Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2198589	08/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Metropolitan Area Ems Authority	2900 Alta Mere Dr, Fort Worth, TX	

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
D0000	An entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.801 Enrollment and testing of proficiency testing samples 493.1250 Analytic Systems 493.1403 Laboratory Director, (moderate complexity) 493.1421 Laboratories performing moderate complexity testing; testing personnel Note: The CMS 2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

	This CONDITION is not met as evidenced by: Based on review of laboratory policy, CMS 116 form, CMS 155 report, and confirmed in staff interview, the laboratory failed to meet the requirements of participating in proficiency testing for the specialty of Chemistry (blood gas) to the date of the survey in 2022. Findings included: 1. Review of the laboratory's policy titled "Blood Gas, Sodium, Potassium, Ionized Calcium (CG8+) using the iSTAT" (revised 02/17/2022) revealed "Proficiency Testing: The MedStar Mobile Healthcare Laboratory is enrolled in approved proficiency testing programs. The director or designee reviews results." 2. Review of the CMS 116 form submitted on the day of the survey revealed the laboratory performed blood gas testing (pH, PO2, PCO2 analytes) on the Abbott i STAT analyzer. The laboratory began patient testing for blood gases on the i STAT analyzer in February 2022. 3. Review of the CMS 155 report revealed no proficiency testing scores for the blood gas analytes pH, PO2, and PCO2. 4. During an interview on 08/29/2022 at 10:32 am, the Assistant Operations Manager confirmed the laboratory was not enrolled in proficiency testing for blood gas analytes pH, PO2, PCO2. Word Key: CMS Center for Medicare & Medicaid Services PO2- oxygen partial pressure PCO2- carbon dioxide partial pressure
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) testing records, the laboratory's CMS (Centers for Medicare & Medicaid Services) 209 form, personnel records, and staff interview, the laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory for 3 of 3 events in 2021 (Event 1, 2, 3) and 2 of 2 events in 2022 (Event 1 and 2). Findings included: 1. Review of the API testing records revealed Testing Person-5 (TP-5) tested the following events: Chemistry & Hematology 2021 Event 1, 2, 3 2022 Event 1, 2 2. Review of the laboratory's CMS 209 form and personnel records revealed 19 Testing Persons (TP-1 through TP-19) were listed as performing moderate complexity testing (chemistry & hematology). Testing Person-1 (TP-1) Hire date: 08/03/2015 Testing Person-2 (TP-2) Hire date: 03 /23/1998 Testing Person-3 (TP-3) Hire date: 07/14/2014 Testing Person-4 (TP-4) Hire date: 11/26/2018 Testing Person-5 (TP-5) Hire date: 10/26/2009 Testing Person-6 (TP-6) Hire date: 04/27/2009 Testing Person-7 (TP-7) Hire date: 01/28/2019 Testing Person-8 (TP-8) Hire date: 09/10/2012 Testing Person-9 (TP-9) Hire date: 04/04/2011 Testing Person-10 (TP-10) Hire date: 04/06/2015 Testing Person-11 (TP-11) Hire date: 08/03/2015 Testing Person-12 (TP-12) Hire date: 07/30/2007 Testing Person-13 (TP-13) Hire date: 04/27/2020 Testing Person-14 (TP-14) Hire date: 07/06/2020 Testing Person-15 (TP-15) Hire date: 05/01/2017 Testing Person-16 (TP-16) Hire date: 03/10/2003 Testing Person-17 (TP-17) Hire date: 02/12/2018 Testing Person-18 (TP-18) Hire date: 06/19/2017 Testing Person-19 (TP-19) Hire date: 03/05/2007 TP-1, TP-2, TP-3, TP-4, TP-6, TP-7, TP-8, TP-9, TP-10, TP-11, TP-12, TP-13, TP-14, TP-15, TP-16, TP-17, TP-18, TP-19 performed testing of patient specimens and did NOT participate in PT events. 4. During an interview on 08/29/2022 at 10:40 am, the

	Assistant Operations Manager confirmed the above findings. The laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to retain a copy of all hematology and chemistry PT records for 2 of 3 events in 2021 (Event 1 and 2) and 2 of 2 events in 2022 (Event 1 and 2). Findings included: 1. Review of API PT records revealed the laboratory failed to retain a copy of the following records for hematology and chemistry events 1 and 2 in 2021 and events 1 and 2 in 2022: Test records 2. During an interview on 08/29/2022 at 10:01 am, the Assistant Operations Manager confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records, and in interview with staff, the laboratory failed to review and evaluate the results obtained in proficiency testing for chemistry and hematology specialties for 3 of 3 events in 2021 (Event 1, 2, 3) and 2 of 2 events in 2022 (Event 1, 2). Findings included: 1. Review of the laboratory's policy titled: " Chemistry Testing using the i-STAT; Chem8+, E3+, Crea Cartridge Types" (page 10) stated the following: "Proficiency Testing ... The director or designee reviews results." 