

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D0641854	<b>(X3) Date Survey Completed</b>  11/19/2025
<b>Name of Provider or Supplier</b>  Petersburg Medical Center	<b>Street Address, City, State</b>  103 Fram Street, Petersburg, AK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5441</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.</p> <p>This STANDARD is not met as evidenced by:</p> <ol style="list-style-type: none"> <li>Based on interviews with testing personnel two (TP2) and technical supervisor two (TS2), review of the manual differential procedure, and the lack of control documents the laboratory failed to have control procedures to monitor the accuracy of stain quality for Wright's Stain used for performing a manual differential on patient samples from a complete blood count (CBC). The findings include: a) In an on-site interview 11/19/25 at 11:30 AM, TP2 stated no Wright's Stain quality control was documented. b) A review of the manual differential procedure did not include instructions to document quality control on Wright's Stain. c) A request was made for documentation of manual differential stain control and no documentation was available. d) An on-site interview with TS2 11/19/25 at 1:30 PM confirmed the findings. e) The laboratory reports 303 manual differentials from 8/1/24 to 8/31/25.</li> <li>Based on review of test result logs and an interview with technical supervisor two (TS2) the laboratory failed to monitor the accuracy of controls for three (3) of three (3) qualitative tests Chlamydia trachomatis and Neisseria gonorrhoeae (CT/GC) on the Cepheid, manual human immunodeficiency virus (HIV), and mononucleosis (Mono). The findings include: a) Review of test result logs for CT/GC, HIV, and</li> </ol>

Mono tests revealed there was no documented review of controls. b) In an on-site interview with TS2 11/19/25 at 1:30 PM confirmed that the laboratory is not reviewing control records. c) The laboratory reports performing 131 tests for CT/GC, HIV, and Mono from 8/1/24 to 8/31/25.

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on review of testing personnel competency assessments and quality control records, lack of delegation and competency records, and an interview with technical supervisor one (TS1) the laboratory director failed to document the delegated responsibilities to the technical and general supervisor for two (2) of two (2) personnel. The findings include: 1. Review of competency assessments revealed personnel evaluating competency for five (5) of five (5) testing personnel did not have a delegation by the laboratory director. 2. Review of control records from Siemens Dimension ExL and Sysmex XN-450 from 2024 and 2025 revealed personnel reviewing quality control records did not have a delegation by the laboratory director. 3. A request was made for technical and general supervisor delegation and competency forms and could not be provided. 4. An interview with TS1 11/18/25 at 11:00 AM confirmed delegations were not done. 5. The laboratory reports performing 62694 tests annually.