards are designed to define component criteria constituting a CLIA condition or address a distinguishable aspect of the condition. Conditions are usually more serious and comprehensive.

The number of deficiencies does not necessarily relate to whether or not a condition level deficiency is found out of compliance. The determination is made based on an evaluation of the impact or potential impact of the identified deficiencies on the quality of laboratory services and the results reported. A condition level deficiency is considered for one or more deficiencies if, in surveyor judgment, the deficiency(ies) constitutes a significant or a serious problem that adversely affects patient test results/patient care or has the potential for adversely affecting patient test results/patient care.

Immediate jeopardy is defined in 42 CFR §493.2 as “a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.” When the possibility of immediate jeopardy exists, the surveyor consults with the state agency (SA) and CMS RO (regional office) before a determination of immediate jeopardy is made.

## **I. Exit Conference**

The purpose of the exit conference is for the surveyor to review findings with the laboratory and is not meant to be all-inclusive. It is the continuation of the educational survey process and the beginning of due process. The exit conference is the first opportunity for the laboratory to present additional information in response to the findings.

If immediate jeopardy or condition level deficiencies are identified, the laboratory will be informed of the seriousness of the problem(s)/finding(s) and indicate that they are not final and are subject to review.

The exit conference will be conducted with the facility's administrator, director, consultant, or supervisor, and/or other invited staff. The following will be discussed:

1. The requirements that are not in compliance and the findings that substantiate these deficiencies

2. Provide the laboratory an opportunity to discuss and provide additional information regarding deficiencies. It is the laboratory's responsibility to determine the corrective actions(s) necessary to remedy the problem(s).
3. Provide instructions and the time frame necessary for submitting a plan of correction as referenced in State Operations Manual (SOM) Chapter 6 §6130.
4. Inform the facility of the intended recommendation to the RO to certify, recertify, or deny certification of the laboratory.
5. At the exit interview, inform the laboratory (director/administrator/supervisor) of changes in test volumes which may result in fee changes.

The laboratory may have an attorney present but should give advance notice of this to the surveyor. The exit conference is an informal process and attorneys do not usually attend. Surveyors have been instructed not to answer any questions from the laboratory's attorney.

A court reporter may not attend the exit conference. If a laboratory wishes to audio record or video tape the exit conference, it must first obtain permission from the surveyor. An identical, simultaneous recording must be given to the surveyor at the conclusion of the exit conference.

Any eavesdropping or any audio recording or videotaping without the express knowledge and permission of the surveyor is considered impeding the survey process. This may result in termination of the survey.

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### III. POST SURVEY

#### A. Explanation Of Deficiency Statements

The surveyor summarizes the survey findings in a written final report. If the surveyor determines that the laboratory is out of compliance with regulations, the surveyor will document those findings. The findings serve as a basis for the laboratory to analyze its deficient practices or system failures and develop plans of correction. Survey findings are documented on the Statement of Deficiencies (SOD), form CMS-2567. Survey findings are sent via certified mail or electronically within 10 days following the exit conference.

#### B. Development Of The Statement Of Deficiencies

A violation exists when a laboratory fails to comply with a federal regulation. The Department of Health Services promulgates and enforces rules and standards necessary to provide safe and adequate care and treatment of patients and to protect the health and safety of patients and employees of laboratories. The department authority is derived from CLIA regulations at 42 CFR Part 493.

The surveyor will choose the most appropriate regulatory citation when documenting a deficiency.

1. *Standard Level Deficiencies.* If noncompliance has been identified, cite the most specific standard available.
2. *Condition Level Deficiencies.* When the deficient practice is of such a serious nature that correction is necessary for the laboratory's testing to continue, cite the most appropriate condition. The laboratory must correct those standard level deficiencies that are used to

support the condition level noncompliance before the condition can be considered back in compliance.

### C. Plan Of Correction (POC)/Allegation of Compliance (AOC)

If, after receiving a SOD, there are questions regarding the survey findings, the laboratory may consult informally with the surveyor or surveyor's supervisor to discuss compliance.

The webpage linked below outlines the DQA electronic process for submission of SODs, POCs, and AOCs: <https://www.dhs.wisconsin.gov/regulations/e-sod.htm>

If opening emails or attachments proves difficult, the previous link also has instructions for viewing encrypted messages.

#### 1. *Content*

To be considered complete, each Plan of Correction (POC) or Allegation of Compliance (AOC) must include the following:

- a. Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice
- b. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has/have been taken
- c. What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur
- d. Who will be responsible for ensuring corrective action is monitored and how this monitoring will be performed in order to ensure the deficient practice does not recur.

Use of personal names in a Plan of Correction /Allegation of Compliance will be cause for rejection. As needed, position titles or other suitable descriptors should be used.

#### 2. *Correction of Violations*

A laboratory is requested to submit a plan to correct the violations (Plan of Correction for standard level deficiencies or Allegation of Compliance for condition level deficiencies). The laboratory shall submit a plan of correction within **10 days** following receipt of the Statement of Deficiencies.

If a laboratory does not provide a timely response to this request or, if the laboratory submits a Plan of Correction that is not acceptable in content and time frames or, if the laboratory does not demonstrate compliance with all CLIA requirements by the specified completion date, DQA may recommend to CMS the imposition of principal sanctions, i.e. suspension, limitation and/or revocation of the laboratory's CLIA certificate and concurrent cancellation of the laboratory's approval for Medicare payments per 42 CFR 493.1816.

#### 3. *Verification of Corrections*

Regulations at 42 CFR 493.1816 state that if a laboratory has deficiencies that are not at the condition level, the laboratory must submit a Plan of Correction that is acceptable to CMS in content and time frames. The laboratory is required to respond within 10 days of receipt of the Statement of Deficiencies. Further, regulations at 42 CFR 493.1816 require all standard level deficiencies to be corrected within 12 months after the last day of the survey. It is important to note that, depending upon the nature and seriousness of the deficiency, the acceptable time frame for correction may be less than 12 months. For

condition level deficiencies, the laboratory must submit documented evidence of compliance to verify that the corrections have been made.

The surveyor will verify correction of all deficiencies during the next survey event. If there are condition level deficiencies, acceptable evidence of correction must be submitted with the AOC. A follow-up survey on condition level deficiencies may occur.

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#### IV. COMPLAINTS

The Bureau of Health Services / Licensing, Certification, and CLIA Section receives complaints and conducts complaint surveys for laboratory practice concerns. To submit a complaint regarding laboratories:

- Call the toll-free complaint line at: **1-800-642-6552**
- File a complaint online at: <https://www.dhs.wisconsin.gov/guide/complaints.htm>
- Write a letter and mail it to: **DHS / Division of Quality Assurance  
BHS / Licensing, Certification, CLIA Section  
P.O. Box 2969  
Madison, WI 53701-2969**