PROGRAM GUIDE - UNIVERSITY CLIA REGISTERED LABORATORIES COMPLIANCE COMMITTEE
I. Introduction

II. Committee Overview and Functions

III. CLIA Compliance Committee

IV. Laboratory Testing
   a. Waived Testing
   b. Provider-Performer Microscopy (PPM) Testing
   c. Triggers for Required CLIA Certificate

V. Process for Applying for a CLIA Certificate

VI. Notification of Laboratory Survey or Inspection

VII. Documentation Requirements for all CLIA Registered Laboratories

VIII. Annual Compliance Walkthrough Elements

IX. Notification of Non-compliance

X. Laboratory Directors

XI. Resources

Appendix A: Registration Form 2015 (Testing Menu)
Appendix B: Laboratory Director Acknowledgment – Proficiency Testing
Appendix C: Initial / Annual Laboratory Compliance Walkthrough
I. **Introduction**

The Ohio State University owns and operates laboratories in a variety of locations, including the OSU Wexner Medical Center, multiple ambulatory sites, and other University campus locations. The operation of these laboratories is regulated by the Center for Medicare and Medicaid Services (“CMS”) pursuant to the Clinical Laboratory Improvement Amendments of 1988 ( “CLIA”) 42 USC 263(a) et seq. and the applicable Medicare and Medicaid requirements for laboratories codified together at 42 CFR Part 493 (the federal laboratory requirements).

Laboratory testing plays an essential role in the delivery of quality health care. Laboratory tests provide physicians, nurses, and other health care providers with objective information that is needed to prevent, diagnose, treat, and manage disease. It is estimated that laboratory data have an impact on over 70 percent of medical decisions.

Laboratory testing is classified as highly complex, moderately complex (including provider performed microscopy- PPM), or waived under CLIA. The Food and Drug Administration (FDA) determines which tests are approved waived. The Centers for Medicare and Medicaid has designated an approved list of PPM testing. The clinical laboratories (highly complex and moderately complex) report to various medical directors within the department of pathology.

II. **Committee Overview and Functions**

In order to provide for the orderly monitoring and operations of these clinical laboratories, the University has established the University CLIA Laboratories Compliance Committee to oversee the University CLIA Registered Laboratories Compliance Program.

The key functions of the Committee include:

1) Verify a current, active CLIA Certificate for any facility performing waived testing or Provider Performed Microscopy (PPM) testing;
2) Grant prior approval to any laboratory / health care facility performing laboratory testing, including waived and PPM laboratory testing, applying for a CLIA Certificate from The Ohio Department of Health;
3) Verify that the laboratory director and testing personnel meet the education and/or experience requirements as defined by CLIA
4) Verify documented training and competency assessments for testing personnel for every test on the test menu, including annual verification of competency
5) Verify that procedures are in accordance with CLIA requirements, manufacturer’s instructions and are signed by the Laboratory Medical Director
6) Review test validations
7) Review Quality Control (QC) documentation
8) Verify training and education documentation regarding CLIA Proficiency Testing;
9) Verify annually the complete and accurate test menu and
10) Provide consultation and serve as an information resource for all laboratories under the Committee’s oversight. The Committee works collaboratively with the Laboratory Director/ Medical Director for the University Hospitals – Main.
11) Provide feedback to the Medical Center Compliance Committee

The Committee members are appointed by the Committee Chair.

The Committee is comprised of the following members:

- Chair: Medical Director, Ambulatory Services
- Administrative Director, Clinical Laboratories, OSUWMC
- Medical Director, Clinical Laboratories, OSUWMC
- Director of Compliance, Clinical Laboratories, OSUWMC
- Point of Care Testing Manager, Clinical Laboratories, OSUWMC
- Associate Vice President and Executive Director Regulatory, Advocacy & Quality Improvement, OSUWMC
- Director, Compliance & Integrity, OSUWMC
- Ambulatory Testing Manager, OSUP
- Director of Outreach, Clinical Laboratories, OSUWMC
This Committee will report to the OSU Wexner Medical Center Compliance Committee.

III. **CLIA Compliance Committee**

The University CLIA Registered Laboratories Compliance Committee (Oversight Committee) is responsible for implementation of the University CLIA Registered Laboratories Compliance Program which performs required oversight and monitoring of all Complex, Waived, and Provider Performed Microscopy (PPM) laboratories owned and operated by The Ohio State University.

