

OFFICE-BASED LABORATORIES

Must office based laboratories be licensed?

Yes. Washington law requires that any “medical test site,” meaning any facility performing testing on material derived from the human body (e.g., tissue, blood, urine, etc.) for health care, treatment,¹ or screening be licensed.² Such facilities also must be certified by the Secretary of Health and Human Services under the Clinical Laboratory Amendments of 1988 (CLIA).³

What kinds of licenses are required?

The kind of license required depends on the complexity of the testing to be performed at the medical test site. If all the tests to be performed are cleared by the Food and Drug Administration (FDA) for home use, and are determined by the Centers for Disease Control (CDC) or FDA to be so simple and accurate that there is little risk of error and no reasonable risk of harm to the patient, then the laboratory can qualify, and apply, for a Certificate of Waiver under Washington law⁴ and CLIA.⁵

How long is a certificate of waiver valid?

A certificate of waiver issued by the Department of Health & Human Services (DHHS) is valid for no more than two years.⁶ An application for renewal of a certificate of waiver must be completed and returned to DHHS not less than nine months, but not more than one year, before the expiration of the certificate.⁷

What laboratory tests may be waived under CLIA and Washington law?

Waived tests are those tests that are cleared by the FDA for home use, that are so simple that there is little risk of error, and that pose no reasonable risk of harm to the patient if performed incorrectly.⁸ The specific tests that are subject to waiver include:

- Dipstick or Tablet reagent urinalysis (non-automated) for the following:⁹
 - Bilirubin.
 - Glucose.

¹ RCW 70.42.010(8).

² RCW 70.42.020.

³ 42 C.F.R. § 493.3(a).

⁴ RCW 70.42.030, WAC 246-338-010(44).

⁵ 42 C.F.R. § 493.15.

⁶ 42 C.F.R. § 493.37(e)(1).

⁷ 42 C.F.R. § 493.37(f).

⁸ WAC 246-338-010(44), 42 C.F.R. § 489.15(a).

⁹ 42 C.F.R. § 489.15(c).

- Hemoglobin.
 - Ketones.
 - Leukocytes.
 - Nitrite.
 - pH.
 - Protein.
 - Specific gravity.
 - Urobilinogen.
- Fecal occult blood.
 - Ovulation tests – visual color comparison tests for luteinizing hormones.
 - Urine pregnancy tests – visual color comparison.
 - Erythrocyte sedimentation rate (non-automated).
 - Hemoglobin – copper sulfate (non-automated).
 - Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use.
 - Spun microhematocrit.
 - Hemoglobin by single analyte instruments with self-contained or component features to perform specific reagent interaction, providing direct measurement and readout.

Is anything further required of an office-based laboratory that obtains and operates under a Certificate of Waiver?

Yes, laboratories operating under a Certificate of Waiver must enroll in the CLIA program, pay applicable certificate fees biennially,¹⁰ comply with on-site inspection rules,¹¹ and follow manufacturers' test instructions.¹²

¹⁰ WAC 246-338-990(1).

¹¹ WAC 246-338-028.

¹² WAC 246-338-246-020, Table 020-1(1).

Are office-based laboratories subject to inspection even if they have been granted a Certificate of Waiver?

Yes. One of the requirements for the issuance of a waiver is that the laboratory issued a certificate of waiver must permit announced or unannounced inspections by the DHHS in accordance with the CLIA rules.¹³ The Center for Medicare and Medicaid Services (CMS) has indicated that it will visit 2% of all laboratory types, including physician office laboratories, annually.¹⁴ Inspectors will focus on the education and training of testing personnel to ensure quality testing.¹⁵ If quality problems are identified, the inspectors will provide assistance to the laboratories to achieve accurate and reliable results.¹⁶ The inspectors will also verify that the laboratories are operating under the correct certificates.¹⁷ Inspections may also be performed by the Washington State Department of Health to ensure compliance with applicable laws and regulations.¹⁸

¹³ 42 C.F.R. § 493.37(b)(2).

¹⁴ CMS *Questions and Answers for On-site Visits of CLIA Certificate of Waiver Laboratories*, Available at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/cliaback.pdf>, last visited 6/15/2012.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ WAC 246-338-028.