Health Screen Testing

333-024-0370

Purpose

OAR 333-024-0370 through 333-024-0400 are for the purpose of carrying out ORS 438.010(8); 438.060; 438.130(2); 438.150(5), (6) and (7). The purpose of the rules is to regulate the quality of health screen testing and to govern the issuance of permits to perform this type of testing.

Stat. Auth.: ORS 438.010(10), ORS 438.060, ORS 438.130(2), ORS 438.150(5), ORS 438.150(6) & ORS 438.150(7)
Stats. Implemented: ORS 438.060, ORS 438.130, ORS 438.150 & ORS 438.310
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0375

Definitions

Except as provided in this section, definitions in OAR 333-024-0010 are applicable to OAR 333-024-0370 through 333-024-0400. Additionally:

(1) "Clinician" means a nurse practitioner licensed and certified by the Oregon State Board of Nursing, or a physician assistant licensed by the Board of Medical Examiners for the State of Oregon.

(2) "Health Screen Testing" means tests performed without a physician's or clinicians's order for the purpose of identifying health risks, providing health information, and referring the person being tested to medical care.

(3) "Health Screen Testing Service" means a service providing health screen testing.

(4) "Health Screen Testing Site" means the permanent location, temporary site or mobile vehicle where health screen testing is performed.

(5) "Human Chorionic Gonadotropin (HCG)" means a hormone produced by the placenta which appears in serum and urine and may be an indication of pregnancy.

(6) "Operator" means the person (e.g., individual, corporation, political subdivision, etc.) which operates the health screen testing service.

(7) "Person" includes individuals, corporations, associations, firms, partnerships and joint stock companies.

(8) "Pertinent Laboratory Experience" means the activity of performing laboratory testing or directing the performance of testing in human clinical chemistry.

(9) "Site Day" means the 24-hour period during which, either all or part of the time, testing is performed at a specific location.

Stat. Auth.: ORS 438.010(10), ORS 438.060, ORS 438.130(2), ORS 438.150(5), ORS 438.150(6) & ORS 438.150(7)
Stats. Implemented: ORS 438.010, ORS 438.060, ORS 438.130 & ORS 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 6-1995, f. & cert. ef. 9-13-95; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0380

Permits

(1) Any person who operates a health screen testing service must obtain a permit from the Division.

(2) OAR 333-024-0370 through 333-024-0400 apply to all health screen testing services and their personnel within the State of Oregon except:

(a) Health screen testing services operated by the United States Government;

(b) Health screen testing performed in a physician's, or clinician's office for the purpose of diagnosis and treatment of their own patients;

(c) Health screen testing provided by an employer to employees if such employer contracts for the testingthrough a licensed physician, a clinical laboratory or a hospital, which is a health screen testing permittee of the Division;

(d) Screening provided by blood banks solely for assuring blood donor suitability;

(e) Health screen testing provided by local health departments; and

(f) Testing by grantee agencies for the purpose of establishing eligibility for programs administered by the Health Division of the Oregon Department of Human Resources.

(3) All out-of-state laboratories performing health screen testing services in Oregon must obtain a permit and meet requirements of OAR 333-024-0370 through OAR 333-024-0400.

(4) The Division will, upon application and payment of the required fee, issue and renew permits to the operators of health screen testing services who demonstrate to the satisfaction of the Division that:

(a) The health screen testing service is equipped to perform within the scope of its permit; and

(b) The health screen testing service meets the rules of the Division for quality assurance procedures, proficiency testing, personnel qualification and standards of counseling and referral of persons being served, as more particularly set out in OAR 333-024-0370 through 333-024-0400.

(5) The permit authorizes the operation of the health screen testing service at those health screen testing sites identified in the application and at those sites identified in compliance with OAR 333-024-0385.

(6) The health screen testing service must have a permanent location in Oregon where the Division may review records, policies and testing procedures. The permit shall be kept at the permanent location. A

copy of the permit shall be displayed at each testing site.

(7) A clinical laboratory certified under the **Clinical Laboratory Improvement Amendments of 1988 Code of Federal Regulations, Part 493 -- Laboratory Requirements**, must meet the requirements of 333-024-0370 through 333-024-0400 for health screen testing, and pay the fee as required in (10)(c) of this rule, in order to perform testing in Oregon without a physician's or clinician's order.

(8) All health screen testing performed outside of a licensed clinical laboratory must have a permit, with the exception of those who qualify for exemption under section (2) of this rule.

