

Synopsis of CLIA Requirements for a Certificate of Waiver 42 CFR Part 493; OAR 333-024-0005 Thru 333-024-0055

Performance of even a single laboratory test on specimens derived from the human body for the purpose of diagnosis and treatment or assessment of health requires a Clinical Laboratory Improvement Amendments (CLIA) certificate. A facility performing *only* one waive test must apply for a Certificate of Waiver and meet minimum requirements as indicated below.

Facilities performing tests not on the waived list must:

- Prior to performing or reporting such test obtain a new CLIA certificate at a higher complexity level (provider performed microscopy procedures (PPMP), Certificate of Compliance (for moderate and high complexity testing) or a Certificate of Accreditation.
- Meet the additional requirements.
- Pay all applicable fees.

WAIVED FROM:

- Personnel standards
- Routine on-site inspections
- Proficiency testing requirements.

SUBJECT TO:

- Obtain a valid CLIA certificate and pay the appropriate fee (\$150) which authorizes performance of waived tests only for a period of up to two years.
- Inspections for compliance and to validate that only waived tests are performed and all other applicable requirements are met.
- Perform tests only at the written request of the following:
 - Medical Doctor
 - Doctor of Osteopathy
 - Doctor of Podiatric Medicine
 - Physician's Assistant
 - Doctor of Chiropractic Medicine
 - Naturopathic Doctor
 - Licensed Direct Entry Midwife
 - Doctor of Dental Science
 - Doctor of Medical Dentistry
 - Optometric Physicians
 - Certified Nurse Practitioner
 - Certified Nurse Midwife
 - Certified Registered Nurse Anesthetist
 - Clinical Nurse Specialist
- Maintain a copy of test requisition orders for 2 years (5 and 6 years for Medicare and Medicaid reimbursement).

- Perform only waived tests (see enclosed waived list).
- Follow manufacturer's instructions for test performance including quality control (QC), calibration & instrument maintenance.
- Provide written procedures for testing personnel and make readily available.
- Maintain complete records for each specimen tested, including QC, calibration and instrument maintenance for 2 years.
- Maintain records on all testing personnel indicating laboratory training & experience.
- Meet Department standards for safety, 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 to the local health department; maintain a log of such reporting.
- Inform Laboratory Compliance & Quality Assurance of changes in laboratory name, owner, director, or address within 30 days after a change occurs.
- Refer specimens only to laboratories operating in compliance with CLIA.
- The referring laboratory must not revise results or information directly related to interpretation of results provided by the testing laboratory.

In compliance with the ADA, this document is available in alternate formats by calling Laboratory Compliance (503) 693-4125.