All clinical laboratories and health care facilities performing laboratory testing must hold an active CLIA certificate. Any site performing laboratory testing, and providing results, must operate under a CLIA certificate.

The core requirements for obtaining and maintaining a CLIA certificate include:
- The certificate must accurately reflect the laboratory testing being performed.
- Each person working in the laboratory must demonstrate and document adequate training and knowledge of proficiency testing.
- Maintaining thorough documentation of training, competency assessment, quality control and quality assurance.
- Following manufacturer’s recommendations for performing testing.
- Maintaining an organized and safe environment.

IV. **Laboratory Testing**

**Clinical Laboratory Test – Triggers for Required CLIA Certificate**

**CLIA Certificate Must be Obtained, and CLIA guidelines followed**

**CLIA certificate not needed must follow safety requirements**

- **Do you perform testing on a blood, urine, or stool sample to produce a result?**
  - Is that result given to the patient, used for a clinical diagnosis or involved in medical decision making?
  - Is that result used only for research, never used for clinical decision making, and never released to the patient?

- **Do you utilize testing kits for sample testing?**
  - Examples: Pregnancy (HCG), Strep, HIV, Mono, Drug Screens

- **Do you use an instrument for sample testing?**
  - Examples: Glucose, INR
Waived Testing

A list of current waived testing is available on the CMS website or through the FDA database. [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm)

The facility must obtain a CLIA certificate before performing any testing. If only waived testing is performed, the facility must obtain a Certificate of Waiver. Laboratories with a Certificate of Waiver are not required to participate in proficiency testing and are not routinely inspected. For waived testing, the manufacturer’s instructions must be followed exactly. If testing personnel change the procedure in any way, the test may not be considered waived and results may not be accurate.

Good laboratory practices for waived testing include: appropriate training, quality control, quality assessment, organized records and proficiency testing.

Provider-Performer Microscopy (PPM) Testing

To qualify for a Certificate of PPM, the laboratory must only perform the following procedures:
- Wet mounts, including preparations of vaginal, cervical, or skin specimens
- All potassium hydroxide (KOH) preparations
- Fern test
- Post-coital direct, qualitative examinations of vaginal or cervical mucous
- Urinalysis, microscopic only
- Fecal leukocyte examination
- Qualitative semen analysis; presence and/or motility of sperm only
- Nasal smears for eosinophils
- Pinworm examinations (regulated analyte, proficiency testing required)

PPM tests **must** be performed by a physician, dentist, nurse midwife, nurse practitioner or physician assistant.

PPM tests are classified as moderately complex and are subject to all applicable CLIA regulations. All subparts, including proficiency testing, quality system, facility administration and personnel, apply to PPM testing. These laboratories / health care facilities are not subject to routine inspections. PPM laboratories may also perform waived testing.

V. Process for Applying for a CLIA Certificate

CLIA requires all facilities that perform even one test, including waived tests, on “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the
assessment of the health of, human beings” to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

The CLIA application (Form CMS-116) is available online at the CMS CLIA website. Forward the completed application to the Ohio Department of Health.

After you apply for your certificate, you will receive a coupon notifying you of the corresponding fee. Follow the instructions on the fee coupon for payment. After CMS receives your payment, your certificate will be mailed to you. You may begin testing once you have received your certificate containing your CLIA number.

You do not need to reapply every two years. Billing coupons are automatically mailed out 6 months prior to the expiration date of the current CLIA certificate. If payment is received in a timely manner, the CLIA certificate for the next cycle is mailed 3 weeks before the expiration date of the current CLIA certificate.

OHIO DEPARTMENT OF HEALTH
CLIA Laboratory Program
246 N. High Street,
2nd Floor Columbus, OH 43215
(614) 644-1845
FAX: (614) 564-2478
Contact: Shannon Richey
Email: CLIA@odh.ohio.gov

To verify an active status of a laboratory: Information is now available on the Ohio Department of Health website, www.odh.ohio.gov that can be printed as proof of certification and to verify any changes you have submitted.

1. On the homepage, scroll down to “Resources”.
2. Click “Online Services”.
3. Click “Licensed Medicare/Medicaid Certified Health Care Provider Information”.
4. Click on “Health Care Provider Real-Time Information”.
5. For Provider Type, select “CLIA Lab” from the dropdown menu.
6. Fill in your CLIA ID Number.
7. Click on your facility name.