(9) Unless sooner suspended or revoked, all permit(s) issued under this section expire on June 30 of even numbered years.

(10) Requirements for permit application and renewal are as follows:

(a) Beginning on and after January 1, 2000, the application for a permit to operate a health screen testing service shall be received by the Division at least 45 days prior to initial testing;

(b) The application for a permit shall be made on forms provided by the Division and shall be executed by the operator or authorized representative of the operator of the health screen testing service. The application shall contain the name(s) of the operator, and officers if applicable, of the health screen testing service, the director, the permanent location, health screen testing sites then known and other information as the Division may require;

(c) Health screen testing services must pay a biennial, non-refundable permit fee of $150; and

(d) The health screen testing service must notify the Division of a change in owner, name or address of the permanent location within 30 days of the change.

(11) Permits may be suspended or revoked if the Division finds after hearing in accordance with ORS chapter 183 for contested cases that:

(a) The facts represented to and relied upon by the Division in issuing the permit are other than represented and relied on;

(b) The required fee has not been paid; or

(c) The operator or director of the health screen testing service has violated any provision of OAR 333-024-0375 through 333-024-0400.

(12) The health screen testing service must also be in compliance with requirements of the **Clinical Laboratory Improvement Amendments of 1988, 42 Code of Federal Regulations, Part 493 -- Laboratory Requirements**.

[Publications: The publication(s) referenced in this rule are available from the agency.]

Stat. Auth.: ORS 438.010(10), ORS 438.060, ORS 438.130(2) & ORS 438.150(5), ORS

438.150(6), ORS 438.150(7) & ORS 341, 1999 OL
Stats. Implemented: ORS 438.010, ORS 438.050, ORS 438.055, ORS 438.060, ORS 438.130 & ORS 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; OHD 5-1999, f. & cert. ef. 7-30-99; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0385

Testing Site Schedule

The health screen testing service shall, in writing, notify the Health Division, Center fir Public Health Laboratories of the proposed testing site schedule. The schedule must be received at the Public Health Laboratory ("CPHL"), 1717 SW Tenth Avenue, Portland, Oregon 97201 at least 15 days prior to testing at each site. All changes and cancellations regarding this schedule must be reported to the CPHL prior to testing date.

Stat. Auth.: ORS 438.010(10), ORS 438.060, ORS 438.130(2), ORS 438.150(5), ORS 438.150(6) & ORS 438.150(7)
Stats. Implemented: ORS 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 20-1994, f. & cert. ef. 7-20-94

333-024-0390

Personnel Qualifications and Responsibilities

(1) Each health screen testing service shall have a director who shall meet at least one of the following qualifications:

(a) Is a Medical Doctor (MD) or a Doctor of Osteopathy (DO) licensed to practice in Oregon and has one or more years of pertinent clinical laboratory experience;

(b) Has an earned Doctor of Science (ScD) or Doctor of Public Health (DrPH) or Doctor of Philosophy (PhD) degree in chemistry, biochemistry, or other closely related science from an accredited institution, and has one or more years of pertinent clinical laboratory experience;

(c) Has an earned Master of Science degree in medical technology, chemistry, biochemistry, or other closely related science from an accredited institution, and has two or more years of pertinent clinical laboratory experience;

(d) Has a Bachelor of Science, Bachelor of Technology, or Bachelor of Arts degree in Medical Technology, Chemistry, or Biochemistry, from an accredited institution, or is a licensed pharmacist, and has four or more years of pertinent clinical laboratory experience; or

(e) Has performed the duties of Director of a health screen testing service for at least six site days during the 12 months prior to January 1, 1990.

(2) The Director of a health screen testing service shall be responsible for the quality of the work. This

shall include, but not be limited to:

(a) Monthly review and documentation of quality control data and instrument maintenance;

(b) The review and documentation of all external proficiency testing, if applicable;

(c) Review and sign procedure manuals and relevant texts initially, and also whenever there is a new procedure, change in method or policy;

(d) Validation of new procedures prior to reporting test results;

(e) Assurance that personnel have received the training in the tests they perform. This shall include documentation of:

(A) Procedure Manual review;

(B) Collection techniques;

(C) Observation and performance of test procedures;

(D) Calibration, quality control, and routine maintenance of equipment;

(E) Waste disposal;

(F) Infection control;

(G) Emergency procedures;

(H) Methods to maintain patient confidentiality;

(I) Patient counseling; and

(J) Proficiency testing.

