



# PPMP LICENSING UPDATES

Health Systems Quality  
Assurance

## Medical Test Sites (MTS) Program

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- Clinical Laboratory Improvement Amendments (CLIA) provides federal standards that are applicable to all U.S. facilities or sites that test human specimens for health assessment to diagnose, prevent, or treat disease.
- Washington is CLIA-exempt, meaning laboratories in WA must obtain a state MTS license instead of a federal CLIA license to perform medical tests. Washington receives approval from CMS CLIA to enforce federal rules for laboratories ([eCFR :: 42 CFR Part 493 -- Laboratory Requirements](#)).
- The DOH MTS program is responsible for ensuring that the public receives accurate and reliable clinical laboratory test results by monitoring and evaluating medical test sites for compliance with the minimal standards of quality assurance under Chapter 70.42 RCW and Chapter 246-338 WAC. This is accomplished by providing technical assistance and performing on-site surveys and investigations of laboratories in the state.

## Exempt State

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- CMS CLIA audits the DOH MTS program regularly to ensure our program meets federal standards for exemption.
- **DOH laws and enforcement must be as stringent as CMS CLIA to maintain exemption.**
- During a 2023 audit, a discrepancy related to provider performed microscopic procedures (PPMP) licensure was discovered that does not comply with federal rules.

# PPMP License Overview

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- A PPMP license allows certain health care providers to perform all tests that are CLIA-waived, as well as an additional 9 approved microscopic procedures that are moderate complexity tests.
- To qualify for the PPMP license, the laboratory director must be an approved health care provider and any personnel performing the tests under that license must also be approved health care providers.

## Provider-performed Microscopy Procedures

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**Q0111** - Wet mounts, including preparations of vaginal, cervical or skin specimens

**Q0112** - All potassium hydroxide (KOH) preparations

**Q0113** - Pinworm examinations

**Q0114** - Fern test

**Q0115** - Post-coital direct, qualitative examinations of vaginal or cervical mucous

**81015** - Urinalysis; microscopic only

**81000** - Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy

**81001** - Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy (NOTE: May only be used when the lab is using an automated dipstick urinalysis instrument approved as waived.)

**81020** - Urinalysis; two or three glass test

**89055** - Fecal leukocyte examination (Effective: January 1, 2004)

**G0027** - Semen analysis; presence and/or motility of sperm excluding Huhner

**89190** - Nasal smears for eosinophils

Source: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf>

## PPMP Licensing

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- Medical test site owners must meet the standards for personnel qualifications and responsibilities in compliance with federal regulation, as listed in 42 C.F.R. Part 493 Subpart M - Personnel for Non-waived Testing.
- 42 C.F.R. Part 493 Subpart M - Personnel for Non-waived Testing
  - 42 CFR definitions 493.1357 and 493.1363 specify that the laboratory director and testing personnel qualifications for a PPMP license includes state licensed **physicians** (doctor of medicine, doctor of osteopathy, doctor of podiatric medicine), **midlevel practitioners** (nurse midwife, nurse practitioner or physician assistant) and **dentists** (doctor of dental medicine or doctor of dental surgery) defined in 42 CFR 493.2.

## PPMP Licensing

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- Under Washington's WAC 246-338-020 (PPMP licensure), microscopic procedures may be performed by one of the licensed professionals, in conjunction with a patient's visit:
  - 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;
  - Advanced registered nurse practitioner, licensed under chapter [18.79](#) RCW, Nursing care;
  - Midwife licensed under chapter [18.50](#) RCW, Midwifery;
  - Physician assistant licensed under chapter [18.71A](#) RCW, Physician assistants;
  - [Naturopath licensed under chapter 18.36A RCW, Naturopathy](#); or
  - Dentist licensed under chapter [18.32](#) RCW, Dentistry.

# PPMP Licensing Comparison

Currently, WAC 246-338-020 for PPMP licensure does not align with the standards for personnel qualifications in federal regulation listed in 42 CFR Part 493 Subpart M – Personnel for Non-waived testing.

Federal Rule	Washington Rule
<ul style="list-style-type: none"> <li>Physician: Doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine</li> <li>Midlevel practitioner: nurse midwife, nurse practitioner, or physician assistant</li> <li>Dentist: Doctor of dental medicine or doctor of dental surgery</li> </ul>	<ul style="list-style-type: none"> <li>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</li> <li>Advanced registered nurse practitioner, licensed under chapter 18.79 RCW, Nursing care</li> <li>Midwife licensed under chapter 18.50 RCW, Midwifery;</li> <li>Physician assistant licensed under chapter 18.71A RCW, Physician assistants               <ul style="list-style-type: none"> <li>Naturopath licensed under chapter 18.36A RCW, Naturopathy</li> </ul> </li> <li>Dentist licensed under chapter 18.32 RCW, Dentistry.</li> </ul>

## Naturopaths

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- Naturopaths do not meet the federal definition of physician, midlevel practitioner, or dentist, therefore, Naturopaths cannot qualify as a Laboratory Director (LD) or testing personnel under a Certificate for PPM as defined in 42 CFR 493.2 Definitions.
- CMS CLIA does not accept the Naturopath as being qualified to serve as the laboratory director or testing personnel under a Certificate for PPM.