VI. Notification of Laboratory Survey or Inspection

If the laboratory undergoes a routine or a complaint survey, CLIA Compliance must be notified. They will notify the CLIA Compliance Committee. This applies to all CLIA registered laboratories, including waived testing.

This includes, but not limited to surveys by: The Ohio Department of Health (ODH), Centers for Medicare and Medicaid (CMS), The College of American Pathologists (CAP), and The Joint Commission (TJC).

Notify within 7 days of inspection to: CLIA.Compliance@osumc.edu

VII. Documentation Requirements for all CLIA Registered Laboratories

Submit documents to CLIA.Compliance@osumc.edu

Initial Requirements
1. Documentation of approval to apply for a CLIA Certificate (after January 1, 2014) from the CLIA Compliance Committee

⇒ Initial Registration Form (Appendix A)
2. Documentation of training and education for Proficiency Testing
   ⇒ Laboratory Director Acknowledgment (Appendix B)

3. Submission of a complete and accurate testing menu

Ongoing Requirements

1. New Testing
   ⇒ Before beginning any new testing, please notify CLIA Compliance to verify testing complexity and method validation.

2. Notification of a Survey or inspection
   ⇒ If the laboratory undergoes a routine or complaint survey, CLIA Compliance must be notified. They will notify the CLIA Compliance Committee. This applies to all CLIA registered laboratories, including waived testing.

Annual Requirements

1. Laboratory Director Education
   ⇒ The laboratory director (or designee) must attend an annual CLIA overview in-service. This in-service will be offered in January and February each year by Laboratory compliance.

2. Documentation of a current CLIA Certificate
   ⇒ Submit a copy of the current CLIA certificate

3. Annual submission of Complete and Accurate Test Menu
   ⇒ Submit a current test menu

4. Annual Laboratory Compliance Walkthrough (elements listed below)
   ⇒ Annual Laboratory Compliance Walkthrough (Appendix C)

5. Documentation of a self-inspection
   ⇒ Using the same walkthrough form, the laboratory must conduct a self-evaluation. Findings and a corrective action plan must be submitted to CLIA Compliance.

VIII. Annual Compliance Walkthrough Elements

General (per test)

- FDA testing classification
- Package insert is available
- Package insert available in laboratory is the most current version
- Testing process follow manufactures' limitations
- Follow manufacturers' clinical guidelines/package insert
- A procedure is available in addition to the package insert
- Documentation present of initial and annual review of package insert/procedure by laboratory director
- Laboratory routinely examine new shipments for updated package inserts
- Number of tests performed per year

Specimen Handling and processing

- Specimen labeled with two identifiers
- Specimen type follows manufactures' guidelines
- Specimen collection follows Universal precautions
- Specimen is stored per manufacturer guidelines
Procedure
- During observation, the reagents are added in the order and amount required by the manufacturer
- During observation, the manufacturers' incubation requirements are followed
- During observation, the manufacturers' timing requirements are followed
- During observation, the manufacturers' procedural steps are followed

Kits/Reagent handling
- Reagents are stored per manufacturers' guidelines (temperature and humidity)
- The are no expired reagents in use
- Kits/reagents are labeled with received, open and expiration dates
- Old lot number reagents are not combined with new lot number

Quality Control
- QC is performed per manufacturers' guidelines
- There is documentation of internal quality control
- There is documentation external quality control
- QC results are documented and reviewed for acceptability before patient testing
- QC/Kit lot numbers are recorded
- QC is performed at frequency of manufacturers' guidelines
- If/when QC fails, there is documentation of QC corrective action
- Personnel understands and can detail action needed if QC fails
- QC logs are maintained for at least 2 years
- Laboratory Director signs QC logs monthly

Report Results
- Results are interpreted per manufacturer's recommendations
- Test result are documented in the patient's chart
- References ranges are reported with patient results
- Results are reported per manufactures' recommendations
- Testing personnel confirms patient results per package insert
- Personnel understands action to take with a critical result

Personnel training / education / competency
- Testing Personnel have documentation of initial training
- Testing Personnel have documentation of annual competency
- there is documentation of testing personnel reading package insert or procedure
- there is documentation of notification to testing personnel with changes
- There is a roster / list of testing personnel available to audit
- Testing personnel can identify unusual results and the required action
- Laboratory Director has signed acknowledgement of proficiency testing

