

Synopsis of CLIA Requirements for a Certificate of Waiver 42 CFR Part 493

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 waived 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 (\$248) which authorizes performance of waived tests only for a period of up to two years.
- Inspections for complaints and random laboratory reviews to validate that only waived categorized tests are performed and manufacturer instructions are met.
- Perform tests only at the written request of the following, per Oregon Revised Statute 438.430(1):

- 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
- Pharmacists

- Perform only waived tests.
- Follow manufacturer's instructions for test performance including quality control (QC), calibration & instrument maintenance.
- 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 of changes in laboratory name, owner, director, or address within 30 days after a change occurs.

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