# PROGRAM GUIDE - UNIVERSITY CLIA REGISTERED LABORATORIES COMPLIANCE COMMITTEE

**GUIDELINES - UNIVERSITY CLIA REGISTERED LABORATORIES COMPLIANCE COMMITTEE AND PROGRAM**

## 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 or review submitted documentation 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
10) Provide annual Laboratory Director training and education information
11) Provide educational resources to Laboratory Directors and laboratory contacts
12) 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.
13) 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
- Director, Compliance & Integrity, OSUWMC

- Ambulatory Testing Manager, OSUP
- Director of Outreach, Clinical Laboratories, OSUWMC
- Senior Director for Environmental Health and Safety, OSU
- Physician Representatives designated by Chair
- Research Representative designated by Chair
- Other individuals approved by Chair / Committee Members

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.

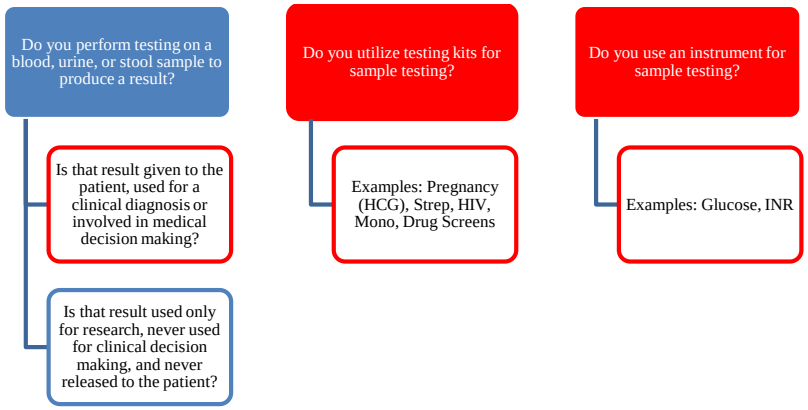
The core requirements for obtaining and maintaining a CLIA certificate include:

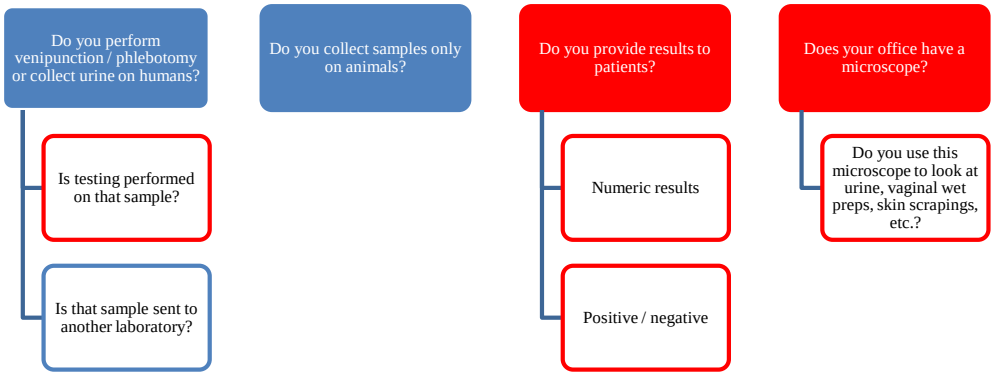
- The certificate must accurately reflect the laboratory testing being performed.
- Each person working in the laboratory must demonstrate and document adequate training and knowledge of proficiency testing.
- Maintaining thorough documentation of training, competency assessment, quality control and 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






**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

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 following 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.

**Joint Commission Requirements**

Testing performed in a provided based environment must also follow The Joint Commission standards. The waived testing chapter is directly applicable to laboratory testing. Refer to the current Joint Commission standards for current regulations.

## 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
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2nd Floor Columbus, OH 43215
(614) 644-1845
FAX: (614) 564-2478
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
2. Complete online learning through Buckeye Learning system
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 and Laboratory Key Contact Education (online)

2. Documentation of a current CLIA Certificate (maintained by Laboratory Compliance)

3. Annual Laboratory Compliance Walkthrough (elements listed below)

4. Documentation of a self-inspection, if deemed necessary by CLIA Compliance
   ⇨ 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

**Comment [SJV1]:** Removed old criteria and replaced with new walkthrough template

| INHERENT RISK OVERSIGHT | | | CONTROL RISK OVERSIGHT | |
|---|---|---|---|---|
| **Laboratory Oversight - POC / Compliance OSUP** | | | **Director Oversight: None / Minimal / Moderate / Thorough** | |
| **Circle the rating** | | | **Circle the rating** | |
| 5 | No direct nor indirect oversight for compliance/accreditation | | 25 | No laboratory director involvement |
| 4 | Minimal oversight through CLIA Compliance | | 20 | Minimal director involvement |
| 3 | Monitored through CLIA Compliance Process | | 15 | Laboratory director understands laboratory requirements, but takes limited action |
| 2 | Directly monitored by OSUP Laboratory Management or Laboratory Compliance | | 10 | Laboratory director understands and completes necessary requirements |
| 1 | Directly monitored by OSUP Laboratory Management or Laboratory Compliance, plus laboratory has designated individual for overseeing compliance/accreditation | | 5 | Laboratory director actively involved with all laboratory operations. |

| CONTROL ASSESSMENT | | | |
|---|---|---|---|
| **Policies and Procedures** | | **Risk rating (5 low - 25 High)** | |
| | | **Circle the rating: Policies and Procedures** | |
| **Policies and Procedures** | Documentation of initial & annual review of package insert/procedure by laboratory director | **25** | No policies or procedures |
| | A procedure is available in addition to the package insert | **20** | Policies/procedures exists but need updating, not consistent with the most current manufacturer guidelines |
| | Follow manufacturers' clinical guidelines / package insert | **15** | Updating of existing policies and procedures in progress |
| | Procedure states the manufacturer's frequency of QC. | **10** | Applicable policies / procedures established but not regularly updated or signed |
| | Procedure matches the manufacturer's package insert | **5** | Policies / Procedures established and regularly updated signed by medical director |
| | Timing in procedure matches manufacturer's package insert | | |
| | Incubation temperatures match manufacturer's package insert | | |
| **Safety (Patient and Laboratory)** | | **Risk rating (5 low-25 High)** | |
| | | **Circle the rating: Safety (Patient and Laboratory)** | |
| **Specimen handling and processing** | Specimen labeled with two identifiers | **25** | More than one incident of patient and/or safety incident in the laboratory |
| | Specimen collection follows Universal precautions | **20** | At least one instance of patient and/or safety incidence in laboratory |
| | Specimen type follows manufacturer's guidelines | **15** | Laboratory in process of improving safety practices |
| | Specimen is stored per manufacturer guidelines | **10** | No present negative impact on patient outcomes, but small improvements can be made in laboratory and patient safety |
| **Report Results** | Results are interpreted per manufacturer's recommendations | **5** | Employs safety laboratory practices through process and procedures; evidence of thorough and accurate patient results |
| | Test results are documented in the patient's (participants') records | | |
| | References ranges are available to staff | | |
| | Personnel understand action to take with a critical result or unusual result | | |
| | Traceability to reagent lot (Product recalls) | | |
| | Laboratory tracks patient safety reports (indicate number if applicable) | | |
| | Laboratory tracks misidentification occurrences (indicate number if applicable) | | |
| | Effective process for entering results (Manual / Electronic) - Manually entered tests are verified | | |
| | For manual tests the patient log includes documentation of: internal QC, reagent lot numbers, patient name and Identifiers, date, and who performed the test. | | |

| | | | |
|---|---|---|---|
| **Instrument function checks and maintenance/ EOC** | 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 instrument error codes available | | |
| | Testing process follows manufacturer's guidelines for frequency of maintenance | | |
| | Safety Shield is present | | |
| | Eye Wash Maintenance is documented | | |
| | Documentation of Laboratory Director (or designee) review of maintenance logs | | |
| | Timers and thermometers are calibrated | | |
| | 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 | | |
| | Waste containers are appropriately labeled and utilized | | |
| | Sharps containers are appropriately utilized and secured | | |
| | Safety occurrence tracking is effective. Number of occurrence, as applicable. | | |
| **Quality Control** | | **Risk rating (5 low-25 High)** | |
| | | **Circle the rating: Quality control** | |
| **Quality Control** | QC is performed per manufacturer's guidelines | **25** | No routine testing nor documentation of quality control |
| | There is documentation of internal quality control | **20** | Deviating from manufacturer guidelines; inconsistent documentation |
| | There is documentation of external quality control | **15** | Following manufacturer guidelines with inconsistent or missing documentation |
| | QC results are documented and reviewed for acceptability before patient testing | **10** | Following manufacturer guidelines with consistent documentation; no process in place for review |
| | QC/Kit lot numbers are recorded | **5** | Following manufacturer guidelines with consistent documentation; signed review |
| | 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 2 years | | |
| | Laboratory Director (or designee) signs QC logs monthly | | |
| **Testing Process** | | **Risk rating (5 low-25 High)** | |

| | | Circle the rating: Testing Process | |
|---|---|---|---|
| **Kit and Reagent Handling** | Reagents are stored per manufacturers' guidelines (compare package insert with temperature logs) | **25** | Performing additional or deviating from package insert (moderate or high testing) |
| | There are no expired reagents in use | **20** | Performing additional or deviating from package insert (waived testing) |
| | Kits/reagents are labeled with received, open and expiration dates | **15** | minimal deviation from packing insert that does not impact patient care |
| | Old lot number reagents are not combined with new lot numbers | **10** | Working on adapting procedures and process to meet all package insert guidelines |
| **Personnel Initial Training and Competency** | Medical Director is qualified<br>Lead is qualified | **5** | Follows package insert and only performs test within limitation of CLIA certificate |
| | Testing Personnel have documentation of initial training | | |
| | Training Checklist(s) are thorough and utilized | | |
| | Testing Personnel have documentation of annual competency | | |
| | Documentation of testing personnel knowledge of package insert or procedure | | |
| | There is documentation of notification to testing personnel with changes | | |
| | Personnel can answer procedural questions and demonstrate testing per manufacturer package insert | | |
| **PPM** | | **Risk rating (5 low-25 High)** | |
| **Personnel Initial Training and Competency** | Documentation of Proficiency Testing for all regulated analytes (Pin worm Prep) | **25** | Not meeting minimum PPM laboratory regulations, at risk for patient safety failures |
| | Documentation of highest education available (PPM Only) | **20** | Not meeting minimum PPM laboratory regulations |
| | Initial Training documentation for all personnel for each test | **15** | Inconsistent processes / policies for meeting PPM laboratory regulations |
| | Annual Competency 6 levels documented | **10** | Meets most and is improving processes / policies for meeting PPM laboratory regulations |
| **Maintenance** | There is documentation of routine cleaning of the microscope | **5** | Meets laboratory regulations for PPM testing |
| | There is documentation of microscope maintenance / calibration | | |
| **Quality Control** | Split sample daily peer review documented | | |
| | There is traceability for patient specimens | | |

IX. Risk Assessment

A risk assessment will be completed annually for each laboratory. The categories align with the walkthrough template.

**Inherent Risk Assessment**

**Impact**

| Rating | Financial | Reputational | Test Menu | Laboratory Oversight |
|---|---|---|---|---|
| 5 | >500K | CLIA sanctions could cause long-term impact to OSU/OSUP/OSUWC Brand | Test menu includes high complexity testing, including with laboratory developed testing | No direct nor indirect oversight for compliance/accreditation |
| 4 | 100K - 500K | CLIA sanctions could cause significant impact to OSU/OSUP/OSUWC Brand | Test menu includes high complexity testing | Minimal oversight through CLIA Compliance |
| 3 | 10K-100K | CLIA sanctions could cause Negative publicity, capable of being managed | Test menu includes moderate, PPM and waived testing only | Monitored through CLIA Compliance Process |
| 2 | 1K-10K | CLIA sanctions would cause minimal publicity, but no action would be necessary | Test menu includes moderate and waived testing only | Directly monitored by OSUP Laboratory Management or Laboratory Compliance |
| 1 | <1K | CLIA sanctions would cause no publicity | Test menu includes only waived testing | Directly monitored by OSUP Laboratory Management or Laboratory Compliance, plus laboratory has designated individual for overseeing compliance/accreditation |

**Controls Assessment**

| Rating | Policies / Procedures | Safety (Patient and Laboratory) | Quality Control | Director Oversight | Testing Process Observed During Walkthrough |
|---|---|---|---|---|---|
| 25 | No policies or procedures | More than one incident of patient and/or safety incident in the laboratory | No routine testing nor documentation of quality control | No laboratory director involvement | Performing additional or deviating from package insert (moderate or high testing) |
| 20 | Policies/procedures exists but need updating, not consistent with the most current manufacturer guidelines | At least one instance of patient and/or safety incidence in laboratory | Deviating from manufacturer guidelines; inconsistent documentation | Minimal director involvement | Performing additional or deviating from package insert (waived testing) |
| 15 | Updating of existing policies and procedures in progress | Laboratory in process of improving safety practices | Following manufacturer guidelines with inconsistent or missing documentation | Laboratory director understands laboratory requirements, but takes limited action | minimal deviation from packing insert that does not impact patient care |
| 10 | Applicable policies / procedures established but not regularly updated or signed | No present negative impact on patient outcomes, but small improvements can be made in laboratory and patient safety | Following manufacturer guidelines with consistent documentation; no process in place for review | Laboratory director understands and completes necessary requirements. | Working on adapting procedures and process to meet all package insert guidelines |
| 5 | Policies / Procedures established and regularly updated signed by medical director | Employs safety laboratory practices through process and procedures; evidence of thorough and accurate patient results | Following manufacturer guidelines with consistent documentation; signed review | Laboratory director actively involved with all laboratory operations | Follows package insert and only performs test within limitation of CLIA certificate |

**Walkthrough Schedule**

| Total Score | Walkthrough Schedule |
|---|---|
| <175 | Annually |
| 175-399 | Biannually |
| 400-499 | Quarterly |
| >499 | Monthly |

## X. 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.

## XI. 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.

## XII. Resources

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

FDA CLIA Complexity website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

CMS website on CLIA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

CLIA Brochures available from the CMS website:
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

- Brochure #1 - How do they affect my laboratory?
- Brochure #2 - Verification of Performance Specifications
- Brochure #3 - Calibration and Calibration Verification
- 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

Ready, Set, Test Booklet – available on the CDC website http://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx

ODH Website for CLIA: http://www.odh.ohio.gov/odhprograms/dspc/labcert/labcert1.aspx

**Registration Form (for use for new CLIA laboratories)-**

Laboratory Information

| | |
|---|---|
| Name | |
| Location: | |
| Contact Person: | |

Laboratory Director Information

| | |
|---|---|
| Name | |
| Office Location | |
| Highest Education Achieved | |
| Experience with Laboratory Testing | |

Laboratory Testing (please list or attach activity menu)

| Test | Manufacturer | CLIA Complexity | Specimen Used |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

*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