Instrument function checks and maintenance
- There is documentation of current maintenance / function check records
- there is documentation of corrective action on instruments / equipment
- Maintenance logs are kept for the life of the instrument
- There is a list of error codes available
- Testing process follows manufacturers' guidelines for frequency of maintenance
- There is documentation of microscope maintenance / calibration
- There is documentation of routine cleaning of the microscope
- Documentation of Laboratory Director review of maintenance logs

PPM labs only
- Documentation of Proficiency Testing for all regulating analyte
• Documentation of highest education available (PPM Only)
• There is documentation of biannual quality assessment or PT for all tests
• All proficiency testing samples are handled as samples and not referred to other locations
• Competency assessment covering all 6 elements is performed for all testing personnel, including physicians

General Equipment Maintenance (per Instrument)
• Timers and thermometers are calibrated and documented
• Temperature is recorded daily for all refrigerators, freezers and incubators
• Laboratory refrigerators are clean; no food or beverage stored with specimens or reagents
• Reagent / Specimen refrigerator and freezers are labeled as biohazard
• Refrigerators are clean and defrosted
• There is a mechanism in place to detect when refrigerators go out of range

Record Retention is generally two years for most documentation. For complex laboratories, follow the regulations set forth by your regulating body.

IX. Notification of Non-compliance

If an issue that arises that has a potential effect on patient results, risks personnel safety, compromises laboratory quality or violates the rules of proficiency testing, any member of CLIA Compliance group will notify the chair immediately and the administrator of the testing location. Laboratory Compliance will investigate the issue. This issue could result from a walkthrough, through observation or from a complaint. The CLIA Compliance Committee will escalate the issue as deemed appropriate through legal, Medical Center Compliance, Medical Center Administration, Campus Compliance and/or any other necessary avenues to resolve the issue.

A summary of the results of the annual walkthrough will be provided to the laboratory director. A plan of correction for unsatisfactory elements must be submitted to the CLIA Oversight Committee within 30 calendar days of the receipt of the results of the annual walkthrough by the laboratory director.

Based on results of the laboratory walkthrough, the CLIA Compliance Committee may require more frequent monitoring and necessary actions to resolve identified issues. These action steps will be based on identified risk, severity of problem, and affect to patient results. Examples of monitoring steps can include, but not limited to: monthly review of quality control documentation; monthly review of temperature documentation; ongoing documentation of competency assessment and training; documentation of educational in-services or online training; documentation of review of laboratory procedures; review of proficiency testing and quality assessments; monthly audit of reference range; and monthly safety walkthrough document.

Failure to submit a written corrective action plan could result in suspension of testing of the rolling calendar. The CLIA Oversight Committee will review and approve plans of correction. If a plan of correction is not submitted, or not followed, the appropriate department chair, dean, other management or the Senior Vice President for Health Sciences will be notified and will receive a copy of the walkthrough.

X. Laboratory Directors

Laboratory Directors are responsible and accountable for adherence to the CLIA requirements for each laboratory for which they are the designated laboratory director. The name of the laboratory director responsible for the laboratory / health care facility is named on the CLIA certificate and indicated on the CMS116 application form.

XI. Resources

Clinical Laboratories Compliance Webpage: [https://clinicallabs.osumc.edu/Pages/Laboratory-Compliance-and-Accreditation.aspx](https://clinicallabs.osumc.edu/Pages/Laboratory-Compliance-and-Accreditation.aspx)


- Brochure #1 - How do they affect my laboratory?
- Brochure #2 - Verification of Performance Specifications
- Brochure #3 - Calibration and Calibration Verification
- Brochure #4 - Equivalent Quality Control Procedures
- Brochure #5 - How to Obtain a CLIA Certificate
- Brochure #6 - How to Obtain a CLIA Certificate of Waiver
- Brochure #7 - Laboratory Director Responsibilities
- Brochure #8 - Proficiency Testing
- Brochure #9 - Complaints, Do You Have a Concern About a Laboratory's Operation?
- Brochure #10 - What Do I Need to Do to Assess Personnel Competency?
- Brochure #11 - CLIA Individualized Quality Control Plan Introduction


