OFFICE OF THE SECRETARY OF STATE
TOBIAS READ
SECRETARY OF STATE

MICHAEL KAPLAN
DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

FILED
03/18/2026 1:04 PM
ARCHIVES DIVISION
SECRETARY OF STATE

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Update to administrative rules for Clinical Laboratories

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 04/21/2026 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Steve Jetter
503-505-2672
publichealth.rules@odhsoha.oregon.gov

7202 NE Evergreen Parkway
Hillsboro,OR 97124

Filed By:
Public Health Division
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 04/21/2026
TIME: 11:00 AM
OFFICER: Staff

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 971-277-2343
CONFERENCE ID: 305968904
SPECIAL INSTRUCTIONS:
This hearing is being held remotely via Microsoft Teams. To provide oral (spoken) testimony during this hearing, please contact publichealth.rules@odhsoha.oregon.gov to register to receive the link for the Microsoft Teams video conference via calendar appointment, or you may access the hearing using the meeting URL above. Alternatively, you may dial 971-277-2343, Phone Conference ID 305 968 904# for audio (listen) only. This hearing will close no later than 12:00PM (noon) but may close as early as 11:30AM if everyone who signs up to provide testimony has been heard from.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsoha.oregon.gov at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can meet the need.

NEED FOR THE RULE(S)

The purpose of these rules is for carrying out ORS chapter 438 to ensure the quality of medical laboratory work by

establishing a regulatory program. The proposed rule changes are to align with changes to statute from the passage of SB 844 (Oregon Laws 2025, chapter 624) in the 2025 legislative session. The statute changes in SB 844 removed reference to an outdated clinical laboratory licensing program which was replaced in the early 2000s when Oregon adopted the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Subsequently, amendments are needed to administrative rules in chapter 333, division 24 to remove references to this unused clinical licensing program, associated fees, and associated definitions, as well as to update language to align with the federal CLIA terminology. Statutes regarding Substances of Abuse testing laboratories and Health Screen Testing facilities were also updated with the passage of SB 844 to change the terms 'registration' or 'license' to 'permit' and therefore administrative rule amendments are needed to align with this change. Some references to state and federal entities were also outdated and are being updated to reflect current names.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

SB 844 (Oregon Laws 2025, chapter 624, sec. 26-40):
https://olis.oregonlegislature.gov/liz/2025R1/Downloads/MeasureDocument/SB844

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

These changes to administrative rule do not represent an actual change in practice, as the agency has been implementing the CLIA program in place of the state licensing program since the early 2000s. Because of this, it is anticipated that there will be a neutral impact on racial equity as a result of these proposed rule changes.

FISCAL AND ECONOMIC IMPACT:

There is no anticipated fiscal or economic impact by these proposed rule changes since the changes are to align with statute and reflect current practice.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) There is no anticipated cost of compliance impact to state agencies, units of local government or the public as a result of these rule changes.

(2)(a) Approximately 3700 clinical laboratories are operated as small businesses in the State of Oregon. There is no anticipated change to the cost of compliance to small businesses as a result of these rule changes.

(b) There is no anticipated change to reporting, recordkeeping or other administrative activities required for compliance with these proposed rules.

(c) There is no anticipated change to equipment, supplies, labor or increased administration required for compliance with these proposed rules.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved with the development of the proposed rules because the rule changes are to align with changes made to statute by the Oregon Legislature. The laboratory community was previously consulted in the development of the legislative concept that was introduced as SB 844 in the 2025 Oregon legislative session.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

A rule advisory committee was not consulted because these rule amendments are in response to a legislative action and the rule updates are not subject to interpretation.

RULES PROPOSED:
333-024-0005, 333-024-0010, 333-024-0012, 333-024-0016, 333-024-0020, 333-024-0021, 333-024-0022, 333-024-0026, 333-024-0035, 333-024-0037, 333-024-0040, 333-024-0043, 333-024-0045, 333-024-0050, 333-024-0053, 333-024-0055, 333-024-0315, 333-024-0320, 333-024-0325, 333-024-0330, 333-024-0340, 333-024-0345, 333-024-0360, 333-024-0365, 333-024-0370, 333-024-0375, 333-024-0380, 333-024-0390, 333-024-0395, 333-024-0400

AMEND: 333-024-0005

RULE SUMMARY: OAR 333-024-0005 is being amended with minor editorial changes.

CHANGES TO RULE:

333-024-0005
Purpose ¶

These rules (OAR 333-024-0005 through 333-024-0055 and 333-024-0260 and 333-024-0265) are for the purpose of carrying out ORS ~~C~~chapter 438~~, the declarative purpose of which is to i~~o ensure the quality of medical laboratory work in order to protect the health and welfare of the people of the State of Oregon by establishing a regulatory program for clinical laboratories.
Statutory/Other Authority: ORS 438.450
Statutes/Other Implemented: ORS~~ 438.030,~~ 438.450

AMEND: 333-024-0010

RULE SUMMARY: OAR 333-024-0010 definitions are amended to align with changes in statute due to the passage of SB 844 (Oregon Laws 2025, chapter 624) and to update reference to state and federal entities. Minor editorial changes are also made.

CHANGES TO RULE:

333-024-0010
Definitions ¶

(1) "Accredited college or university" as used in ~~the Act~~ORS chapter 438 and OAR 333-024-0021 means the accreditation by a nationally recognized accrediting agency or association ~~as determined by~~including any foreign institution of higher education the~~at~~ U.S. ~~Commis~~Health and Human Services or its de~~si~~~~o~~gne~~r of Education.~~e determines meets substantially equivalent requirements. ¶
(2) "Approved accreditation organization" for laboratories means a private, nonprofit association that has formally received the ~~Health Care Financing Administration's~~U.S. Centers for Medicare and Medicaid Service's (CMS) approval.¶
(3) "Accreditation" means a certificate obtained from a non-profit organization that has met the standards as established by the ~~Health Care Financing Administration~~U.S. Centers for Medicare and Medicaid Service (CMS) and approved by the Public Health Division.¶
(4) "Clinical laboratory" or "laboratory" means a facility where the microbiological, serological, toxicological, chemical, hematological, immunological, immunohematological, cytological, pathological, histological, cytogenetical, or other examinations are performed on materials derived from the human body, for the purpose of diagnosis, prevention of disease or treatment of patients by physicians, dentists and other persons who are authorized by license to diagnose or treat humans.¶
(5) "CLIA 88" means the Clinical Laboratory Improvement Amendments of 1988 including the rules that implement the law as published in Section 42 Code of Federal Regulations, Part 493, Laboratory Requirements, February 28, 1992 and January 19, 1993 as amended and revised.¶
(6) "Clinical laboratory specialty" or "laboratory specialty" means the examination of materials derived from the human body for the purpose of diagnosis and treatment of patients, or assessment of health, employing one of the following sciences: microbiology, chemistry, diagnostic immunology, toxicology, cytogenetics, hematology, immunohematology, histocompatibility, cytology, histopathology, or oral pathology.¶
(7) "Clinician" means a nurse practitioner licensed and certified by the Oregon State Board of Nursing, or a physician associate licensed by the ~~Board of~~Oregon Medical ~~Examiners for the State of Oregon~~Board.¶
(8) "Dentist" means a person licensed to practice dentistry by the Oregon Board of Dentistry.¶
(9) "Director of clinical laboratory" or "~~D~~director" means the person who plans, organizes, directs and participates in any or all of the technical operations of a clinical laboratory, including but not limited to reviewing laboratory procedures and their results, training and supervising laboratory personnel, and evaluating the technical competency of such personnel.¶
(10) "Division" means the Public Health Division of the Oregon Health Authority.¶
(11) "Health ~~S~~screen ~~T~~testing" means tests performed for the purpose of identifying health risks, providing health information and referring the person being tested to medical care.¶
(12) "High complexity laboratory" means a facility that performs testing classified as highly complex in the specialties of microbiology, chemistry, hematology, diagnostic immunology, immunohematology, clinical cytogenetics, cytology, histopathology, oral pathology, radiobioassay and histocompatibility and may also perform moderate complexity tests, physician performed microscopy procedures and waived tests.¶
(13) "High complexity test" means a procedure performed on materials derived from the human body that meet the criteria for this category of testing in the specialties of microbiology, chemistry, hematology, immunohematology, diagnostic immunology, clinical cytogenetics, cytology, histopathology, oral pathology, radiobioassay and histocompatibility as established by the ~~Health Care Financing Administration~~ U.S. Centers for Medicare and Medicaid Service (CMS)and the U.S. Centers for Disease Control and Prevention.¶
(14) "Laboratory evaluation system" means a system of testing clinical laboratory methods, procedures and proficiency by periodic performance and reporting on test specimens submitted for examination.¶
(15) "Moderate complexity laboratory" means a facility that performs testing classified as moderately complex in the specialties of microbiology, hematology, chemistry, immunohematology or diagnostic immunology and may also perform any physician performed microscopy procedure and waived test.¶
(16) "Moderate complexity test" means a procedure performed on materials derived from the human body that meet the criteria for this category of testing in the specialties of microbiology, hematology, chemistry,

immunohematology or diagnostic immunology as established by the ~~Health Care Financing Administration~~ U.S. Centers for Medicare and Medicaid Service (CMS)and the U.S. Centers for Disease Control and Prevention.¶
(17) "Owner of a clinical laboratory" means the individual(s), corporation, association, firm, partnership, joint stock companies, or a county, state or municipality owning and operating a clinical laboratory.¶
(18) "Pertinent clinical laboratory experience" or "pertinent experience" as used in ~~the Act~~ORS chapter 438 and OAR 333-024-0021 and OAR 333-024-0022 means laboratory experience gained in a clinical laboratory performing or supervising the same types of laboratory tests as those in common use for the specific specialty involved.¶
(19) "Physician" means a person licensed to practice medicine by the ~~Board of~~Oregon Medical ~~Examiners for the State of Oregon~~Board.¶
(20) "Physician performed microscopy procedure" means a test as defined in OAR 333-024-0016(1)(b) which is personally performed by a physician or other clinician during a patient's visit on a specimen obtained during the examination of the patient.¶
(21) "Specimen" means materials derived from a human being or body.¶
(22) ~~"The Act" as used in OAR 333-024-0005 through 333-024-0055 and 333-024-0260 and 333-024-0265 means Oregon Revised Statutes, Chapter 438.¶~~
~~(23)~~ "Waived laboratory" means a facility that performs only tests as defined in OAR 333-024-0016(1)(a) that are so simple and accurate as to render the likelihood of erroneous results negligible.¶
(24~~3~~) "Waived test" means tests that are so simple and accurate as to render the likelihood of erroneous results negligible, or tests which are categorized as waived for ~~CLIA~~clinical laboratories, by the ~~Health Care Financing Administration and~~U.S. Department of Health and Human Services (HHS)and the U.S. Centers for Disease Control and Prevention.
Statutory/Other Authority: ORS 433.017, 438.010
Statutes/Other Implemented: ORS 438.010-320, 438.430, 438.435, 438.510

AMEND: 333-024-0012

RULE SUMMARY: OAR 333-024-0012 is being amended with minor editorial changes, to update terminology and to update reference to state and federal entities. The changes also remove reference to the outdated state license program including associated application requirements and fees, replacing the references to state license with federal certificate.

CHANGES TO RULE:

333-024-0012
~~Licensure~~ Certification ¶

(1) It shall be unlawful:¶
(a) For any ~~O~~owner or ~~D~~director of a clinical laboratory to operate or maintain a clinical laboratory without a ~~licens~~certificate or without a temporary permit issued under this rule or to perform or permit the performance of any laboratory specialty for which the laboratory is not ~~licens~~certified, unless the laboratory has been issued a valid certificate from the federal government under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, Public Law 100-578, 42.U.S.C. 201 and 263a, except as specified herein;¶
(b) For any person to serve in the capacity of ~~D~~director of a high complexity clinical laboratory without being qualified as a ~~C~~clinical ~~L~~laboratory ~~D~~director under OAR 333-024-0021;¶
(c) For any person to serve in the capacity of ~~D~~director of a moderate complexity clinical laboratory without being qualified as a ~~C~~clinical ~~L~~laboratory ~~D~~director under OAR 333-024-0022; and¶
(d) For any person other than a physician or clinician to direct or perform microscopic procedures listed in OAR 333-024-0016(1)(b) in a ~~P~~physician ~~P~~performed ~~M~~microscopy ~~L~~laboratory.¶
(2) OAR 333-024-0005 through 333-024-0055 and OAR 333-024-0260 and OAR 333-024-0265 apply to all clinical laboratories and laboratory personnel within the State of Oregon, except:¶
(a) Clinical laboratories operated by the United States ~~G~~government; or¶
(b) Clinical laboratories operated and maintained purely for research or teaching purposes, and that involve no patient or public health services.¶
(3) It shall be unlawful for an out-of-state laboratory to perform health screen testing in Oregon without a permit issued as provided in OAR 333-024-0380.¶
(4) The ~~Division shall~~Public Health Division (Division) shall facilitate the issuance and ~~renew~~facilitate the renewal of waived, physician performed microscopy, moderate and high complexity ~~licens~~certificates for any or all clinical laboratory specialties to the ~~O~~owners of clinical laboratories who demonstrate to the satisfaction of the Division that:¶
(a) The clinical laboratory is in compliance with the Clinical Laboratory Improvement Amendments of 1988 (P.L 100-578, 42 U.S.C 201 and 263a) and OAR 333-024-0005 through 333-024-0055, OAR 333-024-0260, OAR 333-024-0265, OAR 333-024-0305 through 333-024-0360 and OAR 333-024-0370 through 333-024-0400;¶
(b) The laboratory is equipped to perform within the scope of its ~~licens~~certificate;¶
(c) The clinical laboratory retains complete laboratory records as stated in OAR 333-024-0050; and¶
(d) The clinical laboratory meets the standards of the Division for safety, disposal of hazardous and infectious waste, ventilation, handling of specimens, and maintenance of equipment to ensure protection of the public health.¶
(5) ~~Requirements for license application, fees, exemptions, expiration, and renewal are as follows:¶~~
~~(a) The application for a license for a clinical laboratory shall be made on forms provided by the Division and shall be executed by the Owner or one of the Owners or by an officer of the firm or corporation owning the clinical laboratory, or in the case of a county or municipality, by the public official responsible for operation of the laboratory, or in the case of an institution, by the administrator of the institution. The application shall contain the names of the Owner, the Director or Directors of the clinical laboratory, the location and physical description of the clinical laboratory, the laboratory specialties for which a license is requested, and such other information as the Division may require:¶~~
~~(A) Not-for-profit, or state, or local government laboratories that engage in limited public health testing may file a single application, provided they have the same owner and director. They may perform a combined total of fifteen test methods listed in the waived, physician performed microscopy and moderate complexity category.¶~~
~~(B) Laboratories that are located at the same site and are under the same director may file a single application.¶~~
~~(b) Laboratories must pay an annual or biennial, non-refundable license fee prior to issuance of a license or permit. Numbers in the fee category indicate the number of tests performed annually; count tests on patient/client specimens only. Count the number of tests in each profile. Do not count waived tests, physician-performed microscopy by physicians and clinicians, standards, controls, calculated tests, or proficiency testing samples.~~

