



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH

October 15, 2020

**SUBJECT:** CONCISE EXPLANATORY STATEMENT EMERGENCY RULES for WAC 246-338-020 and 246-338-026, Medical test site licensure and notification requirements.

1. What does this rule do?

The Department of Health (department) is adopting emergency rules for Medical Test Sites (MTS) in response to changes made to federal Clinical Laboratory Improvement Amendments (CLIA) regulations under Centers for Medicare & Medicaid Services (CMS) authority. This is the second emergency rule for these amendments, and it continues without change the emergency rule that was filed on October 15, 2020 under WSR 20-21-062. These changes were adopted in response to the coronavirus disease 2019 (COVID-19) pandemic. A subsection is added to WAC 246-338-026 mandating reporting of test results intended to detect SARS-CoV-2 or diagnose a possible case of COVID-19 in alignment with the federal changes published in 85 FR 54820. WAC 246-338-020 is amended to add language referencing the new subsection in WAC 246-338-026.

2. Why is this rule necessary?

It is necessary to amend the MTS rules so that a failure to report SARS-CoV-2 test results constitutes a violation of the medical test site rules to provide the department with an enforcement pathway should a medical test site fail to comply with the reporting requirement. It is necessary to amend the MTS rules to provide notice to medical test sites of the enforcement reporting requirements of any test that is intended to detect SARS-CoV-2 or diagnose a possible case of COVID-19, and inform Certificate of Waiver and Provider Performed Microscopy Procedures (PPMP) licenses that may be subject to inspections in order to confirm compliance with the test result reporting requirement.

3. How will this rule affect the public?

Medical Test Sites will be under new reporting and inspection requirements. Over three years the program will start conducting a review of 5% of Certificate of Waiver and

Provider Performed Microscopy medical test sites, in addition to verifying compliance at routine Categorized license surveys and Accredited Validation surveys as applicable. The Medical Test Site will be provided an opportunity to correct any deficiencies found related non-reporting of SARS-CoV-2 (COVID-19) test results during initial, routine, complaint, or validation surveys. The penalty for repeat deficiencies for non-reporting is \$1,000 for the first occurrence and \$500 for each subsequent repeat occurrence. Investigation time and cost recovery may also be added for substantiated complaint investigations. The department will adopt new procedures on the specifics of how and when the reporting is to be completed. The disciplinary action policy will include additional details including the penalty amounts. The public may gain from the additional reported data and resulting information that can be utilized in a variety of ways both immediately and in the future.

Any questions regarding this emergency rule should be directed to Honora Estes, Program Manager, by telephone at (253) 395-6747, by fax at (253) 395-6365, or by email at [honora.estes@doh.wa.gov](mailto:honora.estes@doh.wa.gov).