

# Instructions for Change Request Form for Oregon CLIA Laboratories

This form may be used to notify the CLIA State Agency for Oregon of\*:

1. Change in laboratory name, address, phone number, fax number, email address, Federal Tax ID number.
2. Election to receive electronic notifications\*\*
3. Change in Laboratory Director for a Certificate of Waiver
4. Change in Laboratory Director for a Certificate of Accreditation\*\*\*
5. Adding or deleting non-waived testing from the laboratory's test menu.
6. Closure of CLIA certificate\*\*\*\*

## General Instructions: Items 1-4 Above

Complete the form going down the left-hand column. Place an effective date in the space on the top right.

## Instructions for Adding/Deleting testing from test menu:

Follow the General Instructions, above. Use the spaces provided for adding tests to test menu or deleting tests from test menu in the right-hand column. This is only for non-waived testing. If adding a regulated analyte, indicate your PT provider for the test in the space provided at the bottom of the right-hand column. An additional page may be attached to this form for multiple test menu changes that do not fit on form. Additions and Deletions should be clearly indicated. List Analyte, Test Name, Manufacturer, Volume for each and PT Provider, if applicable.

## Instructions for closing a CLIA certificate:

Follow the General Instructions, above. Mark the box labeled 'CLOSE THIS LABORATORY.'

All submissions must be signed and dated by the Laboratory Director or their designee. Signature should be hand-written or a digitally encrypted signature.

## Submission Instructions:

This form and any accompanying documents may be submitted by the following methods:

Email: [lc.info@odhsoha.oregon.gov](mailto:lc.info@odhsoha.oregon.gov)

Fax: 503-693-5602

Mail:

ATTN: Regulatory Section  
Oregon State Public Health Laboratory  
7202 NE Evergreen Pkwy, Ste 100  
Hillsboro, OR 97124

Please include a statement of the intended change in your email or as a coversheet with fax or mail submissions.

### NOTES:

Please do not submit the same requested change multiple times. If it has already been submitted and you have not heard from us, please inquire as to the status of your submission before resubmitting. Inquiries may be sent to [lc.info@odhsoha.oregon.gov](mailto:lc.info@odhsoha.oregon.gov).

\*This Change Request form cannot be used for: Initial Application, Laboratory Director change for Certificate of Compliance or Certificate of Provider Performed Microscopy, Change in Certificate Type, changing Type of Control (Ownership Type), Reinstatement. These changes require a CMS-116 application be completed. Do not complete both this form (Change Request) and a CMS-116 application.

\*\*Electronic notification is for the sending of fee coupons, certificates and certain other notifications from the CMS CLIA Program. A general email address is preferred to that of a specific person.

\*\*\*Notification to Accrediting Organization is also required in most circumstances. Please inquire with us for more information if you are uncertain how to do this.

\*\*\*\*A CLIA certificate is required for an entity that performs and results even a single clinical laboratory test subject to the CLIA regulations. Please verify that testing is no longer being performed by the entity holding the CLIA certificate before providing notice of closure.



## Change Request Form for Oregon CLIA Laboratories

### Oregon CLIA State Agency

Phone: 503-693-4125

Fax: 503-693-5602

Email: [LC.info@odhsoha.oregon.gov](mailto:LC.info@odhsoha.oregon.gov)

Please complete all sections that contain an asterisk (\*). All information provided will be used to update the federal database. Please verify accuracy before submitting this form to Regulatory Section. If you are closing the lab, please mark the box for 'Close this laboratory.' A hand-written or encrypted, digital signature makes this form valid. This form may be emailed to the address listed above for submission. Please retain the original for your CLIA records.

\*CLIA number must be provided:

38D

\*Effective Date for this change:

\*Laboratory Name:

Add Test/Volume (Non-waived only)

List Analyte/Test Name/Manufacturer and volume for each:

\*Site Address:

\*Mailing Address:

Delete Test/Volume (Non-waived only)

List Analyte/Test Name and volume for each:

\*Laboratory Director:

\*General Email Address:

\*NPI Number:

We elect to receive future  
notifications via email

☐ CLOSE THIS LABORATORY

\*Federal Tax ID Number:

If adding test for a regulated analyte list PT Provider here:

\*Phone Number:

\*Fax Number:

\*Signature of Laboratory Director

Date

STATE USE ONLY

STATE #

☐ ACO \_\_\_\_\_

☐ LQA \_\_\_\_\_

Comments: \_\_\_\_\_

Regulatory Section  
Oregon State Public Health Laboratory  
7202 NE Evergreen Parkway, Suite 100  
Hillsboro, OR 97124-6536

For alternative format documents, call 503-693-4125

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