~~Effective July 1, 1999, the annual fees are:¶~~
~~(A) Waived - Accredited and Non-Accredited - $71;¶~~
~~(B) Physician Performed Microscopy (PPM) - Accredited and Non-Accredited - $95;¶~~
~~(C) Non-Accredited Moderate and High Complexity:¶~~
~~(i) Low Volume A (LVA) 1-2,000 tests - $261;¶~~
~~(ii) A - 2,001 to 10,000 tests; d 3 specialties - $517;¶~~
~~(iii) B - 2,001 to 10,000 tests; e 4 specialties - $650;¶~~
~~(iv) C - 10,001 to 25,000 tests; d 3 specialties - $916;¶~~
~~(v) D - 10,001 to 25,000 tests; e 4 specialties - $1,037;¶~~
~~(vi) E - 25,001 to 50,000 tests - $1,254;¶~~
~~(vii) F - 50,001 to 75,000 tests - $1,584;¶~~
~~(viii) G - 75,001 to 100,000 tests - $1,914;¶~~
~~(ix) H - 100,001 to 500,000 tests - $2,263;¶~~
~~(x) I - 500,001 to 1,000,000 tests - $4,365;¶~~
~~(xi) J - > 1,000,000 tests - $5,298.¶~~
~~(D) Accredited Moderate and High Complexity:¶~~
~~(i) Low Volume A (LVA) 1-2,000 tests - $118;¶~~
~~(ii) A - 2,001 to 10,000 tests; d 3 specialties - $138;¶~~
~~(iii) B - 2,001 to 10,000 tests; e 4 specialties - $145;¶~~
~~(iv) C - 10,001 to 25,000 tests; d 3 specialties - $285;¶~~
~~(v) D - 10,001 to 25,000 tests; e 4 specialties - $295;¶~~
~~(vi) E - 25,001 to 50,000 tests - $401;¶~~
~~(vii) F - 50,001 to 75,000 tests - $620;¶~~
~~(viii) G - 75,001 to 100,000 tests - $840;¶~~
~~(ix) H - 100,001 to 500,000 tests - $1,078;¶~~
~~(x) I - 500,001 to 1,000,000 tests - $3,070;¶~~
~~(xi) J - > 1,000,000 tests - $3,893.¶~~
~~(c) Laboratories must pay an annual or biennial, non-refundable license fee prior to issuance of a license or permit. Numbers in the fee category indicate the number of tests performed annually; count tests on patient/client specimens only. Count the number of tests in each profile. Do not count waived tests, physician-performed microscopy by physicians and clinicians, standards, controls, calculated tests, or proficiency testing samples.~~
~~Effective July 1, 2000, the annual fees are:¶~~
~~(A) Waived - Accredited and Non-Accredited - $75;¶~~
~~(B) Physician Performed Microscopy (PPM) - Accredited and Non-Accredited - $100;¶~~
~~(C) Non-Accredited Moderate and High Complexity:¶~~
~~(i) Low Volume A (LVA) 1-2,000 tests - $275;¶~~
~~(ii) A - 2,001 to 10,000 tests; d 3 specialties - $545;¶~~
~~(iii) B - 2,001 to 10,000 tests; e 4 specialties - $685;¶~~
~~(iv) C - 10,001 to 25,000 tests; d 3 specialties - $965;¶~~
~~(v) D - 10,001 to 25,000 tests; e 4 specialties - $1,092;¶~~
~~(vi) E - 25,001 to 50,000 tests - $1,320;¶~~
~~(vii) F - 50,001 to 75,000 tests - $1,667;¶~~
~~(viii) G - 75,001 to 100,000 tests - $2,015;¶~~
~~(ix) H - 100,001 to 500,000 tests - $2,382;¶~~
~~(x) I - 500,001 to 1,000,000 tests - $4,595;¶~~
~~(xi) J - > 1,000,000 tests - $5,577.¶~~
~~(D) Accredited Moderate and High Complexity:¶~~
~~(i) Low Volume A (LVA) 1-2,000 tests - $125;¶~~
~~(ii) A - 2,001 to 10,000 tests; d 3 specialties - $146;¶~~
~~(iii) B - 2,001 to 10,000 tests; e 4 specialties - $153;¶~~
~~(iv) C - 10,001 to 25,000 tests; d 3 specialties - $300;¶~~
~~(v) D - 10,001 to 25,000 tests; e 4 specialties - $311;¶~~
~~(vi) E - 25,001 to 50,000 tests - $422;¶~~
~~(vii) F - 50,001 to 75,000 tests - $653;¶~~
~~(viii) G - 75,001 to 100,000 tests - $884;¶~~
~~(ix) H - 100,001 to 500,000 tests - $1,136;¶~~
~~(x) I - 500,001 to 1,000,000 tests - $3,232;¶~~
~~(xi) J - > 1,000,000 tests - $4,098.¶~~
~~(d) A prorated fee may be assessed for a license that will be in effect for a year or less;¶~~

~~(e) Unless sooner voided, suspended or revoked, all licenses issued under this section expire on June 30 of the one or two year cycle following the date of issuance and shall be renewable in the manner prescribed by the Division;¶~~
~~(f) All monies received by the Division for the licensure of clinical laboratories shall be credited to the Division account and shall be used for payment of the expenses of the Division in administering OAR 333-024-0005 through 333-024-0055 and 333-024-0260 and 333-024-0265.¶~~
~~(6) A license issued to the Owner of a clinical laboratory shall show on its face the names of the Owners and Directors, the location of the laboratory and the clinical laboratory specialties authorized under the license. The license shall be displayed at all times in a prominent place in the laboratory.¶~~
~~(7) A license issued to the Owner of a clinical laboratory is not transferable. The license of the laboratory is voided 30 days after a change of its Director if it has only one Director or if all Directors change or a change in the ownership or in the location of the laboratory. Upon the death of a laboratory's Director and the immediate notification to the Division, the Division shall be empowered to issue, after the payment of the proper fee, a special temporary permit. This permit shall be of 30 days' duration and issued to an approved substitute Director. If a license is voided or a special temporary permit is issued under this rule, a new license application, accompanied by the non-refundable license fee prescribed in subsection (4)(b) of this rule shall be filed with the Division.¶~~
~~(8) Temporary permit requirements are as follow:¶~~
~~(a) In addition to the license of a clinical laboratory required by this rule, the Division may issue a temporary permit, valid for 45 days from the date of issuance, in any or all clinical laboratory specialties upon payment of the respective required fees as prescribed in subsection (5)(b) or (5)(c) of this rule;¶~~
~~(b) In issuing the temporary permit, the Division may require that:¶~~
~~(A) Plans for compliance with applicable laws and rules be submitted with the application for temporary permit;¶~~
~~(B) During the period in which the temporary permit is in effect, periodic reports be submitted on the progress of the plans for compliance; and¶~~
~~(C) Temporary provisions specified by the Division upon application of the temporary permit be maintained for the protection of the public.¶~~
~~(c) If at any time the Division determines that the clinical laboratory can no longer operate in a manner which protects the public health and safety or that the requirements imposed under paragraphs (7)(b)(A), (B) and (C) of this rule are not being maintained, the Division shall cancel the temporary permit;¶~~
~~(d) One renewal of the temporary permit may be granted if deemed to be in the best interest of public health by the Division. The fee for renewal is the respective required fee as prescribed in subsection (4)(b) of this rule.¶~~
~~(9) Subject to ORS 183.310 to 183.550, the Division may refuse to issue or renew the license or may suspend or revoke the licens~~Subject to ORS 183.160 and ORS 183.310 to 186.450, the Division may refuse to facilitate the issuance or facilitate the renewal of the certificate or may suspend or revoke the certificate of any clinical laboratory, if it finds that the ~~O~~owner or ~~D~~director has:¶
(a) Intentionally made false statements on an application for a clinical laboratory ~~licens~~certificate or any other documents required by the Division, or made any misrepresentation in seeking to obtain or retain a ~~licens~~certificate;¶
(b) Demonstrated incompetence as defined in OAR 333-024-0055;¶
(c) Intentionally falsified any report;¶
(d) Referred a specimen for examination to ~~an unlicensed clinical laboratory in this State unless the laboratory is exempt from the application of this rule, or~~ a clinical laboratory not certified or accredited under the provisions of ~~CLIA 88~~ORS 438.040, or other authorized CLIA exempt state laboratory certification program;¶
(e) Misrepresented the scope of laboratory service offered by the clinical laboratory or the clinical laboratory specialties authorized by the ~~licens~~certificate;¶
(f) Rendered a report on clinical laboratory work actually performed in another clinical laboratory without designating the name and address of the clinical laboratory in which the test was performed;¶
(g) Knowingly had professional connection with or permitted the use of the name of the ~~licens~~certified clinical laboratory or its ~~D~~director by a clinical laboratory that is required to but has not obtained a ~~licens~~certificate;¶
(h) Failed to perform or cause to be performed within the time specified analysis of test samples as stated in OAR 333-024-0040(1) or failed to report on the results of such analysis within the specified time;¶
(i) Failed to permit within a reasonable time the entry or inspection as stated in OAR 333-024-0040(4), (6), (7), (9), (10), (11) and (12);¶
(j) Failed to continue to meet requirements of this rule, inclusive;¶
(k) Violated any provision of OAR 333-024-0005 through 333-024-0055 and OAR 333-024-0260 and OAR 333-024-0265.¶
(~~10~~6) The owner or director must notify the Division within 30 days of a change of laboratory name and technical supervisor.¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 433.017, 438.010, 438.040, 438.~~055~~160

Statutes/Other Implemented: ORS 438.040~~ - 438.055~~, 438.1~~3~~10 - 438.~~16~~45~~0~~0

AMEND: 333-024-0016

RULE SUMMARY: OAR 333-024-0016 is being amended with minor editorial changes, to update terminology (remove license, replace with certificate) and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0016
~~Licensure~~Certification Categories ¶

(1) The four categories of clinical laboratories are:¶
(a) A waived laboratory which may perform only the following; dipstick or tablet reagent urinalysis (nonautomated), fecal occult blood, ovulation test-visual color comparison tests for human luteinizing hormone, urine pregnancy test-visual color comparison tests, erythrocyte sedimentation rate (nonautomated), hemoglobin-copper sulfate (nonautomated), blood glucose (by glucose monitoring devices cleared by the U.S. Food and Drug Administration specifically for home use), spun microhematocrit, and hemoglobin and glucose by Hemocue, Chemtrak Accumeter cholesterol, body fluid occult blood, nitrazine pH paper for all body fluids except blood or any other tests which are categorized as waived for ~~CLIA~~clinical laboratories, by the ~~Health Care Financing Administration and~~U.S. Department of Health and Human Services (HHS) and the U.S. Centers for Disease Control and Prevention:¶
(A) A waived laboratory is exempt from personnel requirements, proficiency testing and routine on-site inspections~~;~~.¶
(B) A waived laboratory shall follow manufacturer's instructions for test performance~~:~~.¶
(b) A physician performed microscopy procedure laboratory which may perform only tests in the waived category and the following: wet mounts (for presence or absence of bacteria, fungi, parasites and human cellular elements), all potassium hydroxide (KOH) preparations, pinworm examinations, fern tests, post-coital direct examinations of vaginal or cervical mucus, nasal smears for granulocytes, qualitative post-vasectomy semen analysis limited to presence or absence of sperm and motility, fecal leukocyte examinations, and urine sediment examinations, or any other tests which are categorized as provider-performed microscopy procedures for ~~CLIA~~clinical laboratories, by the ~~Health Care Financing Administration and~~U.S. Department of Health and Human Services (HHS)and the U.S. Centers for Disease Control and Prevention:¶
(A) A physician performed microscopy laboratory is exempt from routine on-site inspections;¶
(B) A physician performed microscopy laboratory shall follow manufacturer's instructions for test performance; and¶
(C) A physician performed microscopy laboratory shall meet the applicable requirements for quality control, proficiency testing, quality assurance, records and reports.¶
(c) A moderate complexity laboratory which may perform waived, physician performed microscopy procedures, and tests identified as moderate complexity by the ~~Health Care Financing Administration~~U.S. Department of Health and Human Services (HHS) and the U.S. Centers for Disease Control and Prevention;¶
(d) A high complexity laboratory which may perform all categories of testing including the specialties of cytogenetics, cytology, pathology, histocompatibility and radiobioassay.¶
(2) Any test not listed in the waived, physician performed microscopy procedures or moderate complexity category is high complexity.¶
(3) The category of any test may be obtained from the Public Health Division.
Statutory/Other Authority: ORS 438.~~11~~040
Statutes/Other Implemented: ORS 438.~~11~~040

AMEND: 333-024-0020

RULE SUMMARY: OAR 333-024-0020 is being amended with minor editorial changes and to update terminology (remove license, replace with certificate or permit).

CHANGES TO RULE:

333-024-0020
~~Licensure~~Certification for Performance of Laboratory Specialties ¶

(1) ~~Licensure~~Certification for the performance of surgical pathology, autopsy pathology, exfoliative cytology, and immunohematology (except as provided in section (4) of this rule) shall be granted only to a laboratory whose ~~D~~director is a physician or dentist specifically qualified in these fields.¶
(2) A clinical laboratory testing for substances of abuse shall be ~~licens~~permitted under ORS 438.435~~(4)~~ and comply with OAR 333-024-0305 through 333-024-0350, except when performing tests for the purpose of diagnosis, prevention of disease or treatment of patients by physicians, dentists and other persons who are authorized by license to diagnose or treat humans.¶
(3) ~~Licensure~~A permit for the performance of substances of abuse testing in clinical laboratories shall be granted only to a laboratory whose ~~D~~director qualifies under OAR 333-024-0320(1).
Statutory/Other Authority: ORS 438.~~120~~040, ORS 438.435
Statutes/Other Implemented: ORS 438.~~120~~040, ORS 438.435

AMEND: 333-024-0021

RULE SUMMARY: OAR 333-024-0021 is being amended with minor editorial changes and to remove outdated language to align with changes in statute due to the passage of SB 844 (Oregon Laws 2025, chapter 624) and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0021
Qualifications and Responsibilities of Directors for High Complexity Laboratories ¶

(1) The ~~D~~director shall meet at least one of the qualifications defined by the following:¶
(a) Is a pathologist certified in clinical or anatomical pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or is eligible for such certification (~~B~~board eligible);¶
(b) Is certified or board eligible by the American Board of Oral and Maxillofacial Pathology. An oral pathologist shall only direct an oral pathology laboratory;¶
(c) Is a physician who:¶
(A) Is eligible for certification by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Society of Cytology, the American Board of Dermatology, or other national accrediting board related to a laboratory specialty as may be approved by the ~~Division~~Public Health Division (Division); and¶
(B) Has had two or more years of general laboratory training and experience.¶
(d) Has an earned degree of Doctor of Science, Doctor of Public Health, or Doctor of Philosophy or an acceptable degree, as determined by the Division, from an accredited college or university with a major in the chemical, physical, or biological sciences and possesses special qualifications as follows: is certified or is eligible for certification by the American Board of Medical Microbiology, American Board of Bioanalysis, the American Board of Clinical Chemistry, or other national accrediting board related to a laboratory specialty or possesses other special qualifications as approved by the Division; and has one or more years of experience supervising high complexity testing;¶
(e) ~~Was responsible for the direction of a clinical laboratory for at least 12 months within the five years preceding January 1, 1970, and has had at least two years of pertinent clinical laboratory experience as determined by the Division;¶~~
~~(f)~~ Was serving as a laboratory director in Oregon and either previously qualified or could have qualified as a laboratory director in Oregon on or before February 28, 1992, and is a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine, and has two or more years of general laboratory training or experience; or¶
(~~g~~f) Was qualified as a clinical laboratory director under federal regulations prior to February 28, 1992.¶
(2) A person is qualified to act as the laboratory ~~D~~director of the clinical laboratory only at any accredited chiropractic college in this ~~S~~state for the benefit of chiropractic patients if that person is a chiropractic physician licensed by the ~~State~~Oregon Board of Chiropractic Examiners, and possesses special qualifications, as determined by the ~~State~~Oregon Board of Chiropractic Examiners, which enable that person to perform as a laboratory ~~D~~director.¶
(3) The ~~D~~director shall supervise or perform only in those specialties for which qualified.¶
(4) The ~~D~~director is responsible for the overall operation and administration of the laboratory, including the employment of competent personnel, equipment, safety, quality assurance, all testing (including proficiency testing) and test reports.¶
(a) The laboratory director may, if qualified, perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities in writing to other qualified individuals; and ensure that all duties are properly performed; and must be accessible to provide on site, telephone or electronic consultation;¶
(b) The laboratory director may direct no more than five laboratories;¶
(c) The laboratory director must ensure:¶
(A) Quality services for all aspects of test performance;¶
(B) Environmental conditions provide a safe testing site;¶
(C) Test methodologies provide accurate results;¶
(D) Verification procedures are used to determine the accuracy, precision, and other pertinent performance characteristics of the method;¶
(E) Laboratory personnel perform only director approved methods;¶
(F) The laboratory is enrolled in an approved proficiency testing program if required;¶
(G) The proficiency test samples shall be tested in the same manner as patient specimens, results returned within established time frames, reviewed by the director or designate, and corrective action taken, if necessary.¶