(f) Assurance that each person tested receives counseling and referral.

(3) Persons wishing to qualify as Director under subsection (1)(e) of this rule must apply to the Division by December 31, 1990.

(4) The laboratory director may direct no more than a total of five laboratories.

(5) Moderate complexity testing requires a technical and clinical consultant as defined in OAR 333-024-0023(1).

(A) A director qualifying under OAR 333-024-0022(1)(a, b, or c) may act as the technical consultant.

(B) A director qualifying under OAR 333-024-0022(1)(a) may act as the clinical consultant.

(6) Technical and clinical consultants must fulfill the responsibilities listed in OAR 333-024-0023(1).

(7) All testing personnel must have at least an academic high school diploma or equivalent.

Stat. Auth.: ORS 438.010(10), ORS 438.060, ORS 438.130(2), ORS 438.150(5), ORS 438.150(6) & ORS 438.150(7)
Stats. Implemented: ORS 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0395

Tests Performed

(1) The health screening testing service may perform only test procedures of waived or moderate complexity, as defined in OAR 333-024-010(24) and (16), from the following list of allowed tests.

(a) Blood hemoglobin;

(b) Packed red cell volume;

(c) Total cholesterol;

(d) Blood glucose;

(e) Blood in feces;

(f) Human chorionic gonadotropin;

(g) High density lipoprotein cholesterol. If the test is performed outside of a licensed clinical laboratory, only procedures not requiring a pre-precipitation step may be used;

(h) Triglyceride, only after an individual has fasted for 12 to 16 hours;

(i) Low density lipoprotein cholesterol by automated calculation using the Friedenwald equation.

(2) Permitted or licensed health screen testing services may perform testing defined in OAR 333-024-395(1) at the patient's request, without an order from a physician or clinician.

Stat. Auth.: ORS 438.010(10), ORS 438.060, ORS 438.130(2), ORS 438.150(5), ORS 438.150(6) & ORS 438.150(7)
Stats. Implemented: ORS 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; OHD 20-2001, f. & cert. ef. 9-14-01

333-024-0400

Quality Assurance

Quality Assurance shall be comprised of Internal Quality Control, Tests Reports and Records, Quality

Assurance Activities, Safety, External Quality Control, Counseling and Referral:

(1) Internal Quality Control:

(a) Documentation of training of testing personnel as specified in OAR 333-024-390(2)(e) shall be kept on file at the permanent location and made available to the Department at the health screen testing site;

(b) Laboratory procedure manuals and relevant reference materials for current screening methods shall be available for the use of the personnel at the health screen testing site and permanent location and include:

(A) Specimen collection requirements;

(B) Specimen labeling requirements;

(C) Specimen preservation requirements;

(D) Principle and instructions for test performance;

(E) Quality control requirements, including criteria for reporting tests;

(F) Equipment calibration and maintenance procedures;

(G) Normal ranges and test limitations.

(c) Procedure manuals shall be reviewed by the Director;

(d) Performance of each instrument shall be validated according to the manufacturer's specification at each new site;

(e) At each site, standards or controls shall be run which cover the range of expected results and be included at least once per day of use per instrument, per each reagent lot in use, unless the instrument is not moved, in which case it may qualify for external controls with each lot shipment of reagent cartridges per manufacturer's instructions;

(f) When control values are outside the established acceptable range, patient test results shall not be reported;

(g) The following shall be clearly stated and recorded: limits for controls; correction action taken when analyses are outside control limits, and the values for the standards;

(h) For each screening test, data shall be recorded and available to document confirmation of accuracy and precision at least once every six months for each instrument;

(i) Instrument maintenance, reagent storage, and test performance shall be performed according to manufacturer's instructions and recommendations;

(j) Records shall be recorded and retained at each site, with each instrument, for six site days, then

transferred to the permanent location for a period of at least two years for:

(A) Client results;

(B) Instrument performance and calibration if applicable;

(C) Quality control; and

(D) Preventive maintenance.

(k) If an instrument is borrowed, the testing permittee shall have the following information (for the past six site days) on each instrument:

(A) Instrument performance to include, but not be limited to, wavelength verification, linearity, and calibration, if applicable;

(B) Quality control; and

(C) Preventive maintenance.

