

Laboratory Compliance Program

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Synopsis of 42 CFR 493 and OAR 333-024-0005 thru 333-024-0055:

Certificate of 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 from the Centers for Medicare and Medicaid Services (CMS) in compliance with the Clinical Laboratory Improvement Amendments (CLIA) of 1988. These facilities must meet minimum requirements as indicated below. 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. Performance of PPMP tests by someone other than those indicated below requires applying for a Certificate of Compliance as a moderate complexity laboratory.

PPMP Laboratory Requirements

Director Qualifications

The director is legally liable and responsible for all aspects of testing and must meet one of the following qualifications:

- A physician (MD or DO) or podiatrist licensed to practice medicine by the Oregon Board of Medical Examiners.
- A dentist licensed by the Oregon Board of Dentistry.
- A nurse practitioner or nurse midwife licensed and certified by the Oregon Board of Nursing.
- A physician assistant licensed by the Oregon Board of Medical Examiners.

Subject to:

- ORS 438.430(1) Perform tests only at the written request of:
 - Medical Doctor
 - Doctor of Osteopathy
 - Optometric Physician
 - Doctor of Podiatric Medicine
 - Naturopathic Doctor
 - Doctor of Chiropractor Medicine
 - Doctor of Dental Science
 - Doctor of Medical Dentistry
 - Certified Nurse Practitioner
 - Certified Nurse Midwife
 - Licensed Direct Entry Midwife
 - Certified Registered Nurse Anesthetist
 - Clinical Nurse Specialist
 - Physician Assistant
 - Certified Registered Nurse Anesthetist
 - Pharmacist for Medication Therapy Management
- Obtain a CLIA certificate and pay the appropriate fee which 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.

- 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 a MD, DO, Podiatrist, Dentist, Certified NP, CNM, or Physician Assistant (performance by others requires certification for moderate complexity); tests classified as waived may be performed by any individual following appropriate training and documentation.
- Follow manufacturers' instructions for performance of waived tests including quality control (QC), calibration and instrument maintenance.
- Provide written procedures for waived and PPMP test performance which have been approved by the laboratory director, and make readily available to testing personnel.
- Meet director qualifications
- Meet quality control requirements, if applicable
- Meet record and report requirements
- Meet quality assurance requirements
- Perform and document biannual verification or proficiency testing for any nonregulated analyte on the laboratory's test menu.
- 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.
- Inform Laboratory Compliance Program of changes in **laboratory name, owner, director(s), or location** within 30 days after a change occurs.
- Apply for a CLIA Certificate of Compliance or Accreditation, pay the appropriate fees and meet the additional requirements prior to performing or reporting any test not specified on the waived or PPMP lists.

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.

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
 - 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.

Quality Assurance Requirements

The laboratory must establish and follow written policies and procedures for a comprehensive quality assurance (QA) program. It must be designed to monitor and evaluate the ongoing and overall quality of the total testing process (pre-analytic, analytic, post-analytic). The laboratory's QA program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff. All QA activities and corrective action must be documented and discussed with the pertinent staff.

The laboratory must monitor, evaluate and revise, if necessary, the following:

- Criteria for patient preparation, specimen collection, specimen rejection, labeling, preservation and transportation of specimens.
- Completeness and accuracy of test requisition, results, and other information for interpretation of test results.
- Accuracy and reliability of test reporting systems, storage of records and retrieval of results.
- Remedial action for problems in quality control data and errors in reported results;
- Policies and procedures for documenting competency of testing personnel at least every six months for the first year of employment, and then annually thereafter.
- Complaints and complaint policy.

Referral of Specimens

- Refer specimens only to laboratories operating in compliance with the Clinical Laboratory Improvement Amendments (CLIA).
- The referring laboratory must not revise results or information directly related to interpretation of results provided by the testing laboratory.

Exempt from

- Routine on-site inspections.

In compliance with the ADA this document is available in alternate formats by phoning 503-693-4100.