2. Review of API's "Proficiency Testing Performance Evaluation" form revealed the following: "PERFORMANCE REVIEW AND CORRECTIVE ACTION After reviewing the evaluation reports, complete the information below and retain this form along with the enclosed reports for your records." Further review of API testing records revealed that the laboratory failed to document the evaluation and review the following results for proficiency testing in 2021 and 2022: Chemistry & Hematology 2021 Event 1, 2, 3 2022 Event 1, 2 3. During an interview on 08/29/2022 at 10:32 am, the Assistant Operations Manager confirmed the laboratory failed to document the evaluation and review of the PT events mentioned above.

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 review of laboratory policies, manufacturer's instructions, laboratory records, laboratory's CMS 116 form, i STAT data log, quality control (QC) records, patient records, laboratory's Individualized Quality Control Plan (IQCP), corrective action reports, and confirmed in interview, the laboratory failed to meet the requirements of the analytic systems as evidenced by: 1. The laboratory failed to have policies in place that included all required components for laboratory tests. Refer to D5403. 2. The laboratory failed to monitor relative humidity for the Abbott i STAT blood analyzer for 1 of 1 months in 2020 (December), 12 of 12 months in 2021, and 7 of 7 months in 2022 (January-July). Refer to D5413, I. 3. The laboratory failed to monitor temperature for the Abbott i STAT blood analyzer when stored in the facility (not in use) for 1 of 1 months in 2020 (December), 12 of 12 months in 2021, and 7 of 7 months in 2022 (January-July). Refer to D5413, II. 4. The laboratory failed to perform verification studies for the i STAT analyzer prior to reporting patient test results. Refer to D5421. 5. The laboratory failed to have documentation of performing calibration verification every six months for testing using 2 of 2 Abbott i STAT test cartridges (CHEM8+ and CG8+) in 2020, 2021, and 2022. Refer to D5439. 6. The laboratory failed to monitor the accuracy and precision of Tri Control QC material over time for analytes tested on the i STAT analyzer using the CHEM8+ and CG8+ cartridges for 21 of 21 months from 12/2020 through 08/2022 to ensure accurate and reliable test results. Refer to D5441. 7. The laboratory failed to have a complete IQCP to include a Quality Control Plan (QCP) with data to support its reduction in QC frequency to every 30 days and failed to have a Quality Assessment (QA) for the CHEM8+ and CG8+ cartridges tested on the i-STAT analyzer. Refer to D5445. 8. The laboratory failed to perform two levels of control each day of patient testing on the six i STAT analyzers for the CG8+ cartridge containing the sodium (Na), potassium (K), ionized calcium (iCa), glucose (Glu), hematocrit (Hct) analytes for 34 of 34 days in 2022 (random sampling 02/2022 08/2022). Refer to D5447, I. 9. The laboratory failed to perform at least 2 levels of quality control each day of patient testing for the CHEM8+ cartridge on the Abbott i STAT blood analyzer for 19 of 31 days in December 2020, 99 of 365 days in 2021, and 97 of 241 days in 2022. Refer to D5447, II. 10. The laboratory failed to verify the criteria for acceptability of all control materials for 11 of 11 lots used in 2020, 2021 and 2022. Refer to D5469. 11. The laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that included both low and high values on each day of testing on the six i STAT analyzers for the CG8+ blood gas cartridge containing the pH, pO2 (oxygen partial pressure), pCO2 (carbon dioxide partial pressure) analytes for 34 of 34 days in 2022. Refer to D5537. 12. The laboratory failed to verify at least twice annually the accuracy of 13 of 13 analytes in 2021 and 2022 for the chemistry and hematology analytes tested on the i STAT analyzers. Refer to D5775, I. 13. The laboratory failed to verify at least twice annually the accuracy of 4 of 4 analytes in 2022 for the chemistry analytes tested on the CHEM8+ and CG8+ cartridges. Refer to

	D5775, II. 14. The laboratory failed to document corrective action for out of range temperatures on the Abbott i STAT blood analyzer for 1 of 31 days in December 2020, 1 of 31 days in March 2021, 1 of 30 days in September 2021, and 2 of 61 days in 2022 (June, July). Refer to D5781.
