Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D2054618	04/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Health North Family Medicine Llc	2741 Debarr Rd Ste 302, Anchorage, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of verification records and technical consultant interview, the laboratory did not verify the accuracy, precision, and reportable ranges of microalbumin and creatinine on the Bayer DCA 2000 Analyzer prior to reporting patient test results. Findings: 1. The laboratory uses the DCA Microalbumin /Creatinine cartridges on the Bayer DCA 200 analyzer to measure albumin, creatinine, and the albumin/creatinine ratio in urine. 2. The lab began testing patient microalbumin and creatinine on the Bayer DCA 2000 on November 1, 2018, and tests approximately 3 microalbumins and creatinines per month. 3. The verification documents showed 2 levels of liquid controls were performed. Missing were documentation verifying accuracy, precision, and reportable ranges. 4. The technical consultant confirmed these findings during an interview on 4/9/19 at 11:00 am.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following

	for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control logs and technical consultant interview, the laboratory did not test, at a minimum, two levels of external quality control (QC) material to monitor the accuracy and precision of the Bayer DCA 2000 microalbumin and creatinine tests. Findings: 1. A review of the Bayer DCA 2000 quality control logs from 11/1/2019 to the present revealed the laboratory had performed two levels of external quality control material every 30 days and with each new lot and/or shipment of microalbumin/creatinine cartridges. 2. The laboratory performs approximately 3 microalbumin/creatinines per month. 3. The technical consultant confirmed these findings during an interview on 4/16/19 at 1:00 pm.