(H) Quality control and quality assurance programs are established and maintained;¶
(I) Acceptable levels of analytical performance for each test are established and maintained;¶
(J) That all necessary remedial actions are taken and documented whenever necessary and patient test results are reported only when the system is functioning properly;¶
(K) That test results include pertinent information required for interpretation;¶
(L) That consultation is available to the laboratory's clients, if applicable;¶
(M) That a general supervisor provides on-site supervision of high complexity test performance by qualified testing personnel;¶
(N) The employment of a sufficient number of qualified personnel to provide consultation, supervision and accurate test performance and report test results in accordance with their personnel responsibilities;¶
(O) That policies and procedures are established to monitor the competency of the individuals performing the testing and provide remedial training or education as needed;¶
(P) That an approved procedure manual is available to all testing personnel; ~~and~~¶
(Q) The duties and responsibilities of each consultant, supervisor and each testing personnel are specified in writing; and¶
(R) All personnel have appropriate training.
Statutory/Other Authority: ORS 438.~~210~~,040, ORS 438.220
Statutes/Other Implemented: ORS 438.~~210~~,040, ORS 438.220

AMEND: 333-024-0022

RULE SUMMARY: OAR 333-024-0022 is being amended with minor editorial changes.

CHANGES TO RULE:

333-024-0022
Qualifications and Responsibilities for Director of Moderate Complexity Laboratories ¶

(1) The director shall meet at least one of the qualifications in OAR 333-024-0021 or one of the following:¶
(a) Is a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine; and¶
(A) Has one or more years of directing or supervising non-waived laboratory testing; or¶
(B) Has at least 20 continuing medical education credit hours in laboratory practice; or¶
(C) Has ~~1~~one year of laboratory training in non-waived testing during a residency.¶
(b) Has earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and¶
(A) Has at least one year of pertinent laboratory training or experience; and¶
(B) Has at least one year of supervisory laboratory experience in non-waived testing.¶
(c) Has earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and¶
(A) Has at least ~~2~~two years of laboratory training or experience, or both in non-waived testing; and¶
(B) Has at least ~~2~~two years of supervisory laboratory experience in non-waived testing.¶
(2) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of competent personnel, equipment, safety, quality assurance, all testing including proficiency testing, and test reports:¶
(a) The laboratory director may, if qualified, perform the duties of the technical consultant, clinical consultant, and testing personnel or delegate these responsibilities in writing to other qualified individuals; and must ensure that all duties are properly performed, and must be accessible to provide on-site, telephone or electronic consultation;¶
(b) The laboratory director may direct no more than five laboratories;¶
(c) The director must ensure:¶
(A) Quality services for aspects of test performance;¶
(B) Environmental conditions provide a safe testing site;¶
(C) Test methodologies provide accurate results;¶
(D) Verification procedures are used to determine the accuracy, precision, and other pertinent performance characteristics of the method;¶
(E) Laboratory personnel perform only director approved methods;¶
(F) The laboratory is enrolled in an approved proficiency testing program if required;¶
(G) The proficiency test samples shall be tested in the same manner as patient specimens, results returned within established time frames, reviewed by the director or designate, and corrective action taken, if necessary;¶
(H) Quality control and quality assurance programs are established and maintained;¶
(I) Acceptable levels of analytical performance for each test are established and maintained;¶
(J) That all necessary remedial actions are taken and documented whenever necessary and patient test results are reported only when the system is functioning properly;¶
(K) That test results include pertinent information required for interpretation;¶
(L) That consultation is available to the laboratory's clients, if applicable;¶
(M) The employment of a sufficient number of qualified personnel to provide consultation, supervision and accurate test performance and report test results in accordance with their personnel responsibilities;¶
(N) That policies and procedures are established to monitor the competency of the individuals performing the testing and provide remedial training, or education as needed;¶
(O) That an approved procedure manual is available to all testing personnel;¶
(P) The duties and responsibilities of each consultant and each testing personnel are specified in writing; and¶
(Q) All personnel have appropriate training.
Statutory/Other Authority: ORS 438.~~210~~,040, ORS 438.220
Statutes/Other Implemented: ORS 438.~~210~~,040, ORS 438.220

AMEND: 333-024-0026

RULE SUMMARY: OAR 333-024-0026 is being amended with minor editorial changes and to remove outdated language and dates to align with changes in statute due to the passage of SB 844 (Oregon Laws 2025, chapter 624).

CHANGES TO RULE:

333-024-0026
Equipment and Facilities ¶

(1) All equipment shall be maintained in good working order, checked routinely, and precisely calibrated according to manufacturer's requirements or a minimum of every six months.¶
(2) Work bench space shall be ample, clean, well-organized, well-lighted, and convenient to sink, water and electrical outlets.¶
(3) The laboratory shall be ventilated to protect the health of the personnel and patients against accidental release of hazardous vapors or aerosols.¶
(4) Laboratory procedure manuals and policies shall be available for the use of the personnel in the laboratory and shall be reviewed by the ~~D~~director initially and when there is a change in methods or policy.¶
(5) The premises shall be free from unnecessary physical, chemical, and biological hazards. All materials containing pathogenic organisms shall be:¶
(a) Autoclaved at 121º~~C~~degrees Celsius for 30 minutes to ensure nonviability prior to being discarded; or¶
(b) Incinerated in a ~~S~~state-approved incinerator; or¶
(c) Disposed using another Public Health Division approved method.¶
(6) Safety precautions must be posted and observed.¶
(7) Glassware shall be free from excessive scratches and cloudiness and graduations must be legible. "To contain" and "to deliver" pipettes are to be kept separated. Cleanliness of glassware must be adequate for the purpose for which it is used.¶
(8) Blood-letting lancets, needles, and syringes, if not sterile and disposable, shall be sterilized prior to each use by standard and accepted methods. Each sterilizing cycle shall contain a satisfactory indicating device to assure proper sterilization.¶
(9) Electrical equipment shall be maintained in a safe condition with regards to shock and fire hazards. All electrical equipment, except battery operated, shall be grounded. Protective fuses shall not be bypassed.¶
(10) Caustic, explosive, and flammable materials shall carry labels to indicate their nature and shall be placed in containers and stored in locations which are suitable to ensure stability, purity, and safety as is necessary regarding the material involved.¶
(11) The laboratory shall define, establish and document a function check and maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and result reporting.¶
(12) Requirements for calibration and calibration verification for laboratories performing unmodified moderate complexity test procedures that are performed using instruments, kits, or test systems that have been cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) or Premarket Approval (PMA) process:¶
~~(a) Until September 1, 1996, the laboratory must meet the requirements in OAR 333-024-0035(1)(c) and (f);¶~~
~~(b) After September 1, 1996, the laboratory~~ must meet the requirements in OAR 333-024-0026(13). ¶
(13) Requirements for calibration and calibration verification for laboratories performing high complexity testing procedures, tests not cleared by the FDA through the 510(k) or PMA process, modified moderate complexity testing:¶
(a) The laboratory must:¶
(A) Establish the number, type, and concentration of calibration materials required to assure accurate and reliable test results;¶
(B) Establish the frequency and acceptable limits for calibration and calibration verification, if not provided by the manufacturer; and¶
(C) Use calibration materials appropriate for the methodology, and if possible, traceable to a reference method or reference material of known value~~; and.~~¶
(b) The laboratory must perform and document calibration:¶
(A) At the frequency required by the manufacturer;¶
(B) In accordance with criteria established by the laboratory, if more frequent than manufacturer's requirements; and¶
(C) When calibration verification fails to meet the laboratory's acceptable limits for calibration verification.¶
(c) The laboratory must perform calibration verification to verify the laboratory's established reportable range for patient test values using calibration or control materials, including at least a minimal value (zero), a mid-point

value, and a maximum value at the upper limit of that range:¶
(A) When a complete change of reagents is introduced;¶
(B) When there is a major preventative maintenance or replacement of critical parts that may influence test performance;¶
(C) When controls reflect an unusual trend or shift or are outside the laboratory's acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem; and¶
(D) At least once every six months, unless the laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.¶
(d) Calibration and calibration verification must meet the laboratory's acceptable ranges prior to patient test reporting; and¶
(e) Calibration and calibration verification documentation must be maintained for a minimum of two years.
Statutory/Other Authority: ORS 438.~~110, 438.32~~040
Statutes/Other Implemented: ORS 438.~~110, 438.32~~040

AMEND: 333-024-0035

RULE SUMMARY: OAR 333-024-0035 is being amended with minor editorial changes and to remove outdated language and dates to align with changes in statute due to the passage of SB 844 (Oregon Laws 2025, chapter 624) and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0035
Internal Quality Control for Moderate and High Complexity Laboratories ¶

(1) Laboratories that perform testing using unmodified, moderate complexity test systems, cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) or Premarket Approval (PMA) process must~~, until September 1, 1996:~~¶
~~(a) Follow the manufacturer's instructions for test system operation and test performance;~~¶
~~(b) Have a procedure manual as defined in OAR 333-024-0035(4);~~¶
~~(c) Perform and document control procedures using at least two levels of control materials each day of testing;~~¶
~~(d) Perform and document applicable specialty and subspecialty control procedures as specified in OAR 333-024-0037;~~¶
~~(e) Follow the manufacturer's instructions for calibration:~~¶
~~(A) Calibration must be performed at least once every six months, or more frequently if required by manufacturers;~~¶
~~(B) Use calibration materials specified by the manufacturer;~~¶
~~(C) Maintain documentation of all calibration and calibration verification for a minimum of two years. Documentation must define the number, type, concentration of calibration materials, and frequency required;~~¶
~~(f) Perform calibration verification at least every 6 months to verify the laboratory's established reportable range for patient test values using calibration or control materials, including at least a minimal value (zero), a mid-point value, and a maximum value at the upper limit of that range;~~¶
~~(g) Perform and document that remedial action has been taken when problems or errors are identified as specified in OAR 333-024-0035(19); and~~¶
~~(h) Comply with requirements as specified in OAR 333-024-0035(4)-(8), (11)-(13) and (16).~~¶
~~(2) After September 1, 1996, unmodified moderate complexity test systems cleared by the Food and Drug Administration (FDA) through the 510(k) or Premarket Approval (PMA) process, must comply with quality control requirements in OAR 333-024-0035(2)-(22) and~~ comply with quality control requirements in OAR 333-024-0035(3) through (21) and OAR 333-024-0037.¶
(~~3~~2) ~~After final rule adoption, h~~High complexity testing, methods developed in house, devices not subject to clearance by the FDA through the 510(k) or PMA process, or modified test systems must comply with quality control requirements in OAR 333-024-0035(4~~3~~) through 333-024-0035(2~~2~~1) and OAR 333-024-0037.¶
(4~~3~~) The procedure manual must include, when applicable to the test procedure:¶
(a) Requirements for specimen collection and processing, and criteria for specimen rejection;¶
(b) Procedures for microscopic examinations, including the detection of inadequately prepared slides;¶
(c) Step-by-step performance of the procedure, including test calculations and interpretation of results;¶
(d) Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;¶
(e) Calibration and calibration verification procedures;¶
(f) The reportable range for patient test results;¶
(g) Control procedures;¶
(h) Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;¶
(i) Limitations in methodologies, including interfering substances;¶
(j) Reference range (normal values);¶
(k) Imminent life-threatening laboratory results or "panic values";¶
(l) Pertinent literature references;¶
(m) Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;¶
(n) The laboratory's system for reporting patient results including, when appropriate, the protocol for reporting panic values;¶
(o) Description of the course of action to be taken in the event that a test system becomes inoperable;¶
(p) Criteria for the referral of specimens including procedures for specimen submission and handling;¶
(q) Manufacturers' package inserts or operator manuals may be used. Any of the required items for procedure

manuals not provided by the manufacturer must be written by the laboratory;¶
(r) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance. These records must be retained for two years after a procedure has been discontinued; and¶
(s) Textbooks may be used as a supplement to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens.¶
(~~5~~4) Laboratory procedure manuals and relevant texts shall be reviewed, approved and signed by the ~~D~~director, initially and whenever there is a change in method or policy.¶
(~~6~~5) The laboratory must define and document criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation to include water quality, temperature, humidity, protection of test equipment, test result reporting and remedial action taken to correct any conditions that fail to meet the laboratory's criteria.¶
(~~7~~6) Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, must be labeled to indicate:¶
(a) Identity and, when significant, titer, strength or concentration;¶
(b) Recommended storage requirements;¶
(c) Preparation and expiration date; and¶
(d) Other pertinent information required for proper use.¶
(~~8~~7) Reagents, solutions, culture media, control materials, calibration materials and other supplies must be prepared, stored, and handled in a manner to ensure that:¶
(a) They are not used when they have exceeded their expiration date, have deteriorated or are of substandard quality; and¶
(b) Components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.¶
(~~9~~8) Prior to reporting patient test results, the laboratory must verify or establish, for each method; accuracy, precision, analytical sensitivity and specificity, the reportable range of patient test results, the reference range (normal values) and any other applicable performance characteristic.¶
(a) ~~The provisions of this section are not retroactive. Laboratories are not required to verify or establish performance specifications for any test method of moderate or high complexity in use prior to date of final rule adoption;¶~~
~~(b)~~ Each laboratory that introduces a new procedure for patient testing using a device (instrument, kit, or test system) must ~~as~~ensure that it meets the requirements for quality control;¶
(~~c~~b) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications;¶
(~~d~~c) Perform function checks including background or baseline, verifying that they are within established limits and document results; and¶
(~~e~~d) The manufacturer's reference range for each test is appropriate for the laboratory's patient population.¶
(~~10~~9) A laboratory that introduces a new procedure must, prior to reporting patient test results:¶
(a) Verify or establish for each method the performance specifications for the following performance characteristics:¶
(A) Accuracy;¶
(B) Precision;¶
(C) Analytical sensitivity;¶
(D) Analytical specificity to include interfering substances;¶
(E) Reportable range of patient test results;¶
(F) Reference ranges; and¶
(G) Any other performance characteristic required for test performance.¶
(b) Establish calibration and control procedures for the tests as required in OAR 333-024-0026; and¶
(c) Document the verification or establishment of all applicable test performance specifications.¶
(1~~1~~0) The laboratory must have available written policies and procedures for the preparation of patients, specimen collection, specimen labeling, specimen preservation, conditions for specimen transportation, specimen processing and rejection of unacceptable specimens.¶
(1~~2~~1) The laboratory must ~~as~~ensure the identification and integrity of the patient specimen(s) from collection until testing has been completed and the results reported.¶
(1~~3~~2) The laboratory must have written instructions for the handling of referral specimens.¶
(14~~3~~) For qualitative tests, the laboratory must include a positive and negative control each day of testing, unless the manufacturer's instructions, or the laboratory's method validation indicates the need for more frequent control checks to assure accurate testing.¶
(1~~5~~4) For quantitative tests, the laboratory must include at least two samples of different concentrations of either calibration materials, control materials, or a combination thereof at least each day of testing, unless the

