

May 10, 2010

TO: Health Screen Testing (HST) Permit Laboratories

FROM: Laboratory Compliance Section (LCS)
Rita A. Youell, Program Manager

SUBJECT: HST Permit for July 1, 2008 thru June 30, 2010

It is time to renew your HST permit for the period July 1, 2010 through June 30, 2012. If you wish to continue health screen testing, you must have a valid HST permit from the Department of Human Services in addition to your federal Clinical Laboratory Improvement Amendments (CLIA) certification or accreditation. Oregon Administrative Rules filed November 3, 2000, clarify that CLIA does not cover the intent of OAR 333-024-0370 through 333-024-0400 for testing without a physician/clinician's order.

Complete the enclosed re-licensure form. ***The director or owner signature must appear at the bottom of the renewal application to complete the re-application process.*** If you make a change of laboratory director, review the director's qualifications under 333-024-0290 to assure that an application is not submitted with an unqualified director. A 'Director Qualification Appraisal' form must be submitted for any **new** director.

An enclosed HST Self-Survey has been sent to all HST laboratories. ***If your HST testing is surveyed under a CLIA/Accreditation program you do not need to complete the HST Self-Survey.*** If the Self-Survey is complete and the HST service appears to have a quality operation, no onsite survey will be performed. *Your July 1, 2010 through June 30, 2012 Permit will be issued when your renewal application, acceptable Self-Survey and fee are received by LCS.*

The cost for an HST permit is \$150 for the two-year cycle. A payment of \$150 must accompany your completed renewal application, made payable to: Oregon Public Health Division, Fiscal Services. **Attach your renewal form and Self-Survey to your check/money order and mail** to: Oregon Public Health Services, Fiscal Services, PO Box 14260 Portland OR 97293-0260.

Testing may be performed onsite or taken to an offsite location. Always have your permit posted at the primary location, and carry a copy for display during offsite testing.

If you have any questions or need assistance in completing the renewal application or Self-Survey, please call our office at 503-693-4125.

Included in this packet are:

- Cover Letter
- Renewal Application form
- HST Laboratory Self-Survey
- HST Director Qualification Appraisal form
- Director of Health Screen Testing Educational & Experience Requirements

In compliance with the ADA, this document is available in alternate formats by phoning (503) 693-4100.

Application for Health Screen Testing Permit

76700 72551 2130 \$150.00 (Fiscal Use Only)

Oregon State Public Health Division
Laboratory Compliance Section
503-693-4125 Fax: 503-693-5602
TTY: 971-673-0372 www.healthoregon.org/ll



FOR STATE USE ONLY State #

CLIA#

Reopen

Re-license Reviewed:

I. LABORATORY OWNERSHIP

Complete Laboratory Name

Laboratory **Mailing** Address (include street, city, state, zip)

Laboratory **Location** Address (include street, city, state, zip)

Contact person:

Was this lab previously licensed? Yes No (Phone # - include area code)

Is there a current or previous CLIA number? Yes No CLIA #:

Indicate testing location: one fixed location multiple sites mobile

Owner name

County

Telephone #

FAX #

Federal Tax ID #

Indicate the ownership type that best describes this lab:

Corporation - List corporate name, city & state where registered:

Sole Proprietorship

Partnership - Attach list of partners

Government: City County State Federal

II. EXTENT OF SERVICES/TEST VOLUME

Date lab started testing: ____/____/____ Check each service your HST will perform, add estimate of total annual test volume per each:

	Volume	Method Instrument
<input type="checkbox"/> Blood Glucose (whole blood)	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Blood in feces (occult blood)	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Blood Hemoglobin	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> High density lipoprotein (HDL)	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Human Chorionic Gonadotropin (urine)	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Packed cell volume (hematocrit)	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Total Cholesterol	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Triglyceride	<input type="text"/>	<input type="text"/>
TOTAL annual test volume	<input type="text"/>	<input type="text"/>

III. DIRECTOR QUALIFICATIONS - SEE HST SYNOPSIS FOR QUALIFICATION REQUIREMENTS

Name of Director: Phone:

Complete Director Qualification Appraisal form (included) for Health Screen Testing and submit with application
Only for New HST lab Director applicants, or if there has been a Change of HST laboratory Director

Application continues other side →

Instructions for payment and application submittal

- ◆ The cost for a Health Screen Testing Permit is \$150 for the two year cycle beginning July 1, 2010 through June 30, 2012.
- ◆ Submit payment with the application form.
- ◆ Make checks payable to **Oregon Public Health Division**.
- ◆ Attach your check to your application and mail to:
Oregon Public Health Division, Financial Services, PO Box 14260, Portland OR 97293-0260.

Failure to pay the appropriate fee invalidates your application.

IV. DIRECTOR AFFILIATIONS

If the director of this laboratory is also the director for any other laboratories, list below:

Laboratory name	State Laboratory #

V. OPERATION AND SERVICES

List name(s) and address(es) of other laboratories operated by same owner:

VI. PROFICIENCY TESTING

List the proficiency testing program to which you have subscribed: _____
(applies only to Moderate and High Complexity laboratories)

VII. SIGNATURE

The original signature of Director/Owner is required to process application

I attest that the information provided is true and accurate to the best of my knowledge

<p>_____</p> <p>Signature of Director/Owner</p>	<p>_____</p> <p>Date</p>
---	--------------------------

<p>_____</p> <p>Print name of Director/Owner signature</p>
--

For LCS Office Use Only

Applicant qualifies under:

- Health Screen Testing Director - OAR 333-024-0390(1) a b c d e f
- Does not qualify - reason _____

Note: In compliance with the Americans with Disabilities Act (ADA), this form is available in alternate formats by calling 503-693-4100.