Appendix A: Registration Form - 2015

Laboratory Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Location:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact Person:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Laboratory Director Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Office Location</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Highest Education Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Experience with Laboratory Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Laboratory Testing (please list or attach activity menu)

<table>
<thead>
<tr>
<th>Test</th>
<th>Manufacturer</th>
<th>CLIA Complexity</th>
<th>Specimen Used</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I agree to abide by all regulations established by CLIA. I understand that if these regulatory requirements are not met, this laboratory’s approval by the CLIA Compliance Committee to perform laboratory testing may be revoked. I agree that this laboratory will demonstrate satisfactory compliance with CLIA requirements as documented by an annual compliance walkthrough conducted by a representative from the CLIA Compliance Committee.

Laboratory Director Signature _____________________________ Date __________

Laboratory Director Name _____________________________

Please send completed form to: CLIA.compliance@osumc.edu
Appendix B: Laboratory Director Acknowledgment

ACKNOWLEDGMENT

Notification of CMS Rules for Proficiency Testing

I acknowledge receipt and review of this Notification of rules for Proficiency Testing from the OSU Clinical Laboratory and the included CLIA Brochure #8: CLIA Proficiency Testing – Do’s and Don’ts.


I understand that referral of proficiency testing samples to another laboratory for analysis is strictly prohibited. Consequences of intentional referral can include: loss of certification, loss of ability to own or operate a laboratory, civil monetary penalties and loss of ability to serve as laboratory director.

I understand that the University CLIA Compliance Committee is available to respond to any questions that I or any person in the clinical laboratory associated with this CLIA certificate may have about proficiency testing.

______________________________  ______________________________
Laboratory:                                             CLIA Number:

___________________________________________________
Laboratory Director Signature       Date

___________________________________________________
Laboratory Director Name

Please send completed form to: CLIA.compliance@osumc.edu
Appendix C: Initial / Annual Laboratory Compliance Walkthrough

<table>
<thead>
<tr>
<th>Laboratory:</th>
<th>Inspector:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab Address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLIA number:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLIA expiration date</td>
<td>current</td>
<td>Y</td>
</tr>
<tr>
<td>Name of Director on the CLIA license:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Director qualifications:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Directions: In the top row enter the laboratory test performed at your facility. Complete each box for each test on the checklist. Enter Met or Not Met in the box, if Not met fill in action to meet. If not applicable place NA in the box

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Comments / Action taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA testing classification</td>
<td></td>
</tr>
<tr>
<td>Package insert is available</td>
<td></td>
</tr>
<tr>
<td>Package insert available in laboratory is the most current version</td>
<td></td>
</tr>
<tr>
<td>Testing process follow manufactures' limitations</td>
<td></td>
</tr>
<tr>
<td>Follow manufacturers’ clinical guidelines/package insert</td>
<td></td>
</tr>
<tr>
<td>A procedure is available in addition to the package insert</td>
<td></td>
</tr>
<tr>
<td>Documentation present of initial and annual review of package insert/procedure by laboratory director</td>
<td></td>
</tr>
<tr>
<td>Laboratory routinely examine new shipments for updated package inserts</td>
<td></td>
</tr>
<tr>
<td>Number of tests performed per year</td>
<td></td>
</tr>
</tbody>
</table>

| Specimen Handling and processing | |
| Specimen labeled with two identifiers | |
| Specimen type follows manufacturers' guidelines | |
| Specimen collection follows Universal precautions | |
| Specimen is stored per manufacturer guidelines | |