manufacturer's instructions, or the laboratory's method validation indicates the need for more frequent control checks to assure accurate testing.¶
(16~~5~~) Limits for controls shall be clearly stated and recorded. The course of action taken when analyses are outside these control limits shall be clearly stated and recorded. The control limits shall be set so that clinically reliable results are assured. Values for standards shall be clearly stated and recorded.¶
(17~~6~~) The manufacturer's instructions shall be followed unless there is documentation available showing the changes made, and proof these changes do not adversely affect the reliability of the test result.¶
(18~~7~~) All test methods shall meet the following quality control requirements:¶
(a) The laboratory must follow the manufacturer's instructions for control procedures;¶
(b) Each day of use, the laboratory must evaluate the detection phase of direct antigen systems using an appropriate positive and negative control material (organism or antigen extract). When direct antigen systems include an extraction phase, the system must be checked each day of use using a positive organism;¶
(c) If calibration or control materials are not available, the laboratory must have an alternative mechanism to assure the validity of patient test results;¶
(d) Control samples must be tested in the same manner as patient specimens;¶
(e) When calibration or control materials are used, statistical parameters (~~e.g.~~for example, mean and standard deviation) for each lot number of calibration material and each lot of control material must be determined through repetitive testing:¶
(A) The stated values of an assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory and are verified by the laboratory; and¶
(B) Statistical parameters for unassayed materials must be established over time by the laboratory through concurrent testing with calibration materials or control materials having previously determined statistical parameters.¶
(f) Control results must meet the laboratory's criteria for acceptability prior to reporting patient test results; and¶
(g) Reagent and supply checks~~.~~:¶
(A) The laboratory must check each batch or shipment of reagents, discs, stains, antisera and identification systems (systems using two or more substrates) when prepared or opened for positive and negative reactivity, as well as graded reactivity if applicable;¶
(B) Each day of use (unless otherwise specified in OAR 333-024-0037), the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics;¶
(C) The laboratory must check fluorescent stains for positive and negative reactivity each time of use (unless otherwise specified);¶
(D) The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer;¶
(E) The laboratory must follow the manufacturer's specifications for using the media and be responsible for the test results;¶
(F) The laboratory must check each batch or shipment of media for sterility, ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response;¶
(G) The laboratory may use manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the ~~National Committee for~~ Clinical and Laboratory Standards ~~(NCCLS)~~Institute (CLSI) standards for media quality control, except for the following media:¶
(i) Campylobacter agar;¶
(ii) Chocolate agar;¶
(iii) Pathogenic Neisseria selective isolation media;¶
(iv) Media used for the isolation of parasites, viruses, mycoplasmas, chlamydia;¶
(v) Mueller Hinton media used for susceptibility tests; and¶
(vi) Commercially prepared media packaged as a unit or system consisting of two or more different substrates.¶
(19~~8~~) Remedial action policies and procedures must be established, implemented and documented when:¶
(a) The test systems do not meet the laboratory's established performance specifications;¶
(b) Patient test values are outside of the laboratory's reportable range of patient test results;¶
(c) The laboratory's reference range for a test procedure is inappropriate for the laboratory's patient population;¶
(d) Results of control, calibration or calibration verification materials fail to meet the laboratory's established criteria;¶
(e) The laboratory cannot report patient test results within its established time frames; and must notify the appropriate individual of the delayed testing; or¶
(f) Errors are detected in the reported patient test results:¶
(A) The laboratory must promptly notify the authorized person ordering or individual utilizing the test results of the reporting error;¶

(B) Issue a corrected report to the authorized person ordering or individual utilizing the test report; and¶
(C) Maintain exact duplicates of the original and the corrected report for two years.¶
(~~20~~19) For electrophoretic determinations:¶
(a) At least one control sample must be used in each electrophoretic cell; and¶
(b) The control sample must contain fractions representative of those routinely reported in patient specimens.¶
(2~~1~~0) If an initial screen for ~~S~~substances of ~~A~~abuse is positive and confirmatory testing is required as directed under OAR 333-024-0345(1), it must be confirmed by a principle stated in OAR 333-024-0345(3).¶
(2~~2~~1) Additional ~~Q~~quality ~~C~~control practices may be required by the Public Health Division for specialized categories of testing.
Statutory/Other Authority: ORS 438.~~32~~040
Statutes/Other Implemented: ORS 438.~~32~~040

AMEND: 333-024-0037

RULE SUMMARY: OAR 333-024-0037 is being amended with minor editorial changes and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0037
Specialty and Subspecialty Quality Control ¶

(1) Bacteriology quality control requirements are:¶
(a) The laboratory must check positive and negative reactivity with control organisms:¶
(A) Each day of use for catalase, coagulase, betalactamase, oxidase reagents and DNA probes;¶
(B) Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X and V discs or strips; and¶
(C) Each month of use for antisera.¶
(b) Each week of use, the laboratory must check XV discs or strips with a positive control organism;¶
(c) For antimicrobial susceptibility tests, the laboratory must check each new lot shipment of media and each lot of antimicrobial discs before, or with initial use, using approved reference organisms, following the ~~National Committee for~~ Clinical and Laboratory Standards ~~(NC~~Institute (CLSI) approved procedures for antimicrobial susceptibility quality control:¶
(A) The laboratory's zone sizes or minimum inhibitory concentration for reference organisms must be within established quality control limits before reporting patient results; and¶
(B) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.¶
(d) The laboratory must check each batch or lot shipment of media for sterility. Media must also be checked for its ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response.¶
(2) Mycobacteriology quality control requirements are:¶
(a) Each day of use, the laboratory must check the iron uptake test with at least one acid-fast organism that produces a positive reaction and with an organism that produces a negative reaction and check all other reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction;¶
(b) The laboratory must check fluorochrome acid-fast stains for positive and negative reactivity each week of use;¶
(c) The laboratory must check acid-fast stains each week of use with an acid-fast organism that produces a positive reaction; and¶
(d) For susceptibility tests performed on Mycobacterium tuberculosis isolates, the laboratory must check the procedure each week of use with a strain of Mycobacterium tuberculosis susceptible to all antimycobacterial agents tested.¶
(3) Mycology quality control requirements are:¶
(a) Each day of use, the laboratory using the auxanographic medium for nitrate assimilation must check the nitrate reagent with a peptone control;¶
(b) Each week of use, the laboratory must check all reagents used with biochemical tests and other test procedures for mycological identification with an organism that produces a positive reaction;¶
(c) Each week of use, the laboratory must check acid-fast stains for positive and negative reactivity; and¶
(d) For susceptibility tests, the laboratory must test each drug each day of use with at least one control strain that is susceptible to the drug. The laboratory must establish control limits. Criteria for acceptable control results must be met prior to reporting patient results.¶
(4) Parasitology quality control requirements are:¶
(a) The laboratory must have available a reference collection of slides or photographs, and, if available, gross specimens for identification of parasites;¶
(b) The laboratory must calibrate the ocular micrometer for determining the size of ova and parasites; and¶
(c) Each month of use, the laboratory must check permanent stains using a fecal sample control that will demonstrate staining characteristics.¶
(5) Virology quality control requirements are:¶
(a) The laboratory must have available host systems for the isolation of viruses and test methods for the identification of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered;¶
(b) The laboratory must maintain records that reflect the systems used and the reactions observed; and¶
(c) In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.¶

(6) Syphilis ~~S~~serology quality control requirements are:¶
(a) The equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers' specifications;¶
(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control;¶
(c) The laboratory must employ positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages; and¶
(d) The laboratory must not report test results unless the predetermined reactivity pattern of the controls is observed.¶
(7) General ~~I~~immunology quality control requirements are:¶
(a) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity, if applicable, plus a negative control;¶
(b) The laboratory must employ controls that evaluate all phases of the test system (for example, antigens, complement, erythrocyte indicator systems~~, etc.~~) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient; and¶
(c) The laboratory must not report test results unless the predetermined reactivity pattern of the controls is verified.¶
(8) Routine ~~C~~chemistry and ~~E~~endocrinology quality control requirements are:¶
(a) A minimum of two different levels of controls covering the full range of expected results shall be tested with each run of patient specimens, each change of reagents or major maintenance performed;¶
(b) Control samples must be tested in the same manner, if applicable, as a patient specimen; and¶
(c) The laboratory must not report test results unless the control results are within the laboratory's acceptable limits.¶
(9) Blood ~~G~~gas ~~A~~analysis quality control requirements are:¶
(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer;¶
(b) Test one sample of control material each eight hours of testing;¶
(c) Use a combination of calibrators and control materials that include both low and high values on each day of testing; and¶
(d) Include one sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.¶
(10) Toxicology quality control requirements are those listed in general chemistry, in addition, for drug abuse screening using thin layer chromatography:¶
(a) Each plate must be spotted with at least one sample of calibration material containing all drug groups identified by thin layer chromatography which the laboratory reports; and¶
(b) At least one control sample must be included in each chamber, and the control sample must be processed through each step of patient testing, including extraction procedures.¶
(11) Urinalysis quality control requirements are those listed in general chemistry, except for those tests categorized as waived.¶
(12) Hematology quality control requirements are:¶
(a) Cell counts performed manually using a hemocytometer must be tested in duplicate. One control is required for each eight hours of operation;¶
(b) For non-manual hematology testing systems, excluding coagulation, the laboratory must include two levels of controls each eight hours of operation;¶
(c) For all non-manual coagulation testing systems, the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs; and¶
(d) For manual coagulation tests:¶
(A) Each individual performing tests must test two levels of controls before testing patient samples and each time a change in reagents occurs; and¶
(B) Patient and control specimens must be tested in duplicate.¶
(13) Cytology quality control requirements are:¶
(a) All gynecologic smears are stained using a Papanicolaou or modified Papanicolaou staining method;¶
(b) Effective measures are taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process;¶
(c) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains are filtered or changed following staining;¶
(d) Diagnostic interpretations must not be reported on unsatisfactory smears; and¶
(e) All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.¶

(14) A cytology laboratory is responsible for ensuring that:¶
(a) Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic technique examines no more than 100 slides (one patient per slide, gynecologic or nongynecologic, or both) in a 24-hour period, irrespective of the site or laboratory. Previously examined gynecologic and nongynecologic cytology preparations, and tissue pathology slides examined by a technical supervisor are not included in the 100 slide limit;¶
(b) For purposes of workload calculations, each slide preparation (nongynecologic) made using automated, semi-automated, or other liquid-based slide preparatory techniques which result in cell dispersion over one-half or less of the total available slide area and which is examined by nonautomated microscopic technique counts as one-half slide; and¶
(c) Records are maintained of the total number of slides examined by each individual during each 24-hour period, irrespective of the site or laboratory, and the number of hours each individual spends examining slides in the 24-hour period:¶
(A) The maximum number of 100 slides described in this section is examined in no less than an ~~8~~eight hour workday; and¶
(B) For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on other than an ~~8~~eight hour workday basis (includes full-time employees with duties other than slide examination and part-time employees), a period of ~~8~~eight hours must be used to prorate the number of slides that may be examined.¶
(15) The individual who provides technical supervision of cytology must ensure that:¶
(a) All gynecologic smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus-associated changes) or malignant category are confirmed and signed by a technical supervisor in cytology;¶
(b) All nongynecologic cytologic preparations are reviewed and signed by the technical supervisor in cytology;¶
(c) The slide examination performance of each cytotechnologist is evaluated and documented, including performance evaluation through the re-examination of normal and negative cases and feedback on the reactive, reparative, atypical, malignant or premalignant cases; and¶
(d) A maximum number of slides, not to exceed the maximum workload limit, is established by the technical supervisor for each individual examining slide preparations by nonautomated microscopic technique.¶
(A) The actual workload limit must be documented for each individual; and¶
(B) Records are available to document that each individual's workload limit is reassessed at least every ~~6~~six months and adjusted when necessary.¶
(16) The laboratory must establish and follow a program designed to detect errors in the performance of cytologic examinations and the reporting of results:¶
(a) The laboratory must establish a program that includes a review of slides from at least 10 percent of the gynecologic cases interpreted to be negative for reactive, reparative, atypical, premalignant or malignant conditions. This review must be done by a technical supervisor in cytology, a cytology general supervisor, or a qualified cytotechnologist:¶
(A) The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information;¶
(B) Records of initial examinations and rescreening results must be available; and¶
(C) The review must be completed before reporting patient results on those cases selected.¶
(b) The laboratory must compare clinical information, when available, with cytology reports and must compare all malignant and premalignant gynecology reports with the histopathology report, if available in the laboratory (either on-site or in storage), and determine the causes of any discrepancies;¶
(c) For each patient with a current high grade intraepithelial lesion or above (moderate dysplasia or CIN-2 or above), the laboratory must review all normal or negative gynecologic specimens received within the previous five years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report;¶
(d) The laboratory must establish and document an annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation), number of gynecologic cases where cytology and available histology are discrepant, the number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as malignant or premalignant, and the number of gynecologic cases for which histology results were unavailable to compare with malignant or premalignant cytology cases;¶
(e) The laboratory must evaluate the case reviews of each individual examining slides against the laboratory's

overall statistical values, document any discrepancies, including reasons for the deviation, and document corrective action, if appropriate;¶
(f) The laboratory report must:¶
(A) Clearly distinguish specimens or smears, or both, that are unsatisfactory for diagnostic interpretation; and¶
(B) Contain narrative descriptive nomenclature for all results.¶
(g) Corrected reports issued by the laboratory must indicate the basis for correction;¶
(h) The laboratory must retain all slide preparations for five years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time period, provided the laboratory receives written acknowledgement of the receipt of slides by the proficiency testing program and maintains the acknowledgement to document the loan of such slides. Documentation for slides loaned or referred for purposes other than proficiency testing must also be maintained. All slides must be retrievable upon request; and¶
(i) The technical supervisor must ensure that reports are signed, or if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor in cytology.¶
(17) Histopathology quality control requirements are:¶
(a) A control slide of known reactivity must be included with each slide or group of slides for differential or special stains;¶
(b) The laboratory must retain stained slides, and test reports at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination;¶
(c) The laboratory must retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic exam-ination have been examined and a diagnosis made by a qualified individual;¶
(d) Only those individuals who meet the specific requirements in OAR 333-024-0023 for histology, dermatopathology, opthalmic pathology or oral pathology may examine and provide reports in these subspecialties;¶
(e) All tissue pathology reports must be signed by a qualified individual. If a computer report is generated with an electronic signature, it must be authorized by a qualified individual; and¶
(f) The laboratory must utilize acceptable terminology of a recognized system of disease nomenclature in reporting results.¶
(18) Oral ~~P~~pathology quality control requirements are the same as those for histopathology.¶
(19) Radiobioassay quality control requirements are: the laboratory must comply with the applicable requirements of OAR 333-024-0035 and OAR 333-024-0037.¶
(20) Histocompatibility quality control for renal allotransplantation includes the requirements for OAR 333-024-0035, OAR 333-024-0037(7) and (23)~~;~~ and:¶
(a) The laboratory must have available and follow criteria for:¶
(A) Selecting appropriate patient serum samples for crossmatching;¶
(B) The technique used in crossmatching;¶
(C) Preparation of donor lymphocytes for crossmatching; and¶
(D) Reporting crossmatch results.¶
(b) The laboratory must:¶
(A) Have available results of final crossmatches before an organ or tissue is transplanted; and¶
(B) Make a reasonable attempt and document efforts to have available serum specimens for all potential transplant recipients at initial typing, for periodic screening, for pre-transplantation crossmatch and following sensitizing events, such as transfusion and transplant loss.¶
(c) The laboratory's storage and maintenance of both recipient sera and reagents must:¶
(A) Be at an acceptable temperature range for sera and components;¶
(B) Use a temperature alarm system and have an emergency plan for alternate storage; and¶
(C) Ensure that all specimens are properly identified and easily retrievable.¶
(d) The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining.¶
(e) The laboratory must properly label and store cells, complement, buffer and dyes.¶
(f) The laboratory must:¶
(A) HLA type all potential transplant recipients;¶
(B) Type cells from organ donors referred to the laboratory; and¶
(C) Have available and follow a policy that establishes when antigen redefinition and retyping are required.¶
(g) The laboratory must have available and follow criteria for:¶
(A) The preparation of lymphocytes for HLA-A, B and DR typing;¶
(B) Selecting typing reagents, whether locally or commercially prepared;¶
(C) The assignment of HLA antigens; and¶
(D) Assuring that reagents used for typing recipients and donors are adequate to define all major and International