Oregon Public Health Division
Laboratory Compliance Section
PO Box 275
Portland, OR 97207-0275
503-693-4125 Fax 503-693-5602
www.healthoregon.org/li



Laboratory Compliance Section only
Approval date ____/____/____
By _____

Your HST testing is surveyed under a CLIA or Accreditation program. Therefore you are exempt from this survey. *Check box if this applies to you.*

HST Laboratory 2010 Re-Licensure Self Survey

Send copies of the following records for each instrument and test kit:

- ① Calibration records. If applicable, this includes any optics checks. Include all records for the last six testing events not to exceed two years.
- ② Quality control (QC) records for the last six testing events not to exceed two years.
 - **Include the manufacturer's acceptable range for each QC level.**
- ③ Temperature logs of refrigerators used for reagent storage for the last year.

HST Permits will not be released without acceptable documentation for the above items.

This document is available in alternate formats by calling 503-693-4100.

Director Qualification Appraisal – Health Screen Testing Permit Laboratory

For directing State of Oregon Health Screen Testing (HST) Permit laboratories, in compliance with Oregon Administrative Rule 333-024-0390.

General Information (Please print)

Applicant's Name: _____
 Laboratory Name: _____
 Phone and Fax: _____
 CLIA Lab Info: _____ Are you also applying for a new CLIA lab? yes no
 If no, list current CLIA # _____
 Other HST labs: _____
 Directed: _____

Schools Attended and Degrees Received (or attach your CV)

Name and location	From	To	Program Title	Degree or Credential

Clinical laboratory experience (list current or most recent first)

(Please attach additional pages as needed)

Laboratory name, city and state where located	Title/Position	From – To (month & year)	Microbiology	Hematology	Chemistry	Pathology	Specify Other

Add information pertinent to your education, laboratory training, employment etc., not included above

Indicate instruments used & your knowledge of quality control, instrument maintenance and QA practices. Use additional sheet if needed.

Signature Required - Applicant certifies that all statements in this form are true, accurate and correct

Applicant Signature: _____ Date: _____

 Oregon State Public Health Division
Laboratory Compliance Section
 PO Box 275
 Portland, OR 97207-0275
 Phone: 503-693-4125
 Fax: 503-693-5602 TTY: 971-673-0372
www.healthoregon.org/li

<p>FOR STATE USE ONLY</p> <p><i>Applicant qualifies under:</i></p> <p><input type="checkbox"/> Health Screen Testing Director OAR 333-024-0390(1) a b c d e</p> <p><input type="checkbox"/> Does not qualify – reason:</p> <p>_____</p> <p>_____ By: _____</p> <p>Date: _____</p> <p style="text-align: right;">Shared/LC Files/DirectorAppraisal-HST Lab.doc</p>
--

HST Director Education and Experience Requirements: OAR 333-024-0390

Educational Requirements

The HST Director must meet one of the following qualifications:

1. Medical Doctor (MD) or a Doctor of Osteopathy (DO) licensed to practice in Oregon; (provide the state license number issued by the Oregon Medical Board); or
2. 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; or
3. Earned Master of Science degree in medical technology, chemistry, biochemistry, or other closely related science from an accredited institution; or
4. Bachelor of Science, Bachelor of Technology, or Bachelor of Arts degree in medical technology, chemistry, or biochemistry from an accredited institution; or
5. Performed the duties of a director of a health screen testing service for at least six site days during the twelve months prior to 1/1/90. Proof is required.

Experience

Individuals meeting one of the requirements above must also have the appropriate clinical laboratory experience as indicated below:

- Meet educational requirements under 1. and 2. above - must have one or more years of pertinent clinical laboratory experience.
- Meet educational requirement under 3. above - must have two or more years

of pertinent clinical laboratory experience.

- Meet educational requirement under 4. - must have four or more years of pertinent clinical laboratory experience.

➡ *When submitting your HST Director Qualification Appraisal form for approval, provide the following documentation:*

1. A copy of your applicable college or university diploma equivalent to a Bachelor's, Master's, or Doctorate degree.
2. An outline of your pertinent experience in the testing of Health Screen Testing analytes (glucose, cholesterol, hemoglobin, hematocrit, etc.). Please include information regarding your experience in preventive maintenance of equipment, quality control performed (number of controls run and how often), action taken when reagents or strips expired, how you handled out of control results, how records were kept on patients and quality control results, how you detected shifts or trends in quality control, and your participation in collection of blood specimens.

Note - if you offer or have offered training to patients or clients regarding home use of glucose or other laboratory instruments, submit a copy of your training materials. This should include written materials provided to clients regarding the items listed in the above paragraph, if pertinent.

3. Any additional items which you feel would be helpful in qualifying you as an HST director. For example: consultation given to clients/patients and additional laboratory training or laboratory courses that you have taken.

In accordance with the ADA this information is available in alternate formats by phoning 503-693-4100.

I:/LC Files/HST Director requirements