

Synopsis of OAR 333-024-0370 thru 333-024-0400
Health Screen Testing Permit

Health Screen Testing (HST) Laboratory Requirements

Performance of even a single laboratory test on specimens derived from the human body for the purpose of diagnosis, treatment or assessment of health requires licensure or certification or accreditation, under the Clinical Laboratory Improvement Amendments (CLIA). In addition, a laboratory may obtain a health screen testing (HST) permit which allows the performance of the following tests without a clinician's order: Blood hemoglobin, packed red cell volume, total cholesterol, blood glucose, blood in feces, human chorionic gonadotropin, HDL, Triglyceride after an individual fasts 12 to 16 hours, and LDL using the Friedenwald automatic calculation equation. The cost of an HST permit is \$150.00 for all laboratories. The permit expires on June 30 of even numbered years. For those laboratories only performing waived testing under their HST permit, a list of waived HST methods is available.

HST permit laboratories are EXEMPT from the following requirement:

- Clinicians' order

HST permit laboratories are SUBJECT to the following requirements:

- \$150.00 application fee
- Display a copy of the permit at each testing site
- Permanent location in Oregon for record review by the Department
- Announced routine inspections for compliance every two years; unannounced field inspections at any time or paper surveys

- Director requirements including formal education AND clinical laboratory experience:
 - MD, DO plus 1 yr pertinent lab experience; or PhD, Dr PH in chemistry plus 1 yr 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 plus 4 yrs pertinent lab experience
 - Specific Director responsibilities
 - Notify the Department of the test site schedule 15 days prior to testing
 - Perform only tests listed in opening paragraph
 - Provide written procedures and make them readily available to testing personnel
 - Follow manufacturer's instructions for calibration and instrument maintenance; maintain documentation
 - Perform quality control each day of testing, on each instrument, each new reagent lot used, with standards or controls which cover the full range of expected results, at each location where testing occurs
 - Subscribe to and successfully participate in proficiency testing for all non-waived tests
 - 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 tested, including patient/client name, address, test results, QC, calibration and instrument maintenance shall be kept for 2 years
 - 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
- Verify accuracy of test results a minimum of twice a year by any of the following methods: inter-lab comparison, or comparison with different instrument/methods, or proficiency testing
- Assure the public is aware that triglyceride testing can only be performed on a specimen after a person has fasted for 12 to 16 hours
- Meet Department standards for safety, disposal of hazardous and infectious waste
- Notify Laboratory Compliance of any additions or deletions of tests performed
- Notify Laboratory Compliance of changes in **owner, director, or permanent site**; license is void 30 days after a change of owner, all directors or location; reapply for licensure in the aforementioned circumstances
- Provide or contract for counseling and medical referral for each person tested

Note: In compliance with the Americans with Disabilities Act, this document is available in alternate formats by calling Laboratory Compliance Section 503-693-4100.