Workshop HLA-A, B and DR specificities for which reagents are readily available.¶
(h) The laboratory must:¶
(A) Screen potential transplant recipient sera for preformed HLA-A and B antibodies with a suitable lymphocyte panel on sera collected:¶
(i) At the time of the recipient's initial HLA typing; and¶
(ii) Thereafter, following sensitizing events and upon request.¶
(B) Use a suitable cell panel for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits.¶
(i) If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding;¶
(j) If the laboratory uses frozen panels, it must have a suitable storage system;¶
(k) The laboratory must check:¶
(A) Each typing tray using positive and negative control sera;¶
(B) Positive controls for specific cell types when applicable (~~i.e.~~for example, T cells, B cells, and monocytes); and¶
(C) Each compatibility test (~~i.e.~~for example, mixed lymphocyte cultures, homozygous typing cells or DNA analysis) and typing for disease-associated antigens using controls to monitor the test components and each phase of the test system to ensure an acceptable performance level.¶
(l) Compatibility testing for cellularly-defined antigens must utilize techniques such as the mixed lymphocyte culture test, homozygous typing cells or DNA analysis;¶
(m) If the laboratory reports the recipient's or donor's, or both, ABO blood group and D(Rho) typing, the testing must be performed in accordance with the applicable requirements of OAR 333-024-0035, and OAR 333-024-0037(23);¶
(n) If the laboratory utilizes immunologic reagents (such as antibodies or complement) to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the efficacy of the methods must be verified with appropriate quality control procedures;¶
(o) At least once each month, the laboratory must have each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Records of the results for each individual must be maintained; and¶
(p) The laboratory must participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate inter-laboratory reproducibility.¶
(21) Histocompatibility, other testing for:¶
(a) Transfusions and other non-renal transplantation, excluding bone marrow and living transplants, all the requirements specified in this section and OAR 333-024-0035 and OAR 333-024-0037(20), as applicable, except for the performance of mixed lymphocyte cultures, must be met;¶
(b) Bone marrow transplantation, all the requirements specified in this section and OAR 333-025-0035 and OAR 333-024-0037(20), including the performance of mixed lymphocyte cultures or other augmented testing to evaluate class II compatibility, must be met;¶
(c) Non-renal solid organ transplantation, the results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior serum screening except for emergency situations. The laboratory must document the circumstances, if known, under which emergency transplants are performed, and records must reflect any information concerning the transplant provided to the laboratory by the patient's physician;¶
(d) HLA typing for disease-associated studies must meet all the requirements specified in this section and OAR 333-024-0035 and OAR 333-024-0037(20), except for the performance of mixed lymphocyte cultures, antibody screening and crossmatching; and¶
(e) Organ donor HIV testing, the requirements of general immunology in OAR 333-024-0035 and 333-024-0037(7) must be met.¶
(22) Clinical ~~C~~cytogenetics quality control requirements are:¶
(a) When determination of sex is performed by X and Y chromatin counts, these counts must be based on an examination of an adequate number of cells. Confirmatory testing such as full chromosome analysis must be performed for all atypical results;¶
(b) The laboratory must have records that reflect the media used and document the reactions observed, number of cells counted, the number of cells karyotyped, the number of chromosomes counted for each metaphase spread, and the quality of the banding; that the resolution is sufficient to support the reported results; and that an adequate number of karyotypes are prepared for each patient;¶
(c) The laboratory also must have policies and procedures for assuring an accurate and reliable patient sample identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, and photographic printing, and storage and reporting of results or photographs; and¶
(d) The laboratory report must include the summary and interpretation of the observations, number of cells counted and analyzed, and the use of appropriate nomenclature.¶

(23) Immunohematology quality control requirements are:¶
(a) The laboratory must perform ABO group and D(Rho) typing, unexpected antibody detection, antibody identification and compatibility testing in accordance with manufacturer's instructions;¶
(b) The laboratory must perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells;¶
(c) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent;¶
(d) If required in the manufacturer's package insert for anti-D reagents, the laboratory must employ a control system capable of detecting false positive D(Rho) test results;¶
(e) If a facility provides services for the transfusion of blood and blood products, the facility must be under the adequate control and technical supervision of a pathologist or other qualified doctor of medicine or doctor of osteopathy. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood and blood products must be available to meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients;¶
(f) The requirements for blood and blood products storage facilities are:¶
(A) The blood and blood products must be stored under appropriate conditions, which include an adequate temperature alarm system that is regularly inspected:¶
(i) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period; and¶
(ii) Inspections of the alarm system must be documented.¶
(B) If blood is stored or maintained for transfusion outside of a monitored refrigerator, the facility must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.¶
(g) In the case of services provided outside the blood bank, the facility must have an agreement reviewed and approved by the director that governs the procurement, transfer and availability of blood and blood products;¶
(h) There must be provision for prompt ABO blood group, D(Rho) type, unexpected antibody detection and compatibility testing in accordance with the requirements in immunohematology and for laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility on a continuous basis, under the supervision of a pathologist or other qualified doctor of medicine or doctor of osteopathy;¶
(i) According to the facility's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of reactions. The facility must promptly dispose of blood not retained for further testing that has passed its expiration date;¶
(j) The facility, according to its established procedures, must promptly investigate all transfusion reactions occurring in all facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. The facility must document that all necessary remedial actions are taken to prevent future recurrences of transfusion reactions and that all policies and procedures are reviewed to assure that they are adequate to ensure the safety of individuals being transfused within the facility; and¶
(k) Policies to ensure positive identification of a blood or blood product recipient must be established, documnented and followed.
Statutory/Other Authority: ORS 438.3204̲0
Statutes/Other Implemented: ORS 438.3204̲0

AMEND: 333-024-0040

RULE SUMMARY: OAR 333-024-0040 is being amended with minor editorial changes and to update reference to state and federal entities. The term license is replaced with certificate and outdated reference to payment of state license fees is removed.

CHANGES TO RULE:

333-024-0040
External Quality Control (Proficiency Testing Programs and On-Site Inspections) ¶

(1) Physician performed microscopy, moderate and high complexity laboratories shall:¶
(a) At the laboratory's own expense, be required to participate successfully in a proficiency testing program approved by the ~~Health Care Financing Administration~~U.S. Centers for Medicare and Medicaid Service (CMS). Lists of currently approved programs are available from the ~~Division~~Public Health Division (Division). Continued or consistent failure, two out of three testing events, may result in the laboratory's ~~licens~~certificate for that specialty, subspecialty or test being suspended or revoked by the Division;¶
(b) Authorize release of proficiency test results and provide documentation of corrective action to the Division;¶
(c) ~~As~~Ensure proficiency testing is performed on each physician performed microscopy, moderate and high complexity regulated analyte listed in the Clinical Laboratory Improvement Amendments of 1988, 42 CFR, Part 493, subpart I, available on request from the Division;¶
(d) Meet the proficiency testing requirements as described in the Clinical Laboratory Improvement Amendments of 1988, 42 CFR, Part 493, subpart H, available on request from the Division;¶
(e) Notify the Division within six months if the analysis of a specialty, subspecialty or test has been discontinued or added to patient testing;¶
(f) ~~As~~Ensure that individuals performing gynecologic cytology participate successfully in a proficiency testing program approved by the ~~Health Care Financing Administration~~U.S. Centers for Medicare and Medicaid Service (CMS);¶
(g) Be required to participate successfully in the proficiency testing programs conducted by the Division involving the laboratory specialty, subspecialty or tests in which the laboratory performs tests; and¶
(h) Analyze test samples submitted by the Division prior to, during, or subsequent to inspection.¶
(2) A laboratory shall have their ~~licens~~certificate suspended or revoked for one year, pursuant to ORS 438.160, if it submits a proficiency testing sample to another laboratory for analysis prior to reporting to the proficiency testing program.¶
(3) Any laboratory that knowingly receives proficiency testing samples from another laboratory prior to the reporting deadline must notify the Division.¶
(4) On-site inspections and testing may be conducted by representatives of the Division or ~~F~~the federal ~~G~~government at reasonable times during the laboratory's normal business hours without advance notice. The representative shall inspect the facilities, personnel policies, procedures, materials, staff qualifications, equipment, and records:¶
(a) Routine inspections of moderate and high complexity laboratories shall occur at a minimum of every two years.¶
(b) Laboratories accredited by a ~~Health Care Financing Administration~~ U.S. Centers for Medicare and Medicaid Service (CMS)approved accreditation organization are exempt from routine, on-site inspection provided the laboratory submits a copy of their accreditation certificate and authorizes its accreditation organization to release inspection data to the Division. The accreditation organization shall make available, upon request, a copy of the laboratory's statement of deficiencies, plan of correction and proof of accreditation to the Division.¶
(5) The ~~O~~owner or ~~D~~director may be required to submit reports on the operations and procedures of the laboratory to the Division or the ~~F~~federal ~~G~~government.¶
(6) Additional inspections may be performed without notice to verify correction of deficiencies, investigate complaints, validation of accrediting organizations' inspections, review unsatisfactory proficiency testing and verify personnel qualifications or other monitoring of compliance with OAR 333-024-0005 through 333-024-0050 and OAR 333-024-0260 and OAR 333-024-0265.¶
(7) Inspection of waived and physician performed microscopic procedures laboratories:¶
(a) The Division shall conduct inspections of any laboratory during routine hours of operation only to assess validation, complaint, and compliance with the applicable requirements of these rules;¶
(b) The laboratory is required to:¶
(A) Allow the Division or ~~F~~federal ~~G~~government to interview all employees of the laboratory concerning compliance with these rules;¶

(B) Allow the Division or ~~F~~federal ~~G~~government access to all areas of the facility including specimen procurement and processing areas, storage facilities for specimens, reagents, supplies, records and reports, testing and reporting areas;¶
(C) Permit employees to be observed performing tests, data analysis and reporting;¶
(D) Allow the Division to review all information and data necessary to evaluate complaints, determine immediate and serious risk to public health, and confirm that the laboratory is only performing tests within the scope of their license;¶
(E) Provide copies of all records and data that the Division or ~~F~~federal ~~G~~government requires under these rules; and¶
(F) Provide all information and data needed by the Division or ~~F~~federal ~~G~~government to make a determination of compliance with these rules.¶
(8) Failure to permit an inspection under these rules will result in the suspension of the laboratory's ~~licens~~certificate.¶
(9) A waived laboratory conducting moderate ~~and/~~or high complexity tests shall be considered a moderate or high complexity laboratory and the Division shall:¶
(a) Conduct an on-site survey;¶
(A) Examine the records of the laboratory;¶
(B) Give written notice of any deficiencies;¶
(C) Require the laboratory to return a written plan of correction, and verify that the corrections have occurred; and¶
(D) The time frames for the plan of correction and verification are the same as a moderate or high complexity laboratory.¶
(b) Require compliance with Division directives when there is an immediate threat to life, health, or safety.¶
~~(c) Charge the laboratory the appropriate fee.¶~~
(10) A physician performed microscopy procedure laboratory conducting additional moderate complexity or high complexity tests shall be considered a moderate or high complexity laboratory and the Division shall:¶
(a) Conduct an on-site survey:¶
(A) Examine the records of the laboratory;¶
(B) Give written notice of any deficiencies;¶
(C) Require the laboratory to return a written plan of correction, and verify that the corrections have occurred; and¶
(D) The time frames for the plan of correction and verification are the same as a moderate or high complexity laboratory.¶
(b) Require compliance with Division directives when there is an immediate threat to life, health, or safety.¶
(11) Inspection of non-accredited, moderate and high complexity laboratories:¶
(a) The Division will conduct inspections on at least a biennial basis of any laboratory at any time during routine hours of operation;¶
(b) The Division will conduct an on-site inspection prior to facilitating the issuance of a ~~licens~~certificate;¶
(c) The laboratory may be required to:¶
(A) Test samples or perform procedures as the Division or ~~F~~federal ~~G~~government requires;¶
(B) Allow the Division or ~~F~~federal ~~G~~government to interview all employees of the laboratory concerning the laboratory's compliance with these rules;¶
(C) Permit employees to be observed performing tests, data analysis and reporting;¶
(D) Allow the Division or ~~F~~federal ~~G~~government access to all areas of the facility including: specimen procurement and processing areas, storage facilities for specimens, reagents, supplies, records and reports, testing and reporting areas; or¶
(E) Provide copies to the Division or ~~F~~federal ~~G~~government of all records and data it requires.¶
(d) The laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection;¶
(e) The laboratory must provide, upon request, all information and data needed by the Division or ~~F~~federal ~~G~~government to make a determination of the laboratory's compliance with these rules;¶
(f) The Division or ~~F~~federal ~~G~~government may reinspect a laboratory at any time necessary to evaluate the ability of the laboratory to provide accurate and reliable test results; and¶
(g) The laboratory must retain records as specified in OAR 333-024-0050.¶
(12) Inspection of accredited laboratories:¶
(a) The Division and the ~~F~~federal government may conduct random validation inspections of any accredited laboratory at any time during its hours of operation;¶
(b) The Division and the ~~F~~federal government may conduct complaint inspections of an accredited laboratory at any time during its hours of operation upon receiving a complaint about that laboratory; and¶

(c) The laboratory may be required to comply with OAR 333-024-0040(11)(c)- through (f).¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 438.320400
Statutes/Other Implemented: ORS 438.320400

AMEND: 333-024-0043

RULE SUMMARY: OAR 333-024-0043 is being amended with minor editorial changes.

