

# CLIA Corner

State Hygienic Laboratory at The University of Iowa



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## In This Issue of the CLIA Corner we address:

- **Helpful CLIA resources and where to find them**

Are you new to the Clinical Laboratory Improvement Amendments (CLIA)? Have you heard of CLIA but need more information? The CLIA Regulations and Interpretive Guidelines are contained in over 400 pages and consist of over 500 Deficiency Tags (DTags). Who wouldn't feel overwhelmed and anxious? This CLIA Corner is for you! This issue will highlight helpful CLIA resources and where to find them on the Internet.

## Centers for Medicare & Medicaid Services (CMS) website

The official website for CLIA can be found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>. The left hand side of the homepage contains links to various topics related to CLIA. Once a topic is selected, information then populates in the main part of the screen, followed by the "Downloads" and "Related Links" sections. Both of these sections give additional information and websites related to CLIA.

The screenshot shows the CMS.gov website interface. At the top, there is a navigation bar with links for Home, About CMS, Newsroom, FAQs, Archive, Share, Help, and Print. Below this is a search bar with the text 'Learn about your health care options' and a search button. The main navigation menu includes links for Medicare, Medicaid/CHIP, Medicare-Medicaid Coordination, Private Insurance, Innovation Center, Regulations & Guidance, Research, Statistics, Data & Systems, and Outreach & Education. The current page is 'State Agency & Regional Office CLIA Contacts', which is part of the 'Clinical Laboratory Improvement Amendments (CLIA)' section. The page content includes a heading 'State Agency & Regional Office CLIA Contacts', a paragraph explaining how to find information about CLIA contacts, a note about forwarding completed applications to the local State Agency, and a 'Downloads' section with links to 'CLIA State Agency Contacts [PDF, 65KB]' and 'CLIA Regional Office Contacts [PDF, 27KB]'. The page footer indicates it was last modified on 06/07/2012 at 2:03 PM and provides a link for help with file formats and plug-ins.

## ***Helpful Links on the CMS website:***

- [How to Apply for a CLIA Certificate, Including International Laboratories](#)
  - The “Related Links” section contains a link to the CMS-116 CLIA Application Form.
- [State Agency & Regional Office CLIA Contacts](#)
- [Categorization of Tests](#)
  - The “Downloads” section includes a list of waived test systems and a list of provider performed microscopy (PPM) tests.
  - The “Related Links” section provides a link to the Food and Drug Administration (FDA) Test Complexity Database. The database is useful for determining complexity for FDA cleared test systems and specialties and subspecialties of specific analytes.
- [Certificate of Waiver Laboratory Project](#)
  - The information section explains CMS’s Certificate of Waiver Project as well as the requirements for waived testing.
  - The “Ready Set Test Booklet” link in the “Related Links” section is connected to the Centers for Disease Control and Prevention (CDC) CLIA Waived Tests website. CMS and the CDC collaborated to create waived testing educational materials, resulting in a set of booklets, a self-assessment checklist, and a FREE online course designed to guide laboratories on recommended practices for performing patient testing under a CLIA Certificate of Waiver. The educational materials can also be found at the following web address: <https://wwwn.cdc.gov/cli/Resourcs/WaivedTests/default.aspx>.
  - The “Related Links” section also features a link to the CDC’s 2005 Morbidity and Mortality Weekly Report (MMWR), which highlights good laboratory practices for waived testing sites.
- [CLIA Brochures](#)
  - Each brochure in the “Downloads” section explains a different part of CLIA. Brochure topics include, but are not limited to, verification of performance specifications, calibration and calibration verification, proficiency testing, assessing laboratory personnel competency, and Individualized Quality Control Plans (IQCP).
- [Interpretive Guidelines for Laboratories](#)
  - The “Related Links” section contains a link to the State Operations Manual Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.

## ***Quality, Safety & Oversight Letters***

The CMS Quality, Safety and Oversight Group (previously known as the Survey and Certification Group) is responsible for giving guidance, clarification, and instruction with regard to the CLIA regulations. These memoranda to the State Survey Agencies and CMS Regional Offices are available to the public. They can be found at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html>.