## Licensed Midwives

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- Midwives licensed under chapter 18.50 RCW do not meet the qualifications described in 42 CFR 493.2 or final rule CMS-3326-F to serve as laboratory directors or testing personnel of a PPMP MTS license.
- However, a nurse midwife serving as a midlevel practitioner and holding a master's degree in nursing and licensure as an advanced registered nurse practitioner (ARNP) under chapter 18.79 RCW does qualify for serving as the laboratory director and testing personnel of the PPMP MTS license. ARNP is already listed as an approved licensed professional in WAC 246-338-020, therefore, the ARNP designations of nurse practitioner and certified nurse-midwife listed in WAC 246-840-302 will remain qualified for serving as the laboratory director and testing personnel of the PPMP MTS license
- Per final rule [CMS-3326-F](#) published on December 28, 2023, nurse anesthetists and clinical nurse specialists will also be included in the definition of a midlevel practitioner under 42 CFR 493.2 beginning December 28, 2024. These ARNP level nurses will be eligible to serve as the laboratory director and testing personnel of the PPMP MTS license.

## Next Steps

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- DOH and all facilities with an MTS license must comply with the federal law.
- To come into compliance with the federal requirements and to maintain our status as a CLIA-exempt state, DOH will conduct rulemaking to remove Naturopaths licensed under chapter 18.36A RCW and midwives licensed under chapter 18.50 RCW as an option for laboratory director or testing personnel under a PPMP license as described in WAC 246-338-020.
- The proposed rulemaking will limit PPMP lab directors and testing personnel to those listed in 42 CFR 493.1357 and 493.2.
- Upon filing of the CR-102 for rulemaking, DOH will be required to provide a hearing and a public comment period. Once the new rule is in effect, it will require any new or renewing applicants to meet the updated qualifications for PPMP laboratory director and testing personnel.

## Currently Licensed Naturopaths & Midwives

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- All current license holders who do not meet the new requirements will not be able to renew their license on June 30, 2025.
- Other MTS license options are available.

# Alternative MTS License Options

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- **Option 1: Waived license** Perform all CLIA-waived tests. You will no longer be able to perform any of the 9 microscopic procedures.
  - **Lab director & personnel requirements:** None. Follow the manufacturer's instructions.
- **Option 2: Categorized license** –Perform all CLIA waived tests and moderate complexity tests, including the 9 microscopic procedures.
  - **Moderate Complexity Lab Director requirements** (§ 493.1405 Standard; Laboratory director qualifications)
    - 1) Pathologist w/State license
    - 2) MD, DO, DPM with State license + 1 year directing or supervising non-waived testing
    - 3) MD, DO, DPM with State license + 20 CMEs in laboratory practice
    - 4) MD, DO, DPM with State license and lab training during residency equivalent to 20 CMEs
    - 5) Doctor of Optometry performing testing only within their scope of practice
    - 6) PhD in science + board certification (ABB, ABMM, ABCC, ABMLI)
    - 7) PhD in science + 1 yr directing or supervising non-waived testing\*
    - 8) Master in science + 1 yr lab training and/or experience + 1 yr laboratory supervisory experience\*
    - 9) Bachelor in science + 2 yrs lab training and/or experience + 2 yrs laboratory supervisory experience\*

\*These options require additional laboratory personnel. See next side.

# Moderate Complexity Lab Requirements

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- Depending on qualifications, the following additional personnel would be required to obtain this license:
- **Clinical consultant:** Consults with and renders opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care (§ 493.1417 Standard; Clinical consultant qualifications).
  - 1) Pathologist with a state license
  - 2) MD, DO, DPM with a state license
  - 3) PhD in science + board certification (e.g., ABB, ABMM, ABCC, ABMLI)
- **Technical consultant.** Individuals qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service (§ 493.1411 Standard; Technical consultant qualifications).
  - 1) Pathologist with a state license
  - 2) MD, DO, DPM with state license + 1 year training or experience in laboratory specialty
  - 3) PhD or Master in science + 1 year training or experience in laboratory specialty
  - 4) Bachelor in science + 2 years training or experience in laboratory specialty
  - 5) On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements

Questions?

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## Contact Us

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