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 on review of laboratory policies and confirmed in interview, the laboratory failed to have policies in place that included all required components for laboratory tests. (Note: Laboratory testing included Na (sodium), K (potassium), Cl (chloride), iCa (ionized calcium), Glu (glucose), BUN/Urea (blood urea nitrogen), Crea (creatinine), TCO2 (total carbon dioxide), Hct (hematocrit), pH, PO2 (oxygen partial pressure), PCO2 (carbon dioxide patrial pressure) on the CHEM8+ and CG8+ cartridges tested on the i-STAT analyzer) Findings included: 1. Review of the laboratory's policy manual revealed the laboratory failed to implement policies for the following components of the services provided by the laboratory for patient testing: a. Procedures for establishing/verifying the reportable range for test results on the i STAT analyzer were not established. b. Control procedures were not established to include criteria for acceptability for lot-to-lot roll overs, monitoring QC over time were not established, and establishment of control limits. c. Calibration and calibration verification procedures were not established. d. Corrective action or troubleshooting steps to take when QC (quality control) or calibration were unacceptable were not established. e. Verification or establishments of reference intervals (normal range) were not established. f. Procedures for performing twice annual instrument comparisons and twice annual cartridge comparison were not established. 2. During an interview on 08/29/2022 at 11:19 am, the Assistant Operations Manager confirmed the above findings.
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: I. Based on review of the operator's guide, laboratory environmental logs, and confirmed in interview, the laboratory failed to monitor relative humidity for the Abbott i-STAT blood analyzer for 1 of 1 months in 2020 (December), 12 of 12 months in 2021, and 7 of 7 months in 2022 (January-July). The findings include: 1. Review of the Abbott i-STAT blood analyzer system manual revealed: "Specifications ... Relative Humidity 90% (maximum) non-condensing." 2. Review of the laboratory's environmental logs from December 2020 to July 2022 revealed no documentation of relative humidity for Abbott i-STAT blood analyzers stored in the facility (when not in use) or in the climate-controlled vehicles. 3. During an interview on 08/29/2022 at 02:05 p.m., the Assistant Operations Manager confirmed the above findings. II. Based on review of the operator's guide, laboratory environmental logs, and confirmed in interview, the laboratory failed to monitor temperature for the Abbott i-STAT blood analyzer when stored in the facility (not in use) for 1 of 1 months in 2020 (December), 12 of 12 months in 2021, and 7 of 7 months in 2022 (January-July). The findings include: 1. Review of the Abbott i-STAT blood analyzer system manual revealed: "Specifications ... Operating Temperature 16-30C (61-86F) for i-STAT cartridge testing Transport Temperature 10-46C (14-115F)" 2. Review of the laboratory's environmental logs from December 2020 to July 2022 revealed no documentation of temperature for Abbott i-STAT blood analyzers stored in the facility (when not in use). 3. During an interview on 08/29/2022 at 02:05 p.m., the Assistant Operations Manager confirmed the above findings.