CHANGES TO RULE:

333-024-0043
Quality Assurance ¶

(1) Each laboratory performing physician performed microscopy, moderate or high complexity testing must establish and follow written policies and procedures for a comprehensive quality assurance program which is designed to monitor and evaluate the ongoing and overall quality of the total testing process (pre-analytic, analytic, post-analytic).¶
(2) The laboratory's quality assurance 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.¶
(3) The laboratory must meet the requirements of this rule as they apply to the services offered, complexity of testing performed, test results reported, and the unique practices of each testing entity.¶
(4) The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the following:¶
(a) The criteria established for patient preparation, specimen collection, labeling, preservation and transportation;¶
(b) The information solicited and obtained on the laboratory's test requisition for its completeness, relevance, and necessity for the testing of patient specimens;¶
(c) The use and appropriateness of the criteria established for specimen rejection;¶
(d) The completeness, usefulness, and accuracy of the test report information necessary for the interpretation or utilization of test results;¶
(e) The timely reporting of test results based on testing priorities (for example, STAT, routine~~, etc.~~); and¶
(f) The accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results.¶
(5) The laboratory must have an ongoing mechanism to evaluate the corrective actions taken under remedial action.¶
(6) Ineffective policies and procedures must be revised based on the outcome of the evaluation. The mechanism must evaluate and review the effectiveness of corrective actions taken for:¶
(a) Problems identified during the evaluation of calibration and control data for each test method;¶
(b) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and¶
(c) Errors detected in reported results.¶
(7) The corrective actions taken for any unacceptable, unsatisfactory, or unsuccessful proficiency testing result(s) must be evaluated for effectiveness.¶
(8) If a 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.¶
(9) 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.¶
(10) The laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria including:¶
(a) Patient age;¶
(b) Sex;¶
(c) Diagnosis or pertinent clinical data, when provided;¶
(d) Distribution of patient test results, when available; and¶
(e) Relationship with other test parameters, when available within the laboratory.¶
(11) The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence:¶
(a) The assessment of employee competence must be biannually the first year of employment; and¶
(b) Annually thereafter.¶
(12) The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations; Corrective actions must be taken and documented, as necessary, to resolve the problems and minimize communications breakdowns.¶

(13) The laboratory must have a system in place to assure that all complaints and problems are documented. Investigations of complaints must be made and appropriate corrective actions instituted.¶
(14) The laboratory must have a mechanism for documenting and assessing problems identified during quality assurance reviews and discussing them with the staff. The laboratory must take corrective actions necessary to prevent recurrences.¶
(15) The laboratory must maintain documentation of all quality assurance activities including problems identified and corrective actions taken.¶
(16) All quality assurance records must be available to the Public Health Division and maintained for a period of ~~2~~two years.
Statutory/Other Authority: ORS 438.0~~10, 438.324~~0
Statutes/Other Implemented: ~~ORS 438.320~~

AMEND: 333-024-0045

RULE SUMMARY: OAR 333-024-0045 is being amended with minor editorial changes.

CHANGES TO RULE:

333-024-0045
Venereal Disease Testing ¶

Tests for syphilis approved by the Public Health Division are as follows:¶
(1) Venereal Disease Research Laboratory (VDRL) slide tests;¶
(2) Fluorescent Treponemal Antibody - Absorption (FTA-ABS) test;¶
(3) Rapid Plasma Reagin (RPR) and Reagin Screen Test (RST) macroscopic flocculation card tests;¶
(4) Hemagglutination-Treponemal Test for Syphilis (HATTS);¶
(5) Microhemagglutination Assay for Antibodies to Treponema pallidum (MHA-TP) test;¶
(6) Unheated Serum Reagin (USR) test; and¶
(7) Toluidine Red Unheated Serum Test (TRUST).
Statutory/Other Authority: ORS 433.017, 438.010, 438.040
Statutes/Other Implemented: ORS 438.010, 438.040

AMEND: 333-024-0050

RULE SUMMARY: OAR 333-024-0050 is being amended with minor editorial changes, to update terminology (remove license, replace with certificate) and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0050
Records and Reports ¶

(1) Personnel policies, practices, and procedures that support sound laboratory practice shall be available in written form. A current record shall be maintained on each employee and shall include a resume of training and experience.¶
(2) Complete records for each specimen examined, including quality control, shall be kept for not less than two years, immunohematology records not less than five years, cytology and pathology records not less than ten years. Such records shall contain:¶
(a) Laboratory number or other identification of the specimen;¶
(b) The name or other identifier of the person from whom the specimen was taken, if available;¶
(c) The name of the physician or other authorized person or clinical laboratory submitting the specimen;¶
(d) The date and time the specimen was collected or date and time it was received in the laboratory;¶
(e) The type of test performed;¶
(f) The results of the tests in units of measurement where applicable;¶
(g) The signature, initials, or identification of the examiner;¶
(h) The date and time the test results were reported; and¶
(i) Other information as needed to aid in the interpretation of laboratory results.¶
(3) Cytology slides must be maintained for a minimum of ~~5~~five years, histology slides 10 years, and tissue blocks ~~2~~two years.¶
(4) The ~~O~~owner or ~~D~~director of each clinical laboratory ~~licens~~certified under ~~the Act~~ORS chapter 438 shall report communicable disease according to OAR 333-018-0000 through 333-018-0015, and shall maintain a separate log of such reporting:¶
(a) Reports shall not be interpreted as constituting a diagnosis nor shall any laboratory making such report be held liable under the laws of this ~~S~~state for having violated a trust or confidential relationship; and¶
(b) Information contained in such reports may be used in compiling statistical and other data in which persons are not identified by name or otherwise.¶
(5) Requests for examinations of specimens and reporting of test results shall be as follows:¶
(a) The clinical laboratory shall examine specimens only at the oral, written or electronic request of a physician, dentist or other person authorized by law to use the findings of laboratory examinations;¶
(b) Oral requests for laboratory tests are permitted only if the laboratory subsequently requests written authorization for testing within 30 days;¶
(c) No person shall report the result of any test, examination, or analysis of a specimen submitted for evidence of human disease except to a physician, dentist, their agents, or other person authorized by law to employ the results thereof in the conduct of their practice or in the fulfillment of their official duties. Reports shall not be issued to the patient concerned except with the written consent of the physician or other authorized person; and¶
(d) The clinical laboratory may examine specimens for substance of abuse submitted by persons other than medical personnel authorized by law and shall report the result of any test to the person who submitted the specimen.¶
(6) The laboratory must maintain the written test authorization or documentation of efforts made to obtain a written authorization for a minimum of two years.¶
(7) The laboratory must ~~as~~ensure that the requisition or test authorization includes:¶
(a) The name and address or other identifiers of the authorized person requesting the test or the name and address of the laboratory submitting the specimen;¶
(b) For Pap smears, the patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy; and¶
(c) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results.¶
(8) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and confidential manner.¶
(9) The test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the test result, and if applicable, the units of measurement.¶
(10) The laboratory must indicate on the test report any information regarding the condition and disposition of

specimens that do not meet the laboratory's criteria for acceptability.¶
(11) Pertinent "reference" or "normal" ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests or the individual responsible for utilizing the test results.¶
(12) The laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values.¶
(13) The original report or exact duplicates of test reports must be maintained by the laboratory.¶
(14) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.¶
(15) The referring laboratory may permit each testing laboratory to send an additional test result directly to the authorized person who initially requested the test.¶
(16) The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.¶
(17) The test records of the laboratory must include:¶
(a) The patient identification number, accession number, or other unique identification of the specimen;¶
(b) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and¶
(c) The records and dates of all specimen testing, including the identity of the personnel who performed the tests.¶
(18) The laboratory must, upon request, make available to clients:¶
(a) A list of test methods employed by the laboratory;¶
(b) If applicable, the performance specifications of each method used;¶
(c) Information that affect the interpretation of test results such as interferences; and¶
(d) Pertinent updates on testing information whenever changes occur that affect the test results or its interpretation.¶
(19) A laboratory must refer specimens only to a Public Health Division licensed laboratory authorized to perform testing in that specialty or subspecialty at that complexity level~~;~~, except referral specimens may be sent to laboratories outside the ~~s~~State of Oregon to a laboratory operating in compliance with the provisions of CLIA 88.
Statutory/Other Authority: ORS 438.310
Statutes/Other Implemented: ORS 438.310

AMEND: 333-024-0053

RULE SUMMARY: OAR 333-024-0053 is being amended with minor editorial changes, to remove outdated language about state licensing to align with changes in statute due to passage of SB 844 (Oregon Laws 2025, chapter 624) and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0053
Accreditation Organizations and Accredited Laboratories ¶

(1) Accreditation organizations shall:¶
(a) Provide the ~~Division~~Public Health Division (Division) with;¶
(A) Documentation of current deemed status from the ~~Health Care Financing Administration~~U.S. Centers for Medicare and Medicaid Service (CMS);¶
(B) A list of all laboratories and accreditation expiration dates;¶
(C) A list of scheduled surveys and proposed survey dates;¶
(D) Copies of routine survey findings, upon request; and¶
(E) Copies of all complaint investigations performed.¶
(b) Allow the Division to investigate complaints, conduct complaint or random on-site validation surveys and take disciplinary action;¶
(c) Provide a detailed description of the organization's survey process, including:¶
(A) Frequency of surveys performed;¶
(B) Copies of survey forms and guidelines;¶
(C) Accreditation survey review process;¶
(D) Deficiency writing and monitoring process;¶
(E) Policy on facility notification prior to survey;¶
(F) Surveyor qualifications;¶
(G) Policy for the investigation of complaints on accredited laboratories;¶
(H) Description of all types and categories of accreditation offered; and¶
(I) Procedure for proficiency testing monitoring including;¶
(i) Frequency of monitoring;¶
(ii) Correlation of proficiency testing with subspecialties, specialties, and analytes performed by the laboratory;¶
(iii) Definition of unsuccessful performance; and¶
(iv) Action to be taken regarding unsuccessful performance.¶
(d) Notify all of their accredited laboratories within 10 days of the loss of accreditation authority in Oregon;¶
(e) Notify the Division:¶
(A) Within 30 days of any changes in accreditation requirements;¶
(B) Verbally, within ~~5~~five days of identifying any deficiency posing an immediate and serious risk to patient or staff safety or health in an accredited laboratory, to be followed by a written notification within 14 days of the verbal notification;¶
(C) Of actions taken due to unsuccessful proficiency testing performance;¶
(D) Within 30 days of enforcement or sanction actions taken against their accredited laboratories;¶
(E) Within 30 days if a laboratory terminates its accreditation; and¶
(F) Within 30 days if the organization revokes a laboratory's accreditation.¶
(2) Accredited laboratories shall:¶
(a) Notify the Division of accreditation or changes in accreditation status within 30 days of occurrence;¶
(b) Authorize proficiency testing providers to submit copies of all proficiency testing results to the Division; and¶
(c) Allow the Division to investigate complaints, conduct complaint or random on-site validation surveys, and take disciplinary action;¶
~~(d) Have a valid State License;~~¶
(e3) ~~Reapply for licensure within 60 days after the accrediting organization's deeming authority has been withdrawn:¶~~
~~(A) Pay applicable fees;¶~~
~~(B) Submit to survey by the Division; and¶~~
~~(C) Meet all applicable requirements for non-accredited laboratories in the appropriate licensure categorization.¶~~
~~(f) Reapply for licensure within 30 days after the withdrawal or revocation of the laboratory's accreditation by the accrediting organization:¶~~
~~(A) Pay applicable fees;¶~~

~~(B) Submit to survey by the Division; and¶~~
~~(C) Meet all applicable requirements for non-accredited laboratories in the appropriate licensure categorization.¶~~
~~(3) The Division may deny or terminate the licens~~The Division may facilitate the denial or facilitate the termination of the certificate of a laboratory if the owner fails to authorize the accrediting organization to notify the Division of the laboratory's compliance with the accrediting organization requirements.
Statutory/Other Authority: ORS 438.310, ORS 438.160
Statutes/Other Implemented: ORS 438.310, ORS 438.160

AMEND: 333-024-0055

RULE SUMMARY: OAR 333-024-0055 is being amended with minor editorial changes.

CHANGES TO RULE:

333-024-0055
Incompetence ¶

A clinical laboratory ~~O~~owner or ~~D~~director has "demonstrated incompetence" if there is:¶
(1) Repeated error demonstrated in the performance of laboratory tests or procedures or the results thereof;¶
(2) Failure to comply with the requirements of these rules relating to internal and external quality control;¶
(3) Failure to comply with ~~the ORS~~ORS chapter 438 or OAR 333-024-0005 through 333-024-0055 and OAR 333-024-0260 and OAR 333-024-0265;¶
(4) Work assigned to personnel not qualified to perform in that specialty; or¶
(5) Repeated erroneous reporting of test results.
Statutory/Other Authority: ORS 438.160
Statutes/Other Implemented: ORS 438.160

AMEND: 333-024-0315

RULE SUMMARY: ORS 333-024-0315 is being amended with minor editorial changes, to update terminology (remove license, replace with permit) and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0315
Testing for Substances of Abuse: ~~Licensure~~ Permits ¶

(1) It shall be unlawful:¶
(a) For any owner or director of a ~~SOA~~substances of abuse (SOA) laboratory or a clinical laboratory to perform medical or automated non-medical SOA screening tests without a ~~license~~permit issued under this rule unless they have been certified for that testing under the Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578, 42.U.S.C. 201 and 263a;¶
(b) For any person to serve in the capacity of director of an SOA screening laboratory without being qualified as a laboratory director under OAR 333-024-0320(1).¶
(2) OAR 333-024-0305 through 333-024-0350 apply to all SOA screening laboratories and laboratory personnel within the State of Oregon, except:¶
(a) Laboratories screening for SOA operated by the United States Government;¶
(b) Laboratories screening for SOA operated and maintained solely for research or teaching purposes, and that involve no direct patient or public health services;¶
(c) State Police laboratories screening for SOA as a part of the criminal justice system;¶
(d) Special category laboratories operated by state or local correctional agencies to monitor inmates and offenders on parole, probation, or post-prison supervision. These special category laboratories must follow the provisions of OAR 333-024-0360.¶
(3) The ~~Division~~Public Health Division (Division) shall issue and renew ~~license~~permits to the owners of laboratories screening for SOA who demonstrate to the satisfaction of the Division that:¶
(a) The SOA laboratory is in compliance with ORS 438.435;¶
(b) The SOA laboratory is equipped to perform within the scope of its ~~license;~~permit; and¶
(c) The SOA laboratory meets the standards of the Division for safety, sanitary conditions, plumbing, ventilation, handling of specimens, maintenance of equipment and requirements of general hygiene to ensure protection of the public health.¶
(4) Requirements for ~~license~~permit application; fees, exemptions, expiration~~;~~, and renewal are as follows:¶
(a) The application for a ~~license~~permit for an SOA screening laboratory shall be made on forms provided by the Division and shall be executed by the owner or one of the owners or by an officer of the firm or corporation owning the laboratory, or in the case of a county or municipality, by the public official responsible for operation of the SOA laboratory, or in the case of an institution, by the administrator of the institution. The application shall contain the names of the owner, the director or directors of the laboratory, the location and physical description of the SOA laboratory, and such other information as the Division may require;¶
(b) Laboratories must pay an annual or biennial, non-refundable ~~license~~permit fee, prior to issuance of a ~~license~~permit, as described in OAR 333-024-0~~012(5)(c~~365(7);¶
(c) A laboratory certified in toxicology for medical substance of abuse testing under the Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 - Laboratory Requirements, may also perform that testing for non-medical purposes. No separate substance of abuse screening ~~license~~permit or registry is required;¶
(d) Unless sooner voided, suspended or revoked, all ~~license~~permits issued under this section expire on June 30 of the one or two year cycle following the date of issuance and shall be renewable in the manner prescribed by the Division;¶
(e) All monies received by the Division for the ~~licensure~~permitting of SOA screening laboratories shall be credited to the Division account and shall be used for payment of the expenses of the Division in administering OAR 333-024-0005 through 333-024-0350.¶
(5) A ~~license~~permit issued to the owner of an SOA screening laboratory shall show on its face the names of the owners and directors, the location of the laboratory and the laboratory specialty authorized under the ~~license. The license~~permit. The permit shall be displayed at all times in a prominent place in the laboratory.¶
(6) A ~~license~~permit issued to the owner of an SOA screening laboratory is not transferable. The ~~license~~permit of the SOA laboratory is voided 30 days after a change of its director if it has only one director or if all directors change or a change in the ownership or in the location of the laboratory. In the case of death of a director, the Division shall be notified within five working days. The laboratory shall have 30 days to obtain another qualified director.¶