(l) All reagents and solutions shall be labeled to indicate identity, preparation date, lot number, expiration date, and storage conditions as appropriate. No reagents or solutions may be used beyond their expiration date;

(m) All quality control and equipment maintenance records shall be reviewed by the Director each month of operation;

(2) Test reports and records shall include:

(a) Name and address of health screen testing service;

(b) Patient name and results of tests performed;

(c) Date test performed;

(d) Expected ranges;

(e) Initials of individual performing tests;

(f) If indicated, fasting or non-fasting;

(g) Documentation of referral to a licensed physician or clinician for counseling per section (6) of this rule if results are outside expected normal ranges;

(h) Health Screen Testing services must maintain records of patient name, address and test values for at least 2 years;

(i) Health Screen Testing laboratories performing moderate complexity testing must comply with the rules in OAR 333-024-026(12,13) and OAR 333-024-035(1) and (2).

(3) Quality assurance activities:

(a) If the laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(b) If a laboratory performs tests that are not included in an approved proficiency testing program, the laboratory must have a system for verifying the accuracy of its test results at least twice a year.

(c) The health screen testing service shall establish a quality assurance plan and monitors; and document quality assurance activities for test reporting and referral, quality control assessment and annual personnel competency.

(d) Any health screen testing service which tests for triglycerides must clearly display at the testing site a notice that triglyceride testing can only be performed after an individual has fasted for 12 to 16 hours.

(4) Safety: Permitted health screen testing services shall assure that:

(a) Eating, drinking, smoking, or applying cosmetics are prohibited at the bench where specimen collection and sample testing is performed;

(b) Laboratory coats or other protective clothing are worn by health screen testing personnel;

(c) Skin puncture sites are cleansed with an appropriate disinfectant;

(d) Gloves designed for medical use for bloodborne pathogen protection are worn during the skin puncture and changed between clients;

(e) Gloves designed for medical use for bloodborne pathogen protection are worn during specimen handling and testing;

(f) Used lancets, needles and blood tubes are disposed of in impervious biohazard labeled containers;

(g) Other potentially infectious materials are disposed of in a biohazard labeled container; refer to the infectious waste rules under 333-018-0040 through 333-018-0070;

(h) Electrical equipment is maintained in a safe condition with regards to shock and fire hazards;

(i) Work surfaces are disinfected with a virucidal reagent after each blood spill, and prior to and after each day of testing.

(5) External Quality Control:

(a) Permitted health screen testing services shall:

(A) Assure proficiency testing is performed on each moderate or high complexity regulated analyte listed in the **Clinical Laboratory Improvement Amendments of 1988 (CLIA)**, **Subpart I**, available

on request from the Department.

(B) Meet the proficiency testing requirements as described in **CLIA 88**, **42 CFR**, **Part 493**, **Subpart H**, available on request from the Department.

(C) Analyze test samples submitted by the Department prior to, during, or subsequent to inspection if requested by the Department and achieve a score of at least 80 percent.

(D) Notify the Department within six months if the analysis of a test has been discontinued or added to patient testing.

(E) Notify the Department of change of director, owner, name, and address of the permanent location within 30 days of the change.

(b) Surveys for compliance will be performed either onsite or as paper surveys and the entity will be required to submit documentation to the Department that quality control and quality assurance activities and test records meet this rule. Onsite inspections may be conducted by representatives of the Department at reasonable times during the health screen testing service's normal business hours without advance notice. The representative shall review the personnel policies, procedures, staff qualifications/training, equipment records, quality control, reports, specimen handling and waste disposal, as related to health screen testing activities.

(c) Additional inspections may be performed by the Department or HCFA without notice to verify correction of deficiencies, investigate complaints, review unsatisfactory proficiency testing, perform validation surveys, verify personnel qualifications or other monitoring of compliance with OAR 333-024-0370 through 333-024-0400.

(6) Counseling and Referral: The health screen testing service shall provide or contract for counseling and medical referral policies for each person tested and shall include:

(a) The ranges of results expected for that test;

(b) The value or test range that is recommended nationally for each test performed;

(c) A list of possible health risks associated with abnormal results;

(d) The recommended action which a person should follow if the test results are outside the expected value or range; and

(e) Procedures and follow-up for critical values.

Stat. Auth.: ORS 438.010(10), ORS 438.060, ORS 438.130(2), ORS 438.150(5), ORS 438.150(6) & ORS 438.150(7)
Stats. Implemented: ORS 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f & cert. ef. 9-13-95; OHD 9-2000, f. & cert. ef. 11-3-00; OHD 20-2001, f. & cert. ef. 9-14-01