

WAC 246-338-020 Licensure—Types of medical test site licenses.

After July 1, 1990, any person advertising, operating, managing, owning, conducting, opening, or maintaining a medical test site must first obtain a license from the department. License types are described in Table 020-1.

(1) Certificate of waiver.

Applicable if the medical test site performs only the tests classified as waived.

(2) Provider performed microscopic procedures (PPMP).

Applicable if the medical test site restricts its testing performance to one or more of the following moderate complexity tests performed by one of the licensed professionals listed, in conjunction with a patient's visit. In addition, the medical test site can perform tests classified as waived with this type of license.

(a) The following licensed professionals may serve as the laboratory director and testing personnel for microscopic procedures under a PPMP medical test site license:

(i) Physician licensed under chapter 18.71 RCW, Physicians; chapter 18.57 RCW, Osteopathy—Osteopathic medicine and surgery; or chapter 18.22 RCW, Podiatric medicine and surgery;

(ii) Advanced registered nurse practitioner, licensed under chapter 18.79 RCW, Nursing care;

(iii) Physician assistant licensed under chapter 18.71A RCW, Physician assistants; or

(iv) Dentist licensed under chapter 18.32 RCW, Dentistry.

(b) Microscopic procedures authorized under a PPMP license are:

(i) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements;

(ii) All potassium hydroxide (KOH) preparations;

(iii) Pinworm examinations;

(iv) Fern tests;

(v) Postcoital direct, qualitative examinations of vaginal or cervical mucous;

(vi) Urine sediment examinations;

(vii) Nasal smears for granulocytes;

(viii) Fecal leukocyte examinations;

(ix) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility); and

(x) Any other tests subsequently categorized under CLIA as provider-performed microscopy procedures.

(3) Moderate/high complexity.

(a) Low volume, Category A-J, as described in Table 990-1.

Applicable if the medical test site performs any tests that are not classified as waived or qualified as PPMP under subsection (2) of this section. Under this type of license, the medical test site may also perform tests classified as waived.

(b) Accredited: Low volume, Category A-J, as described in Table 990-1.

Applicable if the medical test site performs any tests that are not classified as waived, and is accredited and inspected by an accreditation organization approved by the department under WAC 246-338-040. Under this type of license, the medical test site may also perform tests classified as waived.

020-1 Table of Requirements for Each License Type

LICENSE TYPE	REQUIREMENTS	INSPECTIONS	
		TYPE	FREQUENCY
(1) Certificate of Waiver	<ul style="list-style-type: none"> Restrict testing to tests classified as waived. Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections. Follow manufacturers' instructions for performing the test. 	<ul style="list-style-type: none"> Complaint Technical assistance 	<ul style="list-style-type: none"> When indicated
(2) PPMP	<ul style="list-style-type: none"> Restrict testing to tests classified as PPMP or waived. Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. Follow manufacturers' instructions for performing the test. 	<ul style="list-style-type: none"> Complaint Technical assistance 	<ul style="list-style-type: none"> When indicated
(3) Moderate/High Complexity			
(a) Low Volume, Category A-J	<ul style="list-style-type: none"> Perform tests classified as moderate or high complexity. Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. Follow manufacturers' instructions for performing test. 	<ul style="list-style-type: none"> Initial Routine Complaint On-site follow-up Technical assistance 	<ul style="list-style-type: none"> First 6 months of license Every 2 years When indicated When indicated When indicated
(b) Accredited: Low Volume,	<ul style="list-style-type: none"> Perform tests classified as moderate or high complexity. 	<ul style="list-style-type: none"> Validation 	<ul style="list-style-type: none"> 2.5% of accredited sites annually

LICENSE TYPE	REQUIREMENTS	INSPECTIONS	
		TYPE	FREQUENCY
Category A-J	<ul style="list-style-type: none"> • Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. • Follow manufacturers' instructions for performing the test. • Submit to the department upon request, or authorize the accreditation organization to submit: • Proof of accreditation; • On-site inspection results; • Statement of deficiencies; • Plan of correction for the deficiencies cited; • Any disciplinary action and results of any disciplinary action taken by the accreditation organization against the medical test site. 	<ul style="list-style-type: none"> • Complaint • On-site follow-up • Technical assistance 	<ul style="list-style-type: none"> • When indicated • When indicated • When indicated

[Statutory Authority: RCW 70.42.220. WSR 24-11-059, § 246-338-020, filed 5/13/24, effective 6/13/24. Statutory Authority: RCW 70.42.090 and 2002 c 371. WSR 02-12-105, § 246-338-020, filed 6/5/02, effective 7/6/02. Statutory Authority: RCW 70.42.005, 70.42.060. WSR 01-02-069, § 246-338-020, filed 12/29/00, effective 1/29/01. Statutory Authority: RCW 70.42.005, 70.42.060 and chapter 70.42 RCW. WSR 00-06-079, § 246-338-020, filed 3/1/00, effective 4/1/00. Statutory Authority: RCW 70.42.005. WSR 97-14-113, § 246-338-020, filed 7/2/97, effective 8/2/97. Statutory Authority: Chapter 70.42 RCW. WSR 94-17-099, § 246-338-020, filed 8/17/94, effective 9/17/94; WSR 93-18-091 (Order 390), § 246-338-020, filed 9/1/93, effective 10/2/93; WSR 91-21-062 (Order 205), § 246-338-020, filed 10/16/91, effective 10/16/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-338-020, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.42 RCW. WSR 90-20-017 (Order 090), § 248-38-020, filed 9/21/90, effective 10/22/90.]