(7) Subject to ORS 183.310 to 183.550, the Division may refuse to issue or renew the ~~license~~permit or may suspend or revoke the ~~license~~permit of any SOA laboratory, if it finds that the owner or director has:¶
(a) Intentionally made false statements on an application for an SOA laboratory license or any other documents required by the Division, or made any misrepresentation in seeking to obtain or retain a ~~license~~permit;¶
(b) Demonstrated incompetence as defined in OAR 333-024-0325;¶
(c) Intentionally falsified any report;¶
(d) Referred a specimen, for examination, to an un~~licenc~~certified clinical or SOA laboratory in this state, or a laboratory out of state not certified by the Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 - Laboratory Requirements, or an equivalent out of state laboratory, unless the laboratory is exempt under section (2) of this rule;¶
(e) Misrepresented the scope of laboratory service offered by the SOA laboratory or the laboratory specialty authorized by the ~~license~~permit;¶
(f) Rendered a substances of abuse report performed in another laboratory without designating the name and address of the laboratory in which the test was performed;¶
(g) Knowingly had professional connection with or permitted the use of the name of the ~~licens~~permitted laboratory or its director by a laboratory which is required to but has not obtained a ~~license~~permit;¶
(h) Failed to perform or cause to be performed within the time specified, analysis of test samples as stated in OAR 333-024-0340 or failed to report on the results of such analysis within the specified time;¶
(i) Failed to permit within a reasonable time the entry or inspection as stated in OAR 333-024-0340(2) and (4);¶
(j) Failed to continue to meet the requirements of this rule, inclusive; and¶
(k) Violated any provision of OAR 333-024-0305 through 333-024-0350.¶
(8) Owner shall be responsible for all aspects of the laboratory.¶
(9) The substance of abuse screening laboratory must be in compliance with requirements of the Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 - Laboratory Requirements, if medical testing for substances of abuse is performed.¶
(10) Entities performing only manual, non-automated SOA screens using easily portable screening tests must register with the Division and meet the requirements at OAR 333-024-0365.¶
(11) ~~Licens~~Certified clinical laboratories or permitted SOA screening laboratories performing a combination of medical and manual, non-medical SOA screens are not required to register with the Division and must meet the requirements of OAR 333-024-0365(5)(e) when performing tests which qualify for SOA registration.¶
(12) ~~Licens~~Certified clinical laboratories performing only manual, non-medical SOA screens using easily portable screening tests must register with the Division and meet the requirements of OAR 333-024-0365.¶
(13) Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 - Laboratory Requirements, that perform medical and non-medical substance of abuse screening, must comply with 333-024-0305 through 333-024-0350 and 333-024-0365(5)(e).¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 438.0~~50, 438.130, 438.435~~(4), (5), (6), 438.040~~40~~, ORS 438.435
Statutes/Other Implemented: ORS 438.~~050, 438.130 - 438.~~160, ORS 438.435

AMEND: 333-024-0320

RULE SUMMARY: OAR 333-024-0320 is being amended with minor editorial changes, removal of language associated with dates in the past, and to align with changes in statute.

CHANGES TO RULE:

333-024-0320
Testing for Substances of Abuse: Qualifications and Responsibilities of Directors ¶

(1) The director of a substances of abuse (SOA) screening laboratory shall meet one of the following qualifications:¶
(a) Is a pathologist certified in clinical pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or is eligible for such certification;¶
(b) Is a physician with two or more years of clinical chemistry experience, with one year in toxicology;¶
(c) Has an earned degree of Doctor of Science (ScD), Doctor of Public Health (DrPH) or Doctor of Philosophy (PhD) in chemistry or biochemistry and has two or more years of clinical chemistry training or experience with one year in toxicology;¶
(d) Is certified or is eligible for certification by the American Board of Clinical Chemistry or by the American Board of Forensic Toxicology;¶
(e) Has an earned master of science degree in medical technology, chemistry, or biochemistry and has three or more years of clinical chemistry training or experience, with one year of pertinent experience in toxicology; or¶
(f) Has a bachelor of science, bachelor of technology or bachelor of arts degree in medical technology, chemistry or biochemistry, and has four or more years of clinical chemistry training or experience, with one year experience in ~~toxicology;¶~~
~~(g) Has directed substance of abuse screening for at least 12 months within the four years preceding January 1, 1987, and has at least two years of pertinent experience in~~ toxicology.¶
(2) The director of an SOA screening laboratory shall be responsible for the quality of the work. This shall include, but not be limited to, the following:¶
(a) Monthly review and documentation of quality control data;¶
(b) Review and documentation of external proficiency testing within 30 days of receipt of the final report;¶
(c) Review and documentation of procedure manuals and relevant texts initially and also whenever there is a change in method or policy;¶
(d) Validation of new procedures prior to reporting test results;¶
(e) Review and documentation of preventive maintenance of equipment;¶
(f) Review of additional quality assurance items;¶
(g) Assure that qualified technical personnel perform the tests; and¶
(h) Assure the competency of all testing personnel annually.¶
(3) The director of an SOA screening laboratory shall require the submitter to indicate the need for confirmatory testing as described in ORS 438.435(~~6~~4).¶
(4) A person shall not serve individually as director of more than five substances of abuse screening laboratories.¶
(5) Those individuals qualifying under 333-024-0320(1)(g) must have applied to the Public Health Division by January 1, 1989.
Statutory/Other Authority: ORS 438.~~050, 438.130, 438.435(4), 438.435(5), 438.435(6)~~435
Statutes/Other Implemented: ORS 438.2~~1~~20, ~~438.220,~~ORS 438.435

AMEND: 333-024-0325

RULE SUMMARY: OAR 333-024-0325 is being amended with minor editorial changes.

CHANGES TO RULE:

333-024-0325
Testing for Substances of Abuse: Incompetence ¶

A~~n~~ substances of abuse (SOA) laboratory owner or director has "demonstrated incompetence" if there is:¶
(1) Repeated error demonstrated in the performance of laboratory tests or procedures or the results thereof;¶
(2) Failure to comply with the requirements of OAR 333-024-0335 and 333-024-0340 relating to internal and external quality control;¶
(3) Failure to comply with ORS 438.435 or any regulations pertaining to the laboratory;¶
(4) Work assigned to personnel not qualified to perform in that specialty; or¶
(5) Repeated erroneous reporting of test results.
Statutory/Other Authority: ORS 438.~~050, 438.130, 438.435(4), 438.435(5), 438.435(6)~~435
Statutes/Other Implemented: ORS 438.160, 438.435

AMEND: 333-024-0330

RULE SUMMARY: OAR 333-024-0330 is being amended with minor editorial changes and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0330
Testing for Substances of Abuse: Specimen Collection, Chain of Custody, Records, and Reports ¶

(1) The specimen container shall be clean, tightly sealed and free of any interfering substance. It shall be transported and stored in such a manner as to preserve the integrity and security of the specimen.¶
(2) The specimen container shall be permanently labeled with time and date of collection and at least one of the following:¶
(a) The name of the person from whom the specimen was taken, if available;¶
(b) Social security number;¶
(c) Employee number; or¶
(d) Unique identifying number.¶
(3) The initial request form, used by the person requesting the test, must have a statement indicating whether, if positive, the test results are to be confirmed as required under ORS 438.435(~~7~~4).¶
(4) For those specimens requiring a confirmatory test, a record shall be made of the following:¶
(a) Time and date of collection;¶
(b) Identity of the individual receiving the specimen; and¶
(c) Manner by which the specimen was sent to the laboratory, including the name of the common courier or the individual delivering the specimen.¶
(5) Any laboratory receiving or referring the specimen shall keep for a minimum of two years a record of the following:¶
(a) The condition under which the specimen was collected or received and results of tests or information to rule out adulteration of the specimen;¶
(b) The date, time and one of the unique identifications from the specimen label;¶
(c) Time and date received and referred;¶
(d) Laboratory accession number;¶
(e) Condition of the specimen;¶
(f) The name of the company or individual requesting the test; and if positive, whether the specimen requires confirmatory testing as described in OAR 333-024-0345(1);¶
(g) The type of test performed;¶
(h) The results of the tests and controls in units of measurement where applicable~~;~~, and the type and concentration of standard(s) used in testing;¶
(i) Storage of specimen before and after screening;¶
(j) The signature, initials, or identification of the testing personnel;¶
(k) Date and time the tests were completed; and¶
(l) The name of the clinical laboratory performing the confirmatory testing if required under OAR 333-024-0345(1).¶
(6) Clinical and substance of abuse screening laboratories may examine specimens submitted by persons other than medical personnel authorized by law and shall report the result of any test to the person or company who requested the test except as indicated in ~~number~~section (7) of this rule.¶
(7) A copy of the SOA test results must be provided to the employee or pre-employee from whom the specimen was collected, after the employee or pre-employee submits a written request and proof of identity to the laboratory.¶
(a) When a written request is given to the laboratory in person:¶
(A) The employee or pre-employee must present two proofs of identity to the laboratory, which must include one of the following picture identification cards: state driver's license, state identification card, passport or a non-citizen resident card, such as a Permanent Resident Card or Green Card from the U.S. ~~Department of Immigration and Naturalization Service~~Citizenship and Immigration Services (USCIS).¶
(B) The employee or pre-employee must sign and date a form for release of laboratory records.¶
(b) When a written request for SOA test results is received by mail:¶
(A) The request must be accompanied by a signed and dated form for release of laboratory test results and a notarized statement of the employee's or pre-employee's identity and mailing address.¶
(B) The laboratory will make a copy of the pertinent SOA test results and send this copy by registered or certified mail, or other bonded courier that would assure the confidentiality of the results, to the address requested by the

notarized statement.¶
(c) A copy of the signed release form and picture identification, or the notarized statement, shall be maintained by the laboratory for two years.
Statutory/Other Authority: ORS 438.435
Statutes/Other Implemented: ORS 438.310, ~~438.320,~~ 438.435

AMEND: 333-024-0340

RULE SUMMARY: OAR 333-024-0340 is being amended with minor editorial changes, to update terminology (remove license, replace with permit) and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0340
Testing for Substances of Abuse: External Quality Control (Proficiency Testing Program and On-Site Inspections) ¶

(1) ~~Licensed~~ Permitted substances of abuse (SOA) laboratories shall:¶
(a) At the laboratory's own expense, be required to participate satisfactorily in the proficiency testing programs of the College of American Pathologists, or the American Association of Bioanalysts, or such other substantially equivalent testing program as may be approved by the ~~Division~~Public Health Division (Division) involving substances of abuse testing and make available to the Division all test results;¶
(b) Be required to participate satisfactorily if required in the proficiency testing programs conducted by the Division involving substances of abuse testing;¶
(c) Analyze test samples submitted by the Division prior to, during, or subsequent to inspection if requested to the Division;¶
(d) Achieve satisfactory results on test samples in agreement with reference laboratories or within stated acceptable limits and which results shall be reviewed by the Division. Continued or consistent failure two out of three periods may result in the laboratory's ~~license~~permit being withdrawn by the Division until satisfactory performance is demonstrated; and¶
(e) Ensure that proficiency samples are tested by regularly assigned personnel using routine methods. A specified time shall be allowed for such testing and reporting of results.¶
(2) Biennial on-site inspections may be conducted by representatives of the Division at reasonable times during the laboratory's normal business hours without advance notice. The representative shall inspect the facilities, personnel policies, procedures, materials, staff qualifications, equipment and records.¶
(3) The owner or director of an SOA laboratory may be required to submit reports on the operations and procedures of the laboratory.¶
(4) Additional inspections may be performed without notice to verify correction of deficiencies, investigate complaints, review unsatisfactory proficiency testing and verify personnel qualifications or other monitoring of compliance with OAR 333-024-0305 through 333-024-0350.
Statutory/Other Authority: ORS 438.3~~2~~1~~0~~0, 438.435
Statutes/Other Implemented: ORS 438.3~~2~~1~~0~~0, 438.435

AMEND: 333-024-0345

RULE SUMMARY: OAR 333-024-0345 is being amended with minor editorial changes, to update terminology (remove license, replace with certificate) and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0345
Testing for Substances of Abuse: Confirmatory Testing ¶

(1) When the substances of abuse screening laboratory obtains a positive test result and the submitter indicates the result is to be used to deprive or deny any person any employment or any benefit, that same specimen must be submitted and confirmed prior to the release of the screening results. When performed within the State of Oregon, the confirmatory testing shall be by a clinical laboratory ~~licensed under ORS 438.110 and 438.150 or~~ certified under the Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578, 42 U.S.C. 201 and 263a for that testing. The confirmatory testing shall be as described in section (4) of this rule.¶
(2) The administrator of the ~~Division~~Public Health Division (Division) shall appoint a substances of abuse methods panel to recommend approval of methods used to confirm the presence of substances of abuse. The panel shall be composed of individuals from laboratories performing substances of abuse testing and shall include, but not be limited to, representatives from the Oregon State Police ~~Crime Laboratory~~Forensic Services Division, laboratories ~~licens~~certified under ORS ~~C~~chapter 438, and the Oregon Health and Science~~s~~ University.¶
(3) Any scientifically tested method for substances of abuse analysis may be submitted to the Division, for approval, by written request from a manufacturer, laboratory, or other party. Each candidate method shall be evaluated as to its capacity for accuracy by the panel, with recommendation based thereon, by one or more of the following means:¶
(a) Government or independent studies of the method's accuracy;¶
(b) Comparative data on proficiency test performance of various methods;¶
(c) Application of the method by panel members in performance of analysis; or¶
(d) Other means as determined by the Division.¶
(4) The following methods of chemical analysis to determine substances of abuse have been approved:¶
(a) Chromatography;¶
(b) Immunoassay;¶
(c) Spectroscopy; and¶
(d) Mass spectroscopy.¶
(5) The confirmatory test shall be performed by a different analytical method from that used for the initial screening test.
Statutory/Other Authority: ORS 438.0~~50, 438.130, 438.435(4), 438.435(5), 438.435(6)~~40, ORS 438.435
Statutes/Other Implemented: ORS 438.040, ORS 438.435

AMEND: 333-024-0360

RULE SUMMARY: OAR 333-024-0360 is being amended with minor editorial changes, to remove outdated language to align with changes in statute due to the passage of SB 844 (Oregon Laws 2025, chapter 624) and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0360
Testing for Substances of Abuse: Special Category Laboratories ¶

