Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D2174442	03/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Medical Network Of Alaska	10543 Kenai Spur Highway, Kenai, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's package inserts, patient test reports, and interview with the testing person, the laboratory failed to follow the manufacturer's instructions for reporting the Total Prostate Specific Antigen (PSA), TSH, and Testosterone using the Qualigen FastPack analyzer. Findings: 1. The FastPack package inserts for PSA, TSH, and Testosterone state: 'The results reported by the laboratory to the physician must include the identity of the PSA (or TSH, or Testosterone) assay used.' 2. A review of patient reports on patients #690986, #631867, and #690892 revealed the test results did not include the identity of the Qualigen FastPack Assay. 3. The laboratory reports performing 436 PSA, TSH, and Testosterone tests annually. 4. The technical consultant confirmed these findings in an interview at 3:30 PM on 3/29/2023.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When

	control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 an interview with the testing person, the laboratory failed to evaluate control results to detect any outliers, shifts, or trends due to instrument malfunctions or changes in the analytical system for PSA, TSH, and Testosterone assays. Findings include 1. The laboratory maintained no documentation to indicate that quality controls results were evaluated to detect outliers, shifts, or trends. 2. The laboratory had no documentation to establish or monitor the statistical parameters such as laboratory-specific mean or standard deviations and their review. 3. The laboratory reports performing 436 PSA, TSH, and Testosterone tests annually on their CMS-116 form. 4. The technical consultant confirmed these findings in an interview at 3:30 PM on 3/29/2023.