

Fees in Effect for the CLIA Program in Oregon

January 2024

The following is the fee schedule for CLIA laboratories in Oregon not accredited by one of the approved Accreditation Organizations under the Clinical Laboratories Improvement Amendments (scroll down for Certificate of Accreditation fees). Laboratories applying for a Certificate of Waiver or Certificate of Provider Performed Microscopy Procedures (PPMP) are assessed only one fee for the issuance of the certificate. Certificate of Compliance laboratories (issued for the performance of non-PPMP moderate complexity or high complexity testing) are assessed three fees for an initial application. The first fee is for the issuance of a Registration Certificate. The second fee is for the compliance survey fee. These two will be issued on one invoice for the initial laboratory. The dollar amount of the compliance survey fee and the compliance certificate fee are both based on a combination of the reported test volume and number of specialties. After the successful conclusion of the initial survey the laboratory will be assessed the third fee, for the Certificate of Compliance, itself. After the initial sequence of fees, a laboratory issued a Certificate of Compliance will be assessed the Survey fee and the Certificate fee for every two-year certificate. All fees must be paid to receive a Certificate of Waiver, Certificate of PPMP or a Certificate of Compliance, respectively.

Certificate fees for laboratories not routinely surveyed:

Certificate Type	Certificate Fee
Certificate of Waiver	\$248.00
Certificate of PPMP	\$297.00

Fees for Certificate of Compliance laboratories:

Schedule	Number of Specialties Performed	Annual Test Volume	Registration Certificate Fee	Survey Fee	Certificate Fee
Low Volume A	N/A	Less than 2000	\$123	\$446	\$223
Schedule A	3 or fewer	2001-10,000	\$123	\$1413	\$223
Schedule B	4 or more	2001-10,000	\$123	\$1869	\$223
Schedule C	3 or fewer	10,001-25,000	\$123	\$2356	\$639
Schedule D	4 or more	10,001-25,000	\$123	\$2769	\$654
Schedule E	N/A	25,001-50,000	\$123	\$3181	\$966
Schedule F	N/A	50,001-75,000	\$123	\$3594	\$1635
Schedule G	N/A	75,001-100,000	\$123	\$4005	\$2304
Schedule H	N/A	100,001-500,000	\$123	\$4417	\$3032
Schedule I	N/A	500,001-1,000,000	\$123	\$4830	\$9244
Schedule J	N/A	>1,000,000	\$123	\$5242 +*	\$11,801

*\$411.00 for each 500,000 tests over 1,000,000.

Fees for CLIA Certificate of Accreditation laboratories in Oregon

This page is for laboratories accredited by one of the Accreditation Organizations (AO) that have been approved under the Clinical Laboratory Improvement Amendments (CLIA). These are separate from medical facility accreditation. This pertains, specifically, to CLIA laboratories. The list of approved Accreditation Organizations may be found here:

<https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/aolist.pdf>

The following is the schedule of CLIA fees for all accredited clinical laboratories in Oregon. Fees charged by the Accrediting Organization are separate from this. Laboratories accredited by an approved CLIA AO and performing moderate or high complexity tests are assessed three fees for an initial application. The first fee is for the issuance of a Certificate of Registration. Upon the successful conclusion of the initial survey by the selected Accrediting Organization the laboratory will be charged the second and third fee. These are the validation fee and the certificate fee. All fees must be paid to receive a Certificate of Accreditation.

Schedule	Number of Specialties Performed	Annual Test Volume	Registration Certificate Fee	Validation Fee	Certificate Fee
Low Volume A	N/A	Less than 2000	\$123	\$22	\$223
Schedule A	3 or fewer	2001-10,000	\$123	\$71	\$223
Schedule B	4 or more	2001-10,000	\$123	\$93	\$223
Schedule C	3 or fewer	10,001-25,000	\$123	\$118	\$639
Schedule D	4 or more	10,001-25,000	\$123	\$138	\$654
Schedule E	N/A	25,001-50,000	\$123	\$159	\$966
Schedule F	N/A	50,001-75,000	\$123	\$180	\$1635
Schedule G	N/A	75,001-100,000	\$123	\$200	\$2304
Schedule H	N/A	100,001-500,000	\$123	\$221	\$3032
Schedule I	N/A	500,001-1,000,000	\$123	\$242	\$9244
Schedule J	N/A	>1,000,000	\$123	\$262 +*	\$11,801

*\$21.00 for each 500,000 tests over 1,000,000.

Additional fees listed on page 3, below.

The fee for the issuance of a replacement certificate is \$75.00.

Fees for the Issuance of a Revised Certificate

Certificate Type	Fee
Certificate of Waiver	\$95.00
Certificate of Provider Performed Microscopy	\$150.00
Certificate of Registration	\$150.00
Certificate of Compliance	\$150.00
Certificate of Accreditation	\$95.00

Billing rate for a survey revisit/proficiency testing desk review (if assessed according to regulation): \$111.81/hr. The billing rate is multiplied by the number of hours necessary to perform, including travel time.

All fees subject to change according to Final Rule published in the Federal Register.

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Questions should be emailed to LC.info@odhsoha.oregon.gov or by calling (503) 693-4125.

Mail to:

ATTN REGULATORY SECTION
OREGON STATE PUBLIC HEALTH LABORATORY
7202 NE EVERGREEN PKWY, STE 100
HILLSBORO, OR 97124