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Prepping Your Laboratory for a Successful Survey

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CLINICAL LABORATORY



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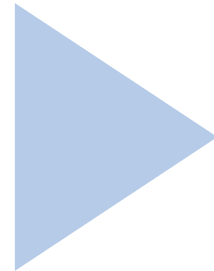


Objectives

- Upon completion of this program, the participant will be able to:
- Understand the basic outline of the survey process.
- List documents that will be requested during the survey.
- Identify actions that can be taken prior to the survey team's arrival to help assure a less stressful and more successful survey experience.

Share the Responsibility

The
Laboratory
Manager
can't do it
all



A successful
survey
belongs to
the entire
staff



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Be Survey ready
every day.



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Standards



Review the Standards

Standard

Required
Elements/Additional
Information

Survey Procedure

Be able to speak to
how you are meeting
the standard.

Review your Processes



- Prior deficiencies cited.
- Staffing qualifications, training, and competency.
- Policies and procedures.
- Proficiency testing program.
- Performance specifications.
- Analyzer management.
- IQCPs.
- Quality assessment program.
- Environmental records.
- Commonly cited laboratory deficiencies.

Before the Survey:



Determine a space with internet access for the surveyors.



Have a plan to enlist the help of someone outside of the laboratory to get the room set up and arranged.



If policies and procedures are in an electronic format, have a plan as to how multiple surveyors can access those documents at the same time.



Make sure that more than one person knows where key documents are located.



Organize documentation prior to surveyor team arrival for easy access.



Have runners available to obtain and deliver documentation to the surveyors.

Opening Conference

Tour of the Laboratory

Document Review

Interviews

POC Testing

Exit Conference

Opening Conference





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Tour of the Laboratory



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Documents

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ITEMS NEEDED FOR SURVEY GENERAL LABORATORY



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This document represents a list of requests that your Surveyor(s) will make during your survey for Clinical Laboratory Accreditation. If you have questions about any of these items, contact your Account Advisor. To facilitate a smooth survey experience, please be prepared with the following:

- For blood bank, please notify the Surveyor when a unit of blood is being issued.
- Inspection reports since the last ACHC survey (state, federal, etc.)
- Corrective Action Report/Plan of Correction from last ACHC survey
- Laboratory personnel education and transcripts (with HR present for discussion)
- For hospital labs, Surveyors will need to meet with the hospital QI/PI coordinator

The table below details documentation that will be reviewed for evidence of compliance and identifies the associated ACHC Standard. Additional documents may be requested.

ACHC Standard	Required Item	Located
Specific to blood bank	<ul style="list-style-type: none"> ■ 08.01.02: Most recent blood bank contract ■ 08.01.04: Look Back Policy and Look Backs for the last two years ■ 08.03.09: Suspected transfusion reactions for the last two years ■ 08.03.07: Emergency release forms for the last two years ■ 08.03.08: Medical records for patients who received blood; one from six months ago, one from 18 months ago 	
01.02.05, 06.03.02, 06.05.00-01, 06.08.01, 07.03.02, 07.05.01, 07.07.01	All calibrations, calibration verifications, and instrument comparisons for the last two years	
01.02.06	Policy for disposition of laboratory records in the event the lab closes	
01.03.02, 01.03.06	Validation of LIS calculations and interface checks	
01.04.07	Eyewash and shower records for two years	
01.04.08	BSC annual hood validation and daily maintenance records	
01.04.21	Safety meeting records/fire drill.	
02.01.01	Verification of the Laboratory Director's state medical licensure	
02.01.03, 02.01.15, 02.04.03	Documentation from the Laboratory Director if duties have been delegated to other personnel	
02.02.04-05, 02.04.03, 03.01.04, 03.02.03	All laboratory staff competency evaluations, including respiratory therapy for blood gas and nursing for POCT	



