Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652268	01/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Medical Center	705 N College St, Albany, MO	

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 instructions, lack of humidity logs for 2020 /2021 and to date January 25, 2022, observation of calibrator materials stored in freezer, 2021 temperature logs and interview with technical supervisor (TS) #3, the laboratory failed to follow manufacturer's instructions for monitoring and documenting humidity and acceptable temperature range for storage of reagents in freezer. Findings: 1. Review of the Sysmex XS-1000i instruction for use states "operate at humidity 30 percent to 85 percent". 2. Review of laboratory logs showed no documentation for humidity in 2020, 2021 and to date January 25, 2022. 3. Review of the manufacturer's instructions for storage of Siemens calibrators LOCI THY CAL, LOCI NTP and CKI/MBI CAL state "must be stored at minus 25 degrees Celsius (C) to minus 15 degrees Celsius". 4. Observation of the laboratory freezer #1 showed 2 boxes of LOCI THY calibrator (lot number IED020, expiration date: 2022 06-01), 2 boxes of LOCI NTP calibrator (lot number IHD009, expiration date: 2022 08-01) and 2 boxes of CKI/MBI calibrator (lot number ICD011, expiration date: 2022 03-01) currently stored in freezer #1. 5. Review of the 2021 laboratory's temperature chart for freezer #1 showed a defined acceptable range of minus 10 degrees C to minus 20 degrees C. For 25 of 365 testing days the laboratory failed to meet the manufacturer's required minus 25 degrees C to minus 15 degree C temperature range. 6. Interview

	with TS #3 on January 25, 2022 at 11:00 AM confirmed the laboratory failed to follow manufacturer's instructions for monitoring and documenting humidity and to maintain an acceptable temperature range for the storage of chemistry reagents.
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 the performance specifications for the new Abbott i-stat analyzer signed into effect: November 4, 2021 and interview with the technical supervisor (TS) #3, the laboratory failed to verify performance specifications prior to initiating patient testing. Findings: 1. Review of the performance specifications for the Abbott i-stat analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: pCO2, pO2, pH, SO2, sodium, potassium, chloride, ionized calcium, total CO2, hematocrit, hemoglobin, lactate, HCO3 and troponin for both venous and arterial specimens prior to the beginning of patient testing in November 2021. 2. Review of patient results from November 14, 2021 to date January 25, 2022 showed 49 results were reported for the analytes: pCO2, pO2, pH, SO2, sodium, potassium, chloride, ionized calcium, total CO2, hematocrit, hemoglobin, lactate and HCO3. No troponin patient results were reported. 3. Interview with the TS #3 on January 25, 2022 at 9:45 AM confirmed the laboratory failed to verify that the Abbott i-stat manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.
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 review of chemistry quality control (QC) records from January 1, 2021 to date January 25, 2022 and interview technical supervisor (TS) #3, the laboratory failed to include two control materials of different concentrations each day of patient testing for troponin. Findings: 1. Review of Abbott i-STAT QC during the period of January 1, 2021 and January 25, 2022 showed two acceptable levels of QC were not performed when patient specimens were assayed for troponins. 2. Interview with the

	TS #3 on January 25, 2022 at 10:30 AM confirmed the laboratory failed to perform two control materials of different concentrations each day of patient testing for troponin.