<p>| Procedure | |
| During observation, the reagents are added in the order and amount required by the manufacturer | |
| During observation, the manufacturers’ incubation requirements are followed | |
| During observation, the manufacturers’ timing requirements are followed | |</p>
<table>
<thead>
<tr>
<th>Kits/Reagent Handling</th>
<th>During observation, the manufacturers’ procedural steps are followed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Kits/reagents are labeled with received, open and expiration dates</td>
</tr>
<tr>
<td></td>
<td>Old lot number reagents are not combined with new lot numbers</td>
</tr>
<tr>
<td>Reagents are stored per manufacturers’ guidelines (compare package insert with temperature logs)</td>
<td></td>
</tr>
<tr>
<td>There are no expired reagents in use</td>
<td></td>
</tr>
<tr>
<td>Quality Control</td>
<td>QC is performed per manufacturers’ guidelines</td>
</tr>
<tr>
<td></td>
<td>There is documentation of internal quality control</td>
</tr>
<tr>
<td></td>
<td>There is documentation of external quality control</td>
</tr>
<tr>
<td></td>
<td>QC results are documented and reviewed for acceptability before patient testing</td>
</tr>
<tr>
<td></td>
<td>QC/Kit lot numbers are recorded</td>
</tr>
<tr>
<td></td>
<td>QC is performed at frequency of manufacturers’ guidelines</td>
</tr>
<tr>
<td></td>
<td>If/when QC fails, there is documentation of QC corrective action</td>
</tr>
<tr>
<td></td>
<td>Personnel understands and can detail action needed if QC fails</td>
</tr>
<tr>
<td></td>
<td>QC logs are maintained for at least 2 years</td>
</tr>
<tr>
<td></td>
<td>Laboratory Director (or designee) signs QC logs monthly</td>
</tr>
<tr>
<td>Report Results</td>
<td>Results are interpreted per manufacturers’ recommendations</td>
</tr>
<tr>
<td>Test results are documented in the patient's chart</td>
<td></td>
</tr>
<tr>
<td>References ranges are reported with patient results</td>
<td></td>
</tr>
<tr>
<td>Results are reported per manufacturers’ recommendations</td>
<td></td>
</tr>
<tr>
<td>Testing personnel confirms patient results per package insert</td>
<td></td>
</tr>
<tr>
<td>Personnel understands action to take with a critical result</td>
<td></td>
</tr>
<tr>
<td>Personnel training / education / competency</td>
<td>Testing Personnel have documentation of initial training</td>
</tr>
<tr>
<td>Testing Personnel have documentation of annual competency</td>
<td></td>
</tr>
<tr>
<td>There is documentation of testing personnel reading package insert or procedure</td>
<td></td>
</tr>
<tr>
<td>Instrument function checks and maintenance</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>There is documentation of current maintenance / function check records</td>
<td></td>
</tr>
<tr>
<td>There is documentation of corrective action on instruments / equipment</td>
<td></td>
</tr>
<tr>
<td>Maintenance logs are kept for the life of the instrument</td>
<td></td>
</tr>
<tr>
<td>There is a list of error codes available</td>
<td></td>
</tr>
<tr>
<td>Testing process follows manufacturers’ guidelines for frequency of maintenance</td>
<td></td>
</tr>
<tr>
<td>There is documentation of microscope maintenance / calibration</td>
<td></td>
</tr>
<tr>
<td>There is documentation of routine cleaning of the microscope</td>
<td></td>
</tr>
<tr>
<td>Documentation of Laboratory Director (or designee) review of maintenance logs</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PPM labs only</th>
<th>Comments / Action taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Name</td>
<td></td>
</tr>
<tr>
<td>Documentation of Proficiency Testing for all regulating analytes</td>
<td></td>
</tr>
<tr>
<td>Documentation of highest education available (PPM Only)</td>
<td></td>
</tr>
<tr>
<td>There is documentation of biannual quality assessment or PT for all tests</td>
<td></td>
</tr>
<tr>
<td>All proficiency testing samples are handled as samples and not referred to other locations</td>
<td></td>
</tr>
<tr>
<td>Performed for all testing personnel, including physicians</td>
<td></td>
</tr>
</tbody>
</table>

*Directions: Complete each column with each piece of equipment*

<table>
<thead>
<tr>
<th>General Equipment Maintenance</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument:</td>
<td></td>
</tr>
<tr>
<td>Timers and thermometers are calibrated and documented</td>
<td></td>
</tr>
<tr>
<td>Temperature is recorded daily for all refrigerators, freezers and incubators</td>
<td></td>
</tr>
<tr>
<td>Laboratory refrigerators are clean; no food or beverage stored with specimens or reagents</td>
<td></td>
</tr>
<tr>
<td>Reagent / specimen refrigerator and freezers are labeled as biohazard</td>
<td></td>
</tr>
<tr>
<td>Refrigerators are clean and defrosted</td>
<td></td>
</tr>
<tr>
<td>There is a mechanism in place to detect when refrigerators go out of range</td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>---</td>
</tr>
</tbody>
</table>

Comments:

Required Actions:

Plan of Correction Needed: