



OSPHL Laboratory Compliance Program



Clinical Laboratory Improvement Amendment CLIA
Health Screen Testing permit HST
Substance of Abuse SOA





▶ **Objective** The participants will learn about CLINICAL LABORATORY REGULATIONS

- ▶ Who we are, when to call and where to contact Laboratory Compliance Section for laboratory questions and concerns
- ▶ Different types of laboratory regulations and the specific requirements for each.
- ▶ Ultimate goal is to achieve and maintain sustainable laboratory compliance to ensure quality laboratory testing



Organizational chart

Public Health Division

Three Centers

1. Health Protection,
2. Prevention and Health Promotion and
3. Public Health Practice

OSPHL includes Virology/Immunology Section

General Microbiology Section

Newborn Screening Section

Laboratory Operations Section

Laboratory Compliance



Organizational chart LCS

Laboratory Compliance Section

Clinical Laboratory Regulation

- ▶ Clinical Laboratory Improvement Amendment (CLIA)
- ▶ Health Screen Testing Permit (HST)
- ▶ Substance of Abuse (SOA)

Environmental Laboratory Regulation

- ▶ Oregon Environmental Accreditation Program (ORELAP)



Who are we

- The Oregon Laboratory Compliance Section within the Oregon State Public Health Laboratory , contracts with the Centers for Medicare & Medicaid Service (CMS) to carry out the Clinical Laboratory Improvement Amendment (CLIA) in Oregon.
- Our office is the State Agency (SA) for CMS CLIA Region 10 Office (RO)
- Our staff is as followed: one full time CLIA inspector, one part time CLIA inspector, one full time Office Admin 2 and one Program Manager.
- General phone 503-693-4125
- General email lc.info@state.or.us website www.healthoregon.org/ll



What do we do

Our office regulates every Oregon clinical laboratory or facility that performs :

- ▶ A clinical laboratory test on human specimens for diagnosis, treatment of care, or health assessment and is 100% funded by federal CMS CLIA Grant **CLIA**
- ▶ Health screening or health fair testing (\$150.00/2 years) **HST**
- ▶ Non-medical (i.e. pre-employment, insurance qualification) substance of abuse testing (\$ 50.00/year) **SOA**



Laboratories in Oregon

Total CLIA Certificates permits registries 3,045

Total CLIA labs 2,787

Compliance Labs	266	10% onsite survey by SA
Accredited Labs	179	6% onsite survey by CAP, JC , COLA
PPMP Labs	617	22% no direct oversight
Waived Labs	1,725	62% minimal direct oversight


Fee Based Labs : 258

HST Permit	100
SOA Registry	158



Current Statistics-Enrollment

<u>CLIA total number of laboratories</u>	254,975	
<u>Total Non-Exempt</u>	246,650	
Compliance	18,385	7.5%
Accredited	16,441	6.6%
Provider Performed Microscopy	34,808	14.1%
Waived	177,016	71.8%
<u>Exempt</u>	<u>8,325</u>	
New York	4,256	
Washington	4,069	



The laboratory of the future moves outside the walls

An entity performing a test is defined by CLIA as a laboratory

- Article in MLO by Anthony Kurec (April 20, 2016) states that studies have concluded that 70% of medical decision-making is based on diagnostic laboratory testing, (reference #2)
- “The earliest published reference to the claim, and the one most frequently cited, is from 1996, by Forsman at the Mayo Clinic in the USA. the author states: ‘We know that, although the laboratory represents a small percentage of medical center costs, it leverages 60–70% of all critical decisions, e.g. admission, discharge and therapy’ ” (reference #3)



When to apply for a CLIA certificate

A CLIA certificate is required when at least one laboratory test is performed for the diagnosis, treatment or health assessment for a patient.

The Food and Drug Administration (FDA) determines the categorization of a test, not CMS CLIA

You may check the categorization of a test on the FDA website at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>

The Code of Federal Regulations (CFR) for the CLIA Standards /Conditions regulations are based on the two categories of tests: waived or non-waived
Which CLIA certificate is appropriate for you?



Types of CLIA certificates

Waived Tests:

- ▶ Certificate of Waiver (COW)

Non waived tests:

- ▶ Certificate of Provider Performed Microscopy Procedures (PPMP)
- ▶ Certificate of Compliance (COC)
- ▶ Certificate of Accreditation (COA)



CLIA requirements for waived testing

- ▶ Enroll in the CLIA program by obtaining a certificate;
- ▶ Pay the certificate fee (\$150.00) every two years;
- ▶ Follow the manufacturers' instructions for the waived tests you are performing;
- ▶ Notify our office (SA) of any changes in ownership, name, address or director within 30 days, or if you wish to add tests that are more complex; and
- ▶ Permit inspections by a CMS agent, such as a surveyor from the SA. However, your laboratory is not subject to a routine survey or inspection.



CDC reference booklet

Ready? Set? Test?

PATIENT TESTING IS IMPORTANT Get the right results.

Office of Surveillance, Epidemiology, and Laboratory Services
Laboratory Science, Policy, and Practice Program Office

<http://wwwn.cdc.gov/clia/Resources/WaivedTests/>



COW - Certificate of Waiver

Waived from:

- ▶ Personnel Standards
- ▶ Routine on-site inspections
- ▶ Proficiency testing requirements

Subject to:

- ▶ Inspections for complaints and if selected for random* inspection to validate only waived categorized tests are performed and manufacturer instructions are met
- ▶ Perform tests only at the written request of authorized provider



Authorized providers ORS 438.430(1)

Medical Doctor

Doctor of Osteopathy

Doctor of Podiatric Medicine

Physicians' Assistant

Doctor of Chiropractic Med

Naturopathic Doctor

Licensed Direct Entry Midwife

Doctor of Dental Science

Doctor of Medical Dentistry

Optometric Physicians

Certified Nurse Practitioner


Certified Nurse midwife

Certified RN Anesthetist

Clinical Nurse Specialist

Pharmacists for MTM

(Medication Therapy Management)



Policies for Written orders to perform a test

The laboratory must have a written policy that clearly identifies

- ▶ Who is the authorized provider to order tests to be performed under the CLIA certificate.
- ▶ The use of standing orders and what interval standing orders should be reconfirmed.
- ▶ Designate testing personnel signed off as trained and competent to perform the test(s)
- ▶ Results are released to the ordering provider responsible for using the test results to provide care to the patient.



Certificate of Waiver (COW)

As defined by CLIA, waived tests are categorized by the FDA as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. “

Currently Oregon has 62% COW labs performing waived tests with minimal oversight.

It is important to always follow the current test system's instructions precisely to be sure your results are accurate.

Failure to use the current instructions could cause inaccurate results that may result in a misdiagnosis or delay in proper treatment of a patient



follow the package insert

“Intended use” to “limitations of the procedure”

- ▶ To follow the manufacturer's instructions for performing the test means to follow all of the instructions in the product insert from “intended use” to “limitations of the procedure.”
- ▶ Test systems, assays and examinations that are waived, but are used in a manner that is inconsistent with manufacturer's instructions are considered high complexity meaning the laboratory is out of compliance- citation and Plan of Correction



State Surveyor survey findings

Top Waived Deficiencies found during survey

Not performing Quality Control required by Manufacturer

Do not have current package insert

Not using correct expiration date for storage method

Not reporting test results per manufacturer's instructions

Not following manufacturer' storage and handling instructions



Provider Performed Microscopy Procedures - PPMP

Facilities performing only tests indicated as “waived” AND “provider-performed microscopy procedures” (PPMP) must apply for a Certificate of PPMP

Director Qualifications are more stringent than the certificate of waiver. The director is legally liable and responsible for all aspects of testing and must meet one of the following qualifications:

- be a Physician, Dentist, Podiatrist or Physician Assistant licensed by the Board of Medical Examiners for the State of Oregon; or a Nurse Practitioner licensed and certified by the Oregon State Board of Nursing.



PPMP

Subject to:

- ▶ ORS 438.430(1) Perform tests only at the written request of an authorized provider
- ▶ Obtain a CLIA certificate and pay the appropriate fee
- ▶ PPMP certificate authorizes the facility to perform only waived and PPMP tests.
- ▶ Inspections for complaints and to validate that only waived and PPMP tests are performed and all other applicable requirements are met.



CDC reference booklet for PPMP

PROVIDER PERFORMED MICROSCOPY PROCEDURES

A Focus on Quality Practices

<http://wwwn.cdc.gov/clia/Resources/PPMP>

Division of Laboratory Systems

Center for Surveillance, Epidemiology, and Laboratory Services

<http://wwwn.cdc.gov/clia/Resources/PPMP>



PPMP applicable requirements

- Maintain a copy of the test order for 2 years (5 and 6 years for Medicare and Medicaid respectively).
- Perform only tests classified as waived or PPMP.
- Meet requirements for testing personnel: tests classified as PPMP may be performed only by an MD, DO, Podiatrist, Dentist, Certified NP
- Follow manufacturers' instructions for performance of waived tests including quality control (QC), calibration and instrument maintenance.



PPMP applicable requirements

- Provide written procedures for waived and PPMP test performance which have been approved by the laboratory director, and make readily available to testing personnel, CNM, or Physician Assistant. **Highly recommend the use of CDC reference booklet.
- Meet director qualifications
- Meet quality control requirements, if applicable
- Meet record and report requirements
- Meet quality assurance requirements



PPMP applicable requirements

Biannual verification and Competency

- ▶ Perform and document biannual verification or proficiency testing for any nonregulated analyte on the laboratory's test menu.
- ▶ Examples: blind testing of materials with known values, other external assessment programs, split samples , comparison with Kodachrome slides from a reference source. Most common and more practical, patient assessment.



PPMP applicable requirements

- Meet the Department's standards for safety and disposal of hazardous and infectious waste.
- Report communicable diseases and other reportable conditions to the local health department where the patient resides; the laboratory collecting the specimen and reporting to the physician/clinician is responsible for reporting; maintain a log of such reporting



PPMP requirements

Quality Control Requirements

- ▶ Waived test performance - follow manufacturers' instructions
- ▶ PPMP test performance - perform and document two levels of controls, covering the full range of expected results each day of testing, if controls are available.
- ▶ Photomicrographs or charts of all possible urine sediment components will meet the control requirement for manual microscopic urinalysis, KOH, fern examinations.



PPMP record and report requirements

Record and Report Requirements (Maintain records of the following)

- ▶ Training and experience of personnel performing laboratory tests
- ▶ Each specimen examined for two years including:
 - ▶ a. Name of person tested (or other identifier)
 - ▶ b. Name of authorized person requesting the test (written or electronic)
 - ▶ c. Date and time of specimen collection and test report



PPMP record and report requirements

- d. Type of test performed
- e. Test result
- f. Signature or identification of person performing the test
- g. Other information which may be needed to aid in interpretation of the result, and
- h. **Name and location of laboratory where the test was performed.**

Test Name	CPT Code	Type of Test
Direct wet mounts	Q0111	Presence or absence of bacteria, fungi, parasites and human cellular elements
Fecal leukocyte examination	89055	Presence or absence of WBC's in feces
Fern tests	Q0114	'Ferning' of cervical mucous
KOH preparation	Q0112	All potassium hydroxide preparations
Nasal smears for granulocytes	89190	Presence or absence of granulocytes
Pinworm examinations	Q0113	Presence or absence of Enterobius vermicularis
Post-coital direct, qualitative exams	Q0115	Examination of vaginal or cervical mucous

Test Name	CPT Code	Type of Test
Qualitative semen analysis (limited to presence or absence of sperm and motility)	G0027	Post vasectomy semen analysis
Urine sediment examinations: Microscopy- Dipstick and microscopy- Automated urinalysis with microscopy- non-automated UA 2 or 3 glass slides-	81015 81000 81001 81020	Presence or absence and quantitation of urine sediment



Certificate of Compliance - CoC Certificate of Accreditation - CoA

- Facilities performing tests not on the Waived and Provider Performed Microscopy Procedures (PPMP) lists must register and obtain a:
- Certificate of Compliance, pay the appropriate fees and meet more extensive requirements, or a
- Certificate of Accreditation- there are seven approved accreditation organizations with deeming authority under the Clinical Laboratory Improvement Amendments (CLIA); CAP, COLA, Joint Commission, American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), American Association for Laboratory Accreditation, AABB



HST - Health Screen Testing Permit

A CLIA certified laboratory may obtain a HST permit which allows the performance of the following 9 tests without an authorized provider order:

Blood hemoglobin

HDL

packed red cell volume

Triglyceride after a 12-16 hour fast

Total cholesterol

LDL using the Friedenwald auto
calculation equation

Blood glucose

Blood in feces

Human chorionic gonadotropin



HST

Note:

HgbA1C- glycated hemoglobin is not a screening test, and may not be performed with a HST permit even though it is a waived test.

Lead test may not be tested under a HST permit

Reminders :

Display a copy of the permit at each testing site.

Verify the test system has been FDA approved and complies with your CLIA certificate type.

A CLIA Waived lab can perform only waived tests.

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HST Director qualifications

Requirements include formal education and Clinical laboratory experience:

- ▶ MD, DO or PhD in a lab science plus 1 year pertinent lab experience; or
- ▶ Master of Science in medical technology or chemistry plus 2 years pertinent lab experience; or
- ▶ Bachelor in medical technology, chemistry or biochemistry or
- ▶ a licensed pharmacist plus 4 years pertinent lab experience.



HST

Specific Director responsibilities

- ▶ Notify our office of the test site schedule 15 days prior to testing
- ▶ Provide written procedures and make them readily available to testing personnel
- ▶ Follow manufacturer's instructions for calibration and instrument maintenance; maintain documentation
- ▶ Perform calibration and quality control each day of testing, for each new reagent lot used, at each location where test occurs.



HST

Specific Director responsibilities cont'd

- ▶ Ensure the integrity of the instrument, reagents and controls during transport and testing
- ▶ Develop and monitor a quality assurance (QA) plan covering all aspects of testing including the pre-analytical, analytical, and post-analytical phases of testing
- ▶ Maintain complete records for each specimen tests, including patient/client name, address, test results, QC, calibration and instrument maintenance shall be kept for 2 years



HST

Specific Director responsibilities cont'd

- ▶ Reporting requirements including the name and address of the health screen testing service on each test report.
- ▶ Maintain records on all testing personnel indicating laboratory training & experience
- ▶ Assure the public is aware that triglyceride testing can only be performed on a specimen after a person has fasted for 1-16 hours.
- ▶ Meet Public Health Department standards for safety, disposal of hazardous and infectious waste.



HST

Specific Director responsibilities con't

- ▶ Notify Laboratory Compliance of changes in owner, director, or permanent site; license is void 30 days after a change of owner, all director or location reapply for licensure in the aforementioned circumstances.
- ▶ Provide or contract for counseling and medical referral for each person tested.



SOA Substance of Abuse

Testing for Non-medical Substances of Abuse (SOA)

- An 'SOA Registration' entity is one that:
 - 1) Performs SOA screening tests on-site using easily portable simple hand-held manual methods; and
 - 2) The screening tests are used for non-medical purposes only, including but not limited to employment, pre-employment, screening of students, testing for insurance eligibility or eligibility for plasmapheresis.



SOA requirements

- Use only tests\kits approved by the Food and Drug Administration (FDA).
- Follow manufacturer's instructions for test performance (including, but not limited to, quality control and temperature, storage and testing requirements).
- Assure appropriate training of testing personnel by the test manufacturer
- Assure that specimens sent to reference laboratories outside of Oregon for confirmation testing are sent only to laboratories which meet or exceed Oregon law.



SOA requirements

- File a registration form with the Division prior to test performance
- Provide the location address and contact individual for all testing sites operated by the entity
- Pay the Division a registration fee of \$50 per entity, per year; fee cycle is January 1st through December 31st.
- Post evidence of registration with the Division in view of the clients, at each location where SOA testing occurs.
- Establish and follow chain of custody procedures.



SOA requirements

Submit the same specimen used to perform the drug screen,

- For confirmation testing, if the test result may be used to deprive or deny any client any employment or benefit or may otherwise result in adverse employment action (to a licensed clinical laboratory authorized by the Division to perform SOA confirmation tests).
- Assure that specimens sent to reference laboratories outside of Oregon for confirmation testing are sent only to laboratories which meet or exceed Oregon law.



Summary

- The objective of the CLIA program is to ensure quality laboratory testing. The evidence of compliance to the standards and conditions for quality laboratory testing is your documentation:
- Training records of testing personnel
- Monitoring storage temperature - room temp, refrigerator, freezer
- Tracking test kits, Quality Control and the lot number, expiration date for each.
- You represent the majority of the CLIA certificate holders, COW and PPMP and have minimal “direct” oversight.



summary

- You are the laboratory outside the walls. We are here to help you to ensure quality laboratory test results are reported for the optimal treatment, assessment of health or a diagnosis for your patients.



Attachments

Attachments

LeadCare II package insert yellow high lighter

LeadCare II QC log form

CMS Brochure #10 Competency

State Surveyor check list

Laboratory Tool



References

- 1. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/factype.pdf>
- 2. Medical Laboratory Observer MLO, The laboratory of the future moves outside the walls ,Anthony Kurec April 20, 2016
- 3. Forsman RW. Why is the laboratory an afterthought for managed care organizations? Clin Chem 1996;42:813–6
- Clinical Laboratory OAR 333-024-0005
- CFR federal regs <http://wwwn.cdc.gov/clia/Regulatory/default.aspx>
- Health Screen Testing HST OAR 333-024-0370
- Substance of Abuse OAR 333-024-0365