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 laboratory's CMS 116 form, i STAT data log, and confirmed in interview, the laboratory failed to perform verification studies for the i STAT analyzer prior to reporting patient test results. Findings included: 1. Review of the laboratory's CMS (Center for Medicare & Medicaid Services) 116 form submitted on the day of the survey revealed the i STAT analyzer was used to test the CHEM8+ cartridges and the CG8+ cartridges. Records further revealed the CHEM8+ cartridges were put in use on 12/2020 and the CG8+ cartridges were put in-use on 02/2022. The analytes tested on the CHEM8+ cartridge included: Na (sodium), K (potassium), Cl (chloride), iCa (ionized calcium), Glu (glucose), BUN/Urea (blood urea nitrogen), Crea

	(creatinine), TCO2 (total carbon dioxide). The analytes tested on the CG8+ cartridge included: Na (sodium), K (potassium), iCa (ionized calcium), Glu (glucose), Hct (hematocrit), pH, PO2 (oxygen partial pressure), PCO2 (carbon dioxide patrial pressure). The laboratory was asked to provide verification studies on the i STAT analyzer prior to reporting 4,742 patient test results that included: a. Accuracy b. Precision c. Reportable range of test results for analytes tested on the CHEM8+ and CG8+ cartridges d. Verification of the i STAT manufacturer's reference intervals for the analytes on the CHEM8+ and CG8+ cartridges that were appropriate for the laboratory's population. No verification studies were provided. 2. During an interview on 08/29/2022 at 11:10 am, the Assistant Operations Manager confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory records from December 2020 through July 2022, the laboratory's submitted CMS 116 application, and staff interview, it was revealed that the laboratory failed to have documentation of performing calibration verification every six months for testing using 2 of 2 Abbott i-STAT test cartridges (CHEM8+ and CG8+) in 2020, 2021, and 2022. Findings include: 1. Review of the "TriControls Control Materials for Liquid QC and Calibration Verification" Technical Bulletin revealed: "CALIBRATION VERIFICATION FOR BLOOD GAS/ ELECTROLYTE/ METABOLITE CARTRIDGES (i-STAT TRICONTROLS) Purpose Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals may be required by regulatory accreditation bodies." 2. A review of the laboratory's records revealed the facility started using the CHEM8+ cartridges on the Abbott i-STAT system in December 2020. The test cartridge contained the following tests: Sodium (Na) Potassium (K) Chloride (Cl) TCO2 Ionized Calcium (iCa) Glucose (Glu) Urea Nitrogen (BUN)/Urea Creatinine (Crea) Hematocrit (Hct) 3. A review of the

	laboratory's records revealed the facility started using the CG8+ cartridges on the Abbott i-STAT system in February 2022. The test cartridge contained the following test: Sodium (Na) Potassium (K) Ionized Calcium (iCa) Glucose (Glu) Hematocrit (Hct) pH Oxygen partial pressure (PO2) Carbon dioxide partial pressure (PCO2) 4. The Abbott i-STAT analyzer performed a single point calibration, and two levels of control material were to be tested each day of patient testing. Thus, calibration verification was required. The laboratory was asked to provide calibration verification records for the CHEM8+ and CG8+ cartridges and none were provided. 5. A review of the laboratory's submitted CMS 116 application revealed an annual test volume of 4742 tests performed. 6. During an interview on 08/29/2022 at 12:10 pm, the Assistant Operations Manager confirmed the above findings.