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02.01.10, 05.04.00-01, 05.05.00, 05.06.00, 05.07.00, 05.08.00-01	QA/QI plans and documentation	
04.00.04-09	Proficiency Testing attestation statements, work submitted, and score card results for the last two years	
05.02.00-01	Documentation and investigation of complaints	
05.05.05	List of reference laboratories with their CLIA certificates	
05.07.01-03, 05.07.06-09	Copy of a report from each department/reference lab/corrected report/critical report	
06.03.00-01	Validation of new tests and/or instruments acquired in the last two years	
06.00.01, 06.01.01	Procedure manuals for each department (if manuals are electronic, please provide computer access for each surveyor.)	
06.01.05	Retired procedure files from the last two years	
06.02.01	Water quality policy Temperature and humidity records for the last two years	
06.04.00-03	All maintenance and function verification records for instruments in the laboratory for last two years (include records of timer, centrifuge, incubator, and safety cabinet checks, pipette calibrations, thermometer calibrations, and day-of-use microscope care)	
06.06.01-04	IQCPs written for any moderate or high complexity testing in lieu of daily QC.	
06.06.00, 06.07.07, 06.08.04-05, 07.00.01-05, 07.01.01-04, 07.02.01-04, 07.03.03-04, 07.04.01-02, 07.07.01, 07.11.01-03, 08.03.00, 09.00.05, 09.00.08, 09.04.05, 09.04.22, 10.00.04, 10.02.04, 10.02.14, 10.02.18, 10.02.26, 03.01.05, 03.02.07	All QC/corrective actions for the last two years.	



ITEMS NEEDED FOR SURVEY PHYSICIAN OFFICE LABORATORY

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This document represents a list of requests that your Surveyor(s) will make during your survey for Clinical Laboratory Accreditation. If you have questions about any of these items, contact your Account Advisor. To facilitate a smooth survey experience, please be prepared with the following:

For any changes since submission of your application, please provide documentation to your Surveyor at the beginning of the survey:

- Proficiency Testing status report
- CLIA license
- State license

Other general documents:

- Inspection reports since the last ACHC survey (state, federal, etc.)
- Corrective Action Report/Plan of Correction from last ACHC survey
- Laboratory personnel education and competency testing
- Fire drill records

The table below details documentation that will be reviewed for evidence of compliance and identifies the associated ACHC Standard.

ACHC Standard	Required Item	Located
01.02.06	Policy for disposition of laboratory records in the event the lab closes	
01.04.07	Eyewash records for two years	
01.04.21	Safety meeting records	
02.01.03, 02.01.15, 02.04.03	Documentation from the Laboratory Director if duties have been delegated to other personnel	
04.00.04-.09	Proficiency Testing attestation statements, work submitted, and score card results for the last two years	
05.05.05	List of reference laboratories with their CLIA certificates	
06.03.00-.01	Validation of new tests and/or instruments acquired in the last two years	
06.00.01, 06.01.01	Procedure manuals (If manuals are electronic, please provide computer access for each Surveyor.)	
06.01.05	Retired procedure files from the last two years	
06.02.01	Temperature and humidity records for the last two years.	
06.04.00-.03	All maintenance and function verification records for instruments in the laboratory for last two years; Records of timer checks, thermometer and humidistat calibrations, and day-of-use microscope care	
03.01.05, 03.02.07, 06.06.00-.07, 06.08.04-.05	All QC/corrective actions for the last two years	



Documents stored off site



Electronic records stored on
analyzers



HR Records



Procedures in Electronic Format



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Interviews



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The Surveyors will likely want to speak with the following individuals:

- CEO
- Laboratory Director
- Quality Improvement Coordinator
- Director of Human Resources
- Lead Technologist in Hematology, Chemistry, Microbiology, Blood Bank, Histology, and Cytology
- Director of Respiratory Therapy
- Point of Care Coordinator



Waived



Provider Performed
Microscopy (PPM)



Moderate (Blood Gas)

Point of Care Testing

- Review of Policies and Procedures
- Observations
 - Patient Identification
 - Test Performance
 - Result Documentation
 - Quality Control
 - Maintenance
 - Environmental Records
 - Infection Control Practices
- Review of HR files
 - Education
 - Training
 - Competency

Anatomic Pathology Services

Frozen Sections

Autopsy Services

Fine Needle Aspirates



Exit Conference

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Exit Conference



The purpose of the exit conference is to provide an overview of the surveyor's findings with the laboratory.



The laboratory may invite members of the organization to attend the exit conference.



Questions?

We are here to help!

References

- What Clinical Laboratories should do to Become Survey Ready- MLO 2/23/22
- Preparing Your Laboratory for Its Next Survey- COLA's Insights- Fall 2016



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Thank you

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