**Quality, Safety & Oversight - General Information**

- [Spotlight](#)
- [Accreditation of Advanced Diagnostic Imaging Suppliers](#)
- [Accreditation of Medicare Certified Providers & Suppliers](#)
- [CMS National Background Check Program](#)
- [Civil Monetary Penalties \(Annual Adjustments\)](#)
- [Civil Money Penalty Reinvestment Resource](#)
- [CLIA](#)
- [CMS Federal Grant Opportunity](#)
- [Contact Information](#)
- [Diabetic Self-Management Training \(DSMT\) Accreditation Program](#)
- [National Partnership to Improve Dementia Care in Nursing Homes](#)
- [Nursing Home Quality Assurance & Performance Improvement](#)

## Policy & Memos to States and Regions

CMS Quality Safety & Oversight memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.

Show entries: 10

Filter On:

Title	Memo #	Posting Date	Fiscal Year
<a href="#">Clinical Laboratory Improvement Amendments (CLIA) Release of Request for Information (RFI)</a>	18-11-CLIA	2018-01-05	2018
<a href="#">CLIA Proficiency Testing (PT) Referral Categories</a>	18-07-CLIA	2017-12-15	2018
<a href="#">Clarification Regarding the Use of Control Materials as Calibrators to Determine Test Cut-off Values</a>	17-46-CLIA	2017-09-29	2017
<a href="#">FY 2016 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program</a>	17-40-AO	2017-07-28	2017
<a href="#">Notice of Final Rule Adjusting Civil Monetary Penalties (CMPs) for Inflation</a>	17-23-NH/HHA/CLIA	2017-03-31	2017
<a href="#">Advanced Copy –Revisions to State Operations Manual (SOM), Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (Clinical Laboratory Improvement</a>	17-11-CLIA	2016-12-01	2017

The database includes memos for providers other than CLIA; for memos specific to CLIA, type “CLIA” in the filter. Click on the “Posting Date” header to bring the most recent memos to the top of the list.

## CMS Integrated Surveyor Training Website (ISTW)

In May 2017, CMS released an online CLIA Surveyor Basic Training course, which includes a comprehensive overview of the regulatory requirements and their application to surveyors. All Regional Office and State Agency surveyors are required to complete the course, which consists of 14 web-based, self-paced lessons. The lessons walk an individual through the CLIA regulations, and include information on a wide variety of CLIA topics, such as proficiency testing, quality control, calibration verification, cytology, quality assessment, and personnel requirements.

The online CLIA Surveyor Basic Training course is FREE to the public. To access the course, go to the CMS Surveyor Training Website at <https://surveyortraining.cms.hhs.gov>.

1. Select the “**I AM A PROVIDER**” link.
2. In the blue bar across the top of the screen, select “**Course Catalog.**”
3. In the gray filter column on the left, scroll down and click on “**CLIA.**”
4. Select the web-based “**CLIA Surveyor Basic Training.**”
5. Scroll down and select the “**Launch this Course**” button.

## Provider-Performed Microscopy (PPM) Procedures Booklet

A CLIA Certificate for Provider-Performed Microscopy (PPM) procedures allows physicians, midlevel practitioners, and dentists to perform a limited list of moderate complexity microscopic tests, as well as

waived tests, as part of a patient's visit. Testing sites performing PPM procedures are not subject to routine biennial inspections. However, a CLIA certificate is required and the testing site must meet the CLIA quality standards for moderate complexity testing. To help providers accomplish these requirements, CMS and the CDC collaborated to create a PPM testing educational booklet that can be found here: <https://www.cdc.gov/clia/Resources/PPMP/>.

