

You must provide a copy of  
your current CLIA Certificate  
when re-applying for  
Oregon's Health Screen  
Testing (HST) Permit

3150 NW 229<sup>th</sup> Avenue, Suite 100  
Hillsboro, OR 97124-7251  
Voice: (503)-693-4125  
Fax: (503)-693-5602  
TTY: (971)-673-0372

May 7, 2012

TO: All Current HST Permit Laboratories

FROM: Rita A. Youell, Program Manager  
Laboratory Compliance Section, Oregon CLIA State Agency

SUBJECT: HST Permit renewal notification

It is time to renew your HST permit for the period of July 1, 2012 through June 30, 2014. 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's/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 application process. If you make a change of laboratory director, review the director's qualifications under OAR 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, 2012 through June 30, 2014 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 and Self Survey form(s), made payable to: Oregon Public Health Division. Attach your renewal form and Self-Survey to your check/money order and mail to: Oregon Public Health Division, Financial 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.



Oregon Public Health Division  
Laboratory Compliance Section  
PO Box 275  
Portland, OR 97207-0275  
☎503-693-4125 Fax 503-693-5602  
[www.healthoregon.org/ll](http://www.healthoregon.org/ll)

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

Our HST testing is surveyed under a CLIA or Accreditation program. Therefore we are exempt from this survey. *Check box if 'yes'*

**HST Laboratory 2012 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.

**Application for Health Screen Testing Permit**

56700 58711 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/lcqa](http://www.healthoregon.org/lcqa)



**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="checkbox"/> Blood in feces (occult blood)	_____	_____
<input type="checkbox"/> Blood Hemoglobin	_____	_____
<input type="checkbox"/> High density lipoprotein (HDL)	_____	_____
<input type="checkbox"/> Human Chorionic Gonadotropin (urine)	_____	_____
<input type="checkbox"/> Packed cell volume (hematocrit)	_____	_____
<input type="checkbox"/> Total Cholesterol	_____	_____
<input type="checkbox"/> Triglyceride	_____	_____
<b>TOTAL annual test volume</b>	_____	_____

**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**

The Health Screen Testing Permit fee is \$150 for period July 1, 2012 through June 30, 2014.

- ◆ Make check payable to: Oregon Public Health Division.
- ◆ Attach payment check to Application and Self Survey, 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>
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<p>_____</p> <p>Print name of Director/Owner signature</p>
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**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.

*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 a licensed pharmacist; 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

→ over

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.

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

I:/LC Files/HST Director requirements



## URGENT RECALL NOTIFICATION UPDATE

March 6, 2012

Re: Alere Cholestech LDX<sup>®</sup> System Recall Notification

Dear Valued Customer:

The purpose of this letter is to update the recall notification that has been previously provided on the Alere Cholestech LDX device and the potential humidity related impact on results for certain analytes tested on the Cholestech LDX<sup>®</sup> System. As indicated in the previous recall notification, we have identified that a bias may exist due to humidity variability as outlined below. The bias is observed in patient samples and it may not be detected by running quality control material. To adjust for this bias, a humidity sensor was incorporated into ROM pack v3.40 that enables the Alere Cholestech LDX<sup>®</sup> analyzer to make adjustments for humidity. However, if your Alere Cholestech LDX<sup>®</sup> Analyzer was not upgraded with a ROM pack v3.40 or higher, then a bias may exist as described in the table below and you must operate your device in a controlled environment that maintains humidity within 40% and 60%. In order to ensure that your environment is controlled, you must monitor the humidity as required in the customer action below.

Analyte	Observed Bias @ 20% Relative Humidity*	Observed Bias @ 80% Relative Humidity*
Glucose (GLU)	4 to 8%	-5 to -8%
Triglycerides (TRG)	5 to 9%	-8 to -11%
Total Cholesterol (TC)	4 to 8%	-4 to -9%
HDL Cholesterol (HDL)	3 to 10%	-9 to -10%
LDL	8%	-8%
ALT	-10 to -21%	10 to 43%
AST	-12 to -16%	13 to 42%

\*As compared to 50% Relative Humidity

You can determine the ROM pack version by pressing, and holding, the STOP button for at least 3 seconds when the analyzer is plugged in.

Firmware Version 3.40
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If you received a new Alere Cholestech LDX<sup>®</sup> analyzer after November 2010, it contains ROM pack v3.40.

CustomerLetter-2879 Revision B



## CUSTOMER REQUIRED ACTION

- If your LDX was not upgraded with the ROM pack v3.40 or higher, you must operate your device in a controlled environment that maintains humidity within 40% and 60%. If you are unable to monitor and maintain a controlled environment for humidity between 40% and 60%, the test system is no longer CLIA waived.
  - Contact Alere if you need assistance in following these instructions.
- If you are currently using ROM pack v3.40 or higher, you may continue to use the LDX System per your normal practices.
- Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.
- If you have forwarded the product listed above to another laboratory, please provide a copy of this letter to them.
- Complete and FAX the enclosed Verification Form within 10 days to confirm your receipt of this notice.

At this point, we are asking that you be aware of the bias and take the required customer actions above. We sincerely regret any inconvenience this may have caused.

Should you have any questions about the information contained in this notification, please contact:

Alere San Diego, Inc.  
9975 Summers Ridge Road  
San Diego, CA 92121  
U.S.A.  
Phone: 877 308 8289  
FAX: 858 805 8457

Sincerely,

Robert Di Tullio  
Vice President  
Global Regulatory & Clinical Affairs  
Alere, Inc.



Please complete this form even if you do not have any involved product and  
Fax Back to Technical Service at Fax Number 858-805-8457.

**Customer Verification Form  
Urgent Recall Notification**

We acknowledge receipt of the Alere San Diego, Inc. notice dated, March 6, 2012 for the Alere Cholestech LDX<sup>®</sup> System Recall Notification

I have read, understood and implemented the required actions.

DATE\*: \_\_\_\_\_  
AUTHORIZED SIGNATURE\*: \_\_\_\_\_  
PRINT NAME\*: \_\_\_\_\_  
TITLE: \_\_\_\_\_ DEPARTMENT: \_\_\_\_\_  
INSTITUTION\*: \_\_\_\_\_  
ADDRESS\*: \_\_\_\_\_  
CITY\*: \_\_\_\_\_ STATE\*: \_\_\_\_\_ PHONE\*: \_\_\_\_\_  
POSTAL CODE\*: \_\_\_\_\_ COUNTRY\*: \_\_\_\_\_  
EMAIL: \_\_\_\_\_

To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt to Technical Service at Fax Number +1 858-805-8457.

\* Mandatory field