Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0641854	09/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Petersburg Medical Center	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) record review and staff interview, the laboratory did not evaluate ungraded PT results for satisfactory performance for the specialties of Hematology and Microbiology. Findings: 1. The laboratory subscribes to PT from the American Proficiency Institute. 2. Proficiency Testing records from 2017 3rd event, 2018 1st, 2nd and 3rd events, and 2019 1st and 2nd events were reviewed. 3. The laboratory did not evaluate their ungraded results for the following PT events: 2017-3: Hematology Advanced and Educational Blood Cell Identification (ID) 2017-3: Microbiology Educational Culture ID and Susceptibility 2018-1: Hematology Blood Cell ID and Advanced Blood Cell ID 2018-1: Microbiology Educational Culture ID and Susceptibility 2018-2: Hematology Blood Cell ID, Advanced and Educational Blood Cell ID 2018-2: Microbiology Educational Culture ID and Susceptibility 2018-2: Microbiology Urine Culture MIC/Zone Diameter 2018-3: Hematology Advanced and Educational Blood Cell ID 2018-3: Microbiology Educational Culture ID and Susceptibility 2019-1: Hematology Advanced and Educational Blood Cell ID 2019-1: Hematology Urine Sediment and Vaginal Wet Prep 2019-1: Microbiology Educational Culture ID and Susceptibility 2019-1: Microbiology CSF Culture MIC /Zone Diameter and Interpretation 2019-1: Microbiology Urine Culture MIC/Zone Diameter and Interpretation 2019-2: Microbiology Educational Culture ID and Susceptibility 2019-2: Microbiology Blood Culture ID 2019-2: Microbiology Urine Culture MIC Testing 4. The laboratory was unaware of the requirement to evaluate

	ungraded responses. 5. The technical consultant confirmed these finding on 9/18/19 at 12:00 pm.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records and staff interview, the laboratory did not test, at a minimum, two levels of external quality control material to monitor the accuracy and precision of Cepheid GeneXpert chlamydia and gonorrhoeae tests each day of patient testing. 1. A review of the Cepheid GeneXpert quality control logs from 5/8/19, when the test was approved for patient testing, to 9/18/19 revealed the laboratory had performed 2 levels of external quality control (QC) when the new lot of cartridges was opened on 4/27/19. 2. The procedure states external quality controls will be performed with each new lot and or shipment of cartridges. 3. The laboratory performed 19 patient tests from 5/8/19 to 9/18/19. 4. The technical consultant confirmed these finding on 9/18/19 at 12:00 pm.