Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2185808	08/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Manhattan Medical Group	200 Research Drive, Manhattan, KS	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the failure to follow procedures, availability of procedures and documentation with required information, testing performed prior to lack of the establishment validation\verification, lack of required documentation and interview with Cardiac Practice Manager, the laboratory failed to have a reference range, Analytical Measurement Range (AMR) and panic values located in the i-STAT procedure (refer to D5403); failed to provide any temperature storage documentation (written/electronic) of Quality Controls (QC) and the EG7+ testing cartridge (refer to D5413); failed to provide documentation of validation/verification performed on i-STAT EG7+ tests cartridge prior to patient testing (refer to D5421); failed to perform QC on day of patient testing on the i-STAT EG7+ for arterial blood gases with no established Individual Quality Control Plan (IQCP) for arterial blood gas (refer to D5445).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based upon a review of the laboratory procedures and interview, the laboratory failed to define in the written procedures the Reference intervals (normal values), Analytical Measurement Range (AMR) and panic (critical) values for the i-STAT (SN: 21-409847) EG7+ Arterial Blood Gas (ABG) for seven measured and five calculated analyte policies at time of survey. Findings: 1. The policies for the i-STAT EG7+ (Sodium (Na), Potassium (K+), Ionized Calcium (iCa), Hematocrit (Hct), pH, Partial Pressure of Oxygen (PO2), Patial Pressure of Carbon Dioxide (PCO2), Oxygen Saturation (sO2), Hemoglobin (Hgb), Bicarbonate (HCO3), Total Carbon Dioxide (TCO3) and Base Excess (BE)) did not contain information for the reference intervals (normal values). 2. The policies for the i-STAT EG7+ (Na, K+, iCa, Hct, pH, PO2, PCO2, sO2, Hgb, HCO3, TCO3 and BE) did not contain information for the AMR. 3. The policies for the i-STAT EG7+ (Na, K+, iCa, Hct, pH, PO2, PCO2, sO2, Hgb, HCO3, TCO3 and BE) did not contain information for the panic values. 2. Interview with the Cardiologist Practice Manager (CPM) on August 22, 2022 at 10:20 a.m. confirmed, the laboratory failed to define in the written procedures: Reference intervals (normal values), Analytica Measurement Range (AMR) and panic values for the i-STAT EG7+ Arterial Blood Gas policies at time of survey.
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 insert instructions for the time period of 8/1/21 - 8/22/22, and interview, the laboratory was unable to prove storage requirements to store quality control (QC) materials and EG7+ cartridges under conditions consistent with the manufacturer's instructions in one of one refrigerators every day since testing began at time of survey. Findings: 1. Review of the Abbott

	Aqueous TriControl (AQC) Level 1 & 3 package inserts and the EG7+ Cartridge package insert indicated that the storage temperature range was 2 - 8 degrees Centigrade (C) or 35 - 46 degrees Fahrenheit (F) for both QC materials and EG7+ Cartridges until expiration date. 2. The staff could not provide any documentation (written or electronic) of any temperatures taken for the refrigerator used for storage of the AQC Levels 1 & 3 quality controls and EG7+ cartridges since testing began on 8/1/21. 3. Interview with the Cardiology Practice Manager on 8/22/22 at 10:45 a.m. confirmed the laboratory failed to document the storage of QC materials and EG7+ Cartridges under conditions consistent with the manufacturer's instructions in one of one refrigerators everyday since testing began.
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 the lack of documentation of performance verifications, non-waived test list, and interview with the Cardiology Practice Manager (CPM), the laboratory failed to perform a validation/verification on Abbott's i-STAT analyzer performance specifications prior to reporting patient test results. Findings: 1. Request was made to review the performance verifications of one of one Abbott's i-STAT analyzer analytes; serial number (S/N) 21-409847. No documentation of verification of the manufacturer's performance characteristics for accuracy, precision, reportable range, and normal values appropriate for the laboratory's patient population were made available for the EG7+ Arterial Blood Gas (ABG) cartridge containing seven measured and five calculated analytes performed on the analyzer at the time of survey. 2. The seven measured and five calculated analytes performed on the analyzer were: Sodium (Na), Potassium (K+), Ionized Calcium (iCa), Hematocrit (Hct), pH, Partial Pressure of Oxygen (PO2), Patial Pressure of Carbon Dioxide (PCO2), Oxygen Saturation (sO2), Hemoglobin (Hgb), Bicarbonate (HCO3), Total Carbon Dioxide (TCO3) and Base Excess (BE). The CPM stated the laboratory began reporting patient test results on the analyzer as of 8/1/21. 3. Patient results were released for 8 ABGs on 8 patients from 8/1/21 to date of survey. 4. Interview with the CPM on 8/22/22 at 10: 20 a.m. confirmed, the laboratory failed to perform a verification/validation for Abbott's i-STAT analyzer performance specifications prior to reporting patient test results.
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 review of quality control (QC) documentation and interview on the Abbott's i-STAT EG7+ testing, the laboratory failed to perform QC as required by CFR 493. 1256: (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 and (d)(3) At least once each day patient specimens are assayed or examined performed. Findings: 1. Review of the QC Aqueous TriControl (AQC) Levels 1 & 3 documentation, the laboratory only performed QC on new lot numbers of EG7+ received in the laboratory. No Individualized Quality Control Plan (IQCP) for the EG7+ cartridge was initiated at the time of survey. 2. Review of the QC logs revealed the laboratory failed to perform QC on any day of patient testing for the EG7+ cartridge for eight of eight patients from August 2021 through August 2022 at time of survey. 3. Interview with Cardiac Practice Manager on 8/22/22 at 10:24 a.m. confirmed the laboratory failed to perform QC on the Abbott's i-STAT EG7+ every day of patient testing since August 2021 and no IQCP was established.