Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D2054623	02/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Health North Family Medicine Llc	35911 Kenai Spur Hwy, Suite 6, Soldotna, 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
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on procedure review and interview with the laboratory manager, the laboratory failed to have a procedure to establish the number, type, and frequency of control materials, detect immediate errors, and monitor the accuracy and precision of tests performed on the Beckman Coulter Access 2 Immunoassay system. Findings include: 1. The laboratory's policy and procedure manual and Beckman Coulter Access 2 Operator's Guide were reviewed. 2. No documentation or policy or procedure was found that describes the number, type, and frequency of control materials for TSH, Free T4, Free T3, Progesterone, Prostate Specific Antigen, Estradiol, Vitamin D, and Testosterone or how the accuracy and precision of controls material are monitored for these tests. 3. The laboratory reports performing 1000 endocrinology tests annually on their CMS-116 form. 4. The laboratory manager confirmed these findings in an interview at 11:30 am on 2/2/2023.
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 laboratory manager, the laboratory failed to establish and monitor statistical parameters for control materials for tests performed on the Beckman Coulter Access 2 Immunoassay system. Findings include: 1. The laboratory used Biorad Liquichek Immunoassay Controls for the Beckman Coulter Access 2 Immunoassays. 2. The laboratory maintained no documentation of the review of current or historical control lot numbers, in-use dates, or expiration dates for procedure was found that describes the number, type, and frequency of control materials for TSH, Free T4, Free T3, Progesterone, Prostate Specific Antigen, Estradiol, Vitamin D, and Testosterone. 3. The laboratory had no documentation to establish or monitor the statistical parameters such as laboratory-specific mean or standard deviations and their review. 4. The laboratory reports performing 1000 endocrinology tests annually on their CMS-116 form. 5. The laboratory manager confirmed these findings in an interview at 11:30 am on 2/2/2023.