(1) Theis rules in this section sets standards for special category screening laboratories, as authorized in ORS 438.435(4), (6) and (7). Theseis rules apply ies to the testing of inmates within state and local correctional facilities and to the testing of offenders on parole, probation, or under post-prison supervision.¶
(2) Special category laboratories as defined in this rule must use only manual or automated substance of abuse screening methods approved by the U.S. Food and Drug Administration. Any alcohol screening test must meet the requirements of the conforming products list found in the United States Department of Transportation National Highway Traffic Safety Administration Docket No. 94-004 and meets the standards of the United States Department of Transportation Alcohol Testing Procedure, 49 C.F.R. part 40, in effect on October 23,1999.¶
(3) Individuals who perform screening tests for substances of abuse must complete a training course offered by the manufacturer or provider of the test, an educational facility, or training provided by the Oregon Department of Corrections Drug ControlProfessional Development Unit with curriculum acceptable to the Public Health Division. No testing is to be performed prior to the completion of this training. A certificate of satisfactory completion, including the dates and hours of training completed, shall be kept by the substances of abuse (SOA) testing program manager at each facility and parole office. A copy shall also be on file within the Drug Control Manager at theOregon Department of Corrections training records.¶
(4) Protocols, procedures, and records of all testing shall be maintained as described in this section and shall be followed:¶
(a) Each local and state correctional facility or parole office shall have a designated substance of abuse program manager who shall assure that:¶
(A) Written policies established by the Department of Corrections are followed regarding specimen collection, specimen identification, and chain of custody, as defined in OAR 333-024-0310(2);¶
(B) Written procedure manuals are available to testing individuals, and that the written procedures require following the manufacturer's testing protocol. The written procedures must describe the test limitations and the use of approved standards and quality control, as defined in OAR 333-024-0310(4) and (21).¶
(C) There is a written record of the:¶
(i) Date and time the specimen was obtained;¶
(ii) Date and time the test was performed;¶
(iii) Lot number of the test kit used, test results, including the results of controls; and¶
(iv) Signature or initials of the analyst.¶
(b) Quality control procedures as described in this subsection shall be followed:¶
(A) Each instrument shall be calibrated according to the manufacturer's specifications, with each new lot or shipment of reagents, and after major maintenance;¶
(B) For manual methods, known positive and negative controls, as defined in OAR 333-024-0310(4), shall be included with each batch of tests or with every ten samples for each analyte of each kit. Known positive and negative controls must be run with each lot shipment, and at least once per month, if internal procedural controls are included with each test;¶
(C) For automated instruments, a positive and negative control, as defined in OAR 333-024-0310(4) shall be included at least once per day of use, or following each ten10th sample analyzed;¶
(D) All calibration and control data shall be recorded;¶
(E) The minimum detectable limit of the analytical method for each substance tested shall be available;¶
(F) Limits for controls shall be clearly stated and recorded. The corrective action taken when analyses are outside these control limits shall be clearly stated and recorded;¶
(G) No reagent shall be used beyond its expiration date;¶
(H) A record shall be kept of each testing individuals' quality control performance. This record will be reviewed by the SOA program manager at least every six months;¶
(I) Each local and state correctional facility, parole, probation, and post prison program shall be required to participate satisfactorily in a proficiency testing program, as defined in OAR 333-024-0310(16). The proficiency testing programs available from the College of American Pathologists, or the American Association of Bioanalysts,

or other proficiency testing program acceptable to the Public Health Division may be used; and¶
(J) Proficiency testing results and control data shall be reviewed every six months by the SOA program testing manager, and corrective action shall be taken and documented when appropriate. ~~A copy of the report and corrective action must be sent to the Drug Control Manager of the Department of Corrections for review.~~¶
(c) If an initial test shows a result indicating the presence of a substance of abuse in the body, a confirmatory test shall be conducted in a ~~licensed clinical laboratory, or a~~ laboratory certified for that testing under the Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations Part 493 - Laboratory Requirements, or an equivalent out of state laboratory, if the results are to be used to deprive or deny any person of any benefit, probation, or parole except as described in ORS 438.435~~(7)~~.¶
(d) If any test for substances of abuse is performed outside this state the results of which are used to deprive or deny any person any benefit, the person desiring to use the test shall have the burden to show that the testing procedure used meets or exceeds the testing standards of this state.
Statutory/Other Authority: ORS 438.~~050, 438.130, 438.435(4), 438.435(5), 438.435(6)~~435
Statutes/Other Implemented: ORS 438.435

AMEND: 333-024-0365

RULE SUMMARY: OAR 333-024-0365 is being amended with minor editorial changes, to update reference to state and federal entities and to update terminology (remove license, replace with certificate or permit).

CHANGES TO RULE:

333-024-0365
Testing for Substances of Abuse: Substance of Abuse ~~Registr~~Permit Applic̲ation ¶

(1) It shall be unlawful for any entity to perform any on-site test for non-medical substance̲s of abuse (SOA) screening tests prior to filing a ~~registr~~n applic̲ation form with the ~~Division~~Public Health Division (Division) and payment of the ~~registration~~permit fee, except laboratories:¶
(a) Owned and operated by the U.S. Government;¶
(b) Performing pure research;¶
(c) Performing substance̲s of abuse tests for forensic purposes only;¶
(d) Performing substance̲s of abuse tests from autopsy specimens;¶
(e) Identified as teaching facilities only training students in test performance; or¶
(f) Owned and operated by the Oregon State Police performing substance̲s of abuse screens for forensic purposes.¶
(2) SOA ~~registration is~~permits are not transferable to another entity.¶
(3) It shall be unlawful for a ~~register~~permitted substance̲s of abuse entity to perform medical testing.¶
(4) Clinical and SOA screening laboratories must meet the requirements under subsections (5)(e) of this rule when performing tests which qualify for SOA ~~registration.¶~~
~~(5) Registr~~permit.¶
(5) Permit applic̲ation̲s shall be on a form provided by the Division and shall contain:¶
(a) The entity name and address;¶
(b) Name of legal owner and tax identification number;¶
(c) Telephone number;¶
(d) Name of individual contact at each on-site facility operated by the entity; and¶
(e) Signature of the operator certifying that:¶
(A) Only SOA kits approved by the U.S. Food and Drug Administration (FDA) or alcohol screening tests that meet the requirements of the conforming products list found in the United States Department of Transportation National Highway Traffic Safety Administration Docket No. 94-004 and meet the standards of the United States Department of Transportation Alcohol Testing Procedure, 49 C.F.R. part 40, in effect on October 23, 1999, are used;¶
(B) Tests are administered according to the manufacturer's package insert;¶
(C) Custody chain procedures are written and followed;¶
(D) Operators of the SOA on-site screening facility are trained in the use of the SOA screening tests by the manufacturer; and¶
(E) When the SOA on-site facility obtains a positive result on a specimen and the entity indicates that the test result is to be used to deny or deprive any person of employment or any benefit, or may otherwise result in adverse employment action, the same specimen shall be submitted to a clinical laboratory ~~licensed under ORS 438.110 or 438.150, or~~ certified under the Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578, 42 .U.S.C. 201 and 263a for that testing, or an equivalent out of state laboratory and the presence of a substance of abuse confirmed, using a different analytical method, prior to the release of the on-site test result.¶
(6) Evidence of ~~registration~~a permit with the Division shall be posted at the entity location shown on the registration form and at each on-site facility.¶
(7) The annual fee for filing a ~~registr~~permit applic̲ation form with the Division is $50 for each entity. The fee cycle shall be January 1 through December 31~~, beginning 1998~~.¶
(8) All monies received by the Division for the registration of SOA entities shall be credited to the Division account and shall be used for payment of the expenses of the Division in administering OAR 333-024-0365.¶
(9) A list of ~~register~~permitted entities is available, upon request, from the Division.¶
(10) SOA entities may examine specimens submitted by persons other than medical personnel and shall report the result of any SOA test to the person or company who requested the test except as indicated in ~~number~~section (11) of this rule.¶
(11) A copy of the SOA test results must be provided to the employee or pre-employee from whom the specimen was collected, after the employee or pre-employee submits a written request and proof of identity to the registered SOA entity.¶
(a) When a written request is given to the SOA entity in person:¶

(A) The employee or pre-employee must present two proofs of identity to the registered SOA entity, which must include one of the following picture identification cards: state driver's license, state identification card, passport or a non-citizen resident card, such as a Permanent Resident Card or Green Card from the U.S. ~~Department of Immigration and Naturalization Service~~Citizenship and Immigration Services (USCIS).¶
(B) The employee or pre-employee must sign and date a form for release of laboratory records.¶
(b) When a written request for SOA test results is received by mail:¶
(A) The request must be accompanied by a signed and dated form for release of laboratory test results and a notarized statement of the employee's or pre-employee's identity and mailing address.¶
(B) The laboratory will make a copy of the pertinent SOA test results and send this copy by registered or certified mail, or other bonded courier that would assure the confidentiality of the results, to the address requested by the notarized statement.¶
(C) A copy of the signed release form and picture identification or the notarized statement, shall be maintained by the registered SOA entity for two years.
Statutory/Other Authority: ORS 438.435
Statutes/Other Implemented: ORS 438.435

AMEND: 333-024-0370

RULE SUMMARY: OAR 333-024-0370 is being amended with minor editorial changes.

CHANGES TO RULE:

333-024-0370
Health Screen Testing: Purpose ¶

OAR 333-024-0370 through 333-024-0400 are for the purpose of carrying out ORS 438.010(~~8);~~6), ORS 438.060~~; 438.130(2); 438.150(5), (6) and (7)~~, and ORS 438.150. 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.
Statutory/Other Authority: ORS 438.010~~(10)~~, 438.060, 438.1~~30(2), 438.150(5), (6), (7)~~50
Statutes/Other Implemented: ORS 438.060, ~~438.130,~~ 438.150, 438.310

AMEND: 333-024-0375

RULE SUMMARY: OAR 333-024-0375 is being amended with minor editorial changes and update reference to state and federal entities in the definitions.

CHANGES TO RULE:

333-024-0375
Health Screen Testing: Definitions ¶

Except as provided in this ~~section~~rule, 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 associate licensed by the ~~Board of~~Oregon Medical ~~Examiners for the State of Oregon~~Board.¶
(2) "Health ~~S~~screen ~~T~~testing" means tests performed without a physician's or clinician~~s~~'s order for the purpose of identifying health risks, providing health information, and referring the person being tested to medical care.¶
(3) "Health ~~S~~screen ~~T~~testing ~~S~~service" means a service providing health screen testing.¶
(4) "Health ~~S~~screen ~~T~~testing ~~S~~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.,~~including but not limited to 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 ~~L~~laboratory ~~E~~experience" means the activity of performing laboratory testing or directing the performance of testing in human clinical chemistry.¶
(9) "Site ~~D~~day" means the 24-hour period during which, either all or part of the time, testing is performed at a specific location.
Statutory/Other Authority: ORS 438.010~~(10)~~, 438.060, 438.1~~30(2), 438.150~~(5), (6), (7)50
Statutes/Other Implemented: ORS 438.010, 438.060, ~~438.130,~~ 438.150

AMEND: 333-024-0380

RULE SUMMARY: OAR 333-024-0380 is being amended with minor editorial changes, to remove language associated with dates in the past, and to update reference to state entities.

CHANGES TO RULE:

333-024-0380
Health Screen Testing: Permits ¶

(1) Any person who operates a health screen testing service must obtain a permit from the ~~Division~~Public Health Division (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 testing through 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 Oregon Health Authority, Public Health Division.¶
(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 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 subsection (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, t~~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 ~~C~~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: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 438.010~~(10)~~, 438.060, 438.1~~30(2) & 438.150(5), (6) & (7) & 341, 1999 OL~~50, 1999 OL ch. 341, 438.040
Statutes/Other Implemented: ORS 438.010, 438.0~~5~~60, 438.~~055, 438.060, 438.130, 438.15~~150, 438.040

AMEND: 333-024-0390

RULE SUMMARY: OAR 333-024-0390 is being amended with minor editorial changes and to remove language associated with dates in the past.

CHANGES TO RULE:

333-024-0390
Health Screen Testing: 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; or¶
(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 ~~D~~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 ~~M~~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~~4) 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~~5) Technical and clinical consultants must fulfill the responsibilities listed in OAR 333-024-0023(1).¶
(~~7~~6) All testing personnel must have at least an academic high school diploma or equivalent.
Statutory/Other Authority: ORS 438.010~~(10)~~, 438.060, 438.1~~30(2), 438.150(5), (6), (7)~~50
Statutes/Other Implemented: ORS 438.150

AMEND: 333-024-0395

RULE SUMMARY: OAR 333-024-0395 is being amended with minor editorial changes and to update terminology removing reference to state license.

CHANGES TO RULE:

333-024-0395
Health Screen Testing: 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(243) 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; and¶
(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 333-024-0395(1) at the patient's request, without an order from a physician or clinician.
Statutory/Other Authority: ORS 438.010~~(10)~~, 438.060, 438.130~~(2), 438.150(5), (6), (7)~~50
Statutes/Other Implemented: ORS 438.150

AMEND: 333-024-0400

RULE SUMMARY: OAR 333-024-0400 is being amended with minor editorial changes and to update reference to state and federal entities.

CHANGES TO RULE:

333-024-0400
Health Screen Testing: Quality Assurance ¶

Quality Aassurance shall be comprised of linternal Qquality Ccontrol, Ttests R reports and Rrecords, Qquality Aassurance Aactivities, Ssafety, Eexternal Qquality Ccontrol, Ccounseling and Rreferral:¶
(1) Internal Qquality Ccontrol:¶
(a) Documentation of training of testing personnel as specified in OAR 333-024-0390(2)(e) shall be kept on file at the permanent location and made available to the AuthorityOregon Health Authority (Authority) 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; and¶
(G) Normal ranges and test limitations.¶
(c) Procedure manuals shall be reviewed by the Ddirector;¶
(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; and¶
(m) All quality control and equipment maintenance records shall be reviewed by the Ddirector 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 ~~S~~screen ~~T~~testing services must maintain records of patient name, address and test values for at least ~~2~~two years; and¶
(i) Health ~~S~~screen ~~T~~testing laboratories performing moderate complexity testing must comply with the rules in OAR 333-024-0026(12) & (13) and OAR 333-024-0035(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 ~~as~~ensure 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~~;r~~. Refer to the infectious waste rules under OAR 333-018-0040 through 333-018-0070;¶
(h) Electrical equipment is maintained in a safe condition with regards to shock and fire hazards; and¶
(i) Work surfaces are disinfected with a virucidal reagent after each blood spill, and prior to and after each day of testing.¶
(5) External ~~Q~~quality ~~C~~control:¶
(a) Permitted health screen testing services shall:¶
(A) ~~As~~Ensure 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 Authority.¶
(B) Meet the proficiency testing requirements as described in CLIA 88, 42 CFR, Part 493, Subpart H, available on request from the Authority.¶
(C) Analyze test samples submitted by the Authority prior to, during, or subsequent to inspection if requested by the Authority and achieve a score of at least 80 percent.¶
(D) Notify the Authority within six months if the analysis of a test has been discontinued or added to patient testing.¶
(E) Notify the Authority 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 on-site or as paper surveys and the entity will be required to submit documentation to the Authority that quality control and quality assurance activities and test records meet this rule. On-site inspections may be conducted by representatives of the Authority 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 Authority or ~~HCFA~~U.S. Centers for Medicare and Medicaid Service (CMS) 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 ~~R~~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.
Statutory/Other Authority: ORS 438.010~~(10)~~, 438.060, 438.1~~30(2), 438.150~~(5), ~~(6), (7)~~50
Statutes/Other Implemented: ORS 438.150