## State Hygienic Laboratory (SHL) Biosecurity Course

In collaboration with the Association of Public Health Laboratories (APHL), the State Hygienic Laboratory recently developed a new course designed to help clinical laboratories improve their knowledge of biosecurity practices. "Biosecurity for Clinical Laboratories" is FREE and available on the Training-Source.org website. To access the course, go to the website at [www.training-source.org](http://www.training-source.org). Users must sign on to the website with an existing Training-Source account or create a new account.

## CLIA Corner

Have you ever thought that you read some helpful information in the CLIA Corner before, but you just cannot find it? Fortunately, all previously published CLIA Corner newsletters have been archived on the SHL's website. To access them, go to the SHL website at <http://www.shl.uiowa.edu/>.

1. Select "Lab Certification" from the green bar at the top of the screen.
2. Click on the link for "[Clinical Laboratory Improvement Amendments \(CLIA\) program.](#)"
3. On the left hand side of the screen, click on "[CLIA Corner Archive](#)" to view all CLIA Corners written over the years. \*NOTE: Some CLIA Corner newsletters have been removed due to inaccurate and/or obsolete information.

The screenshot shows the website for the State Hygienic Laboratory at the University of Iowa. The header includes navigation links (Home, Contact, IT, Careers) and a search bar. The main content area features a large image of a laboratory setting with a rack of test tubes. Below the image, the text reads "IOWA CLIA LABORATORY PROGRAM". On the left side, there is a vertical menu with links to various sections: About the SHL, Environmental, Newborn Screening, Disease Control, Education / Training, Lab Certification Programs (highlighted), IDNR Laboratory Certification, Publications, News, and Center for the Advancement of Laboratory Science. The "Lab Certification Programs" section is expanded, showing "Iowa CLIA Laboratory Program" and "CLIA Corner archive". The "CLIA Corner archive" link is highlighted in green. On the right side, there is a "Contact Information" box with details for the Iowa CLIA Laboratory Program, including contact information for Kristine Rotzoll and Melinda Bochmann. Below the contact information is a "CLIA Corner" logo and a brief description of the service.

Home Contact IT Careers

Google Custom Search

State Hygienic Laboratory at The University of Iowa

IOWA CLIA LABORATORY PROGRAM

**About the SHL**  
In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA), establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed.

**Environmental**

**Newborn Screening**

**Disease Control**  
The federal law states any laboratory or facility that performs laboratory testing of human specimens for the purpose of providing information for the diagnosis, prevention or treatment of disease or impairment of, or the assessment of the health of, human beings is required to obtain a CLIA certificate and to meet certain requirements.

**Education / Training**

**Lab Certification Programs**  
Iowa CLIA Laboratory Program  
CLIA Corner archive

**IDNR Laboratory Certification**  
This rule applies whether or not the facility bills Medicare, Medicaid, other insurance, the patient, or provides the service for no charge. The type of CLIA certificate a laboratory must have depends on the type of testing the laboratory performs.

**Publications**

**News**

**Center for the Advancement of Laboratory Science**

**How is the Hygienic Lab involved?**  
The State Hygienic Laboratory is under contract with the Iowa Department of Inspections and Appeals and the Centers for Medicare & Medicaid Services to oversee the CLIA Laboratory Program for the State of Iowa. The Hygienic Laboratory administers the program and provides laboratory surveys to conduct clinical laboratory inspections. Iowa does not have additional State licensure or certification requirements for laboratories.

**How does a lab apply for CLIA certification?**  
Complete the Application for Certification ([form CMS-116](#)) and submit it to the appropriate State Agency. Laboratories within Iowa may submit the application to Hygienic Lab. Laboratories outside Iowa should contact the [CLIA State Agency](#) for the state in which they are located. Refer to the [Centers for Medicare and Medicaid Services for more information](#).

**Contact Information**  
Iowa CLIA Laboratory Program  
State Hygienic Laboratory  
UI Research Park  
2490 Crosspark Road  
Coralville, IA 52241-4721  
phone 800.421.IOWA or 319.335.4500  
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**CLIA Corner**  
The Hygienic Lab's CLIA Corner can help. To subscribe, email one of the CLIA Compliance professionals listed above.