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 review of laboratory policies, quality control (QC) records, patient records, and confirmed in staff interview, the laboratory failed to monitor the accuracy and precision of Tri-Control QC material over time for analytes tested on the i STAT analyzer using the CHEM8+ and CG8+ cartridges for 21 of 21 months from 12/2020 through 08/2022 to ensure accurate and reliable test results. Findings include: 1. Review of the laboratory's policies for the CHEM8+ and CG8+ cartridges revealed the laboratory did not have a procedure for monitoring the accuracy and precision of test performance over time. 2. The laboratory was asked to provide documentation of monitoring QC over time for analytes tested on the CHEM8+ and CG8+ cartridges on the i-STAT analyzer using the Tri-Control QC material. None was provided. The analytes tested on the CHEM8+ cartridge included: Na (sodium), K (potassium), Cl (chloride), iCa (ionized calcium), Glu (glucose), BUN/Urea (blood urea nitrogen), Crea (creatinine), TCO2 (total carbon dioxide). The analytes tested on the CG8+ cartridge included: Na (sodium), K (potassium), iCa (ionized calcium), Glu (glucose), Hct (hematocrit), pH, PO2 (oxygen partial pressure), PCO2 (carbon dioxide patrial pressure). 3. The laboratory had an annual volume of 4742 tests performed. 4. During an interview on 08/29/2022 at 12:10 pm, the Assistant Operations Manager confirmed the laboratory failed to monitor the accuracy and precision of Tri-Control QC material over time to ensure accurate and reliable 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 manufacturer's instructions, laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to have a complete IQCP to include a Quality Control Plan (QCP) with data to support its reduction in QC frequency to every 30 days and failed to have a Quality Assessment (QA) for the CHEM8+ and CG8+ cartridges tested on the i-STAT analyzer. Findings include: 1. Review of the manufacturer's Procedure Manual (revision date 29-Mar-19) for the i-STAT System revealed: "QUALITY CONTROL Daily Procedures Handheld Verification Verify the performance of each handheld in the i-STAT 1 System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, hematocrit, ACT, and PT/INR ... Integrity Testing* Verify the integrity of cartridges included in every shipment, upon receipt, by analyzing two levels of appropriate controls (see table below) along with a representative sample of each new lot and by comparing the results to the expected values published in the Value Assignment Sheets. Any analyzer that has passed the Electronic Simulator test may be used in the verification. *Note: the information in the above paragraph is not a manufacturer's system instruction. It is a suggestion to comply with regulatory requirements that may pertain to your laboratory." 2. Review of the laboratory's IQCP revealed: The laboratory did NOT develop a QCP to include the number, type, frequency of testing and criteria for acceptable results of the quality controls. The IQCP failed to have in house data to support its reduction in frequency to every 30 days for the CHEM8+ and CG8+ cartridges tested on the i-Stat analyzer. The laboratory did NOT develop a QA plan to include QC review, proficiency testing records (scores, testing failures, trends), patient result review, specimen rejection, turnaround time reports, records of preventative measures, corrective actions, personnel competency records. The laboratory also failed to establish written policies and procedures for the ongoing monitoring of the QCP and evaluation of its effectiveness. 3. A review of laboratory records revealed the laboratory used six i-STAT analyzers (Serial #s: 347982, 373621, 342346, 375370, 398548, 399238) to perform testing on the CHEM8+ and CG8+ cartridges. 4. A random sampling of QC and patient records from December 2020 through August 2022, revealed QC was not performed every day of patient testing on the CHEM8+ and CG8+ cartridges. Refer to D5447, I and D5447, II. The CG8+ cartridge also contained the blood gas analytes pH, PO2 (oxygen partial pressure) and PCO2 (carbon dioxide partial pressure) and therefore, QC was required every 8 hours each day of patient testing. A random sampling of QC and patient records from February 2022 through August 2022, revealed QC was not performed each 8 hours of testing using one level of control materials on each day of patient testing and patients were analyzed on the CG8+ cartridge on the i-STAT analyze. Refer to D5537. 5. During an interview on 08/29/2022 at 11:19 am, the Assistant Operations Manager confirmed the above findings.
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:
I. Based on review of manufacturer's instructions, laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to perform two levels of control each day of patient testing on the six i-STAT analyzers for the CG8+ cartridge containing the sodium (Na), potassium (K), ionized calcium (iCa), glucose (Glu), hematocrit (Hct) analytes for 34 of 34 days in 2022 (random sampling 02/2022-08/2022). Findings include: 1. Review of the manufacturer's Procedure Manual (revision date 29-Mar-19) for the i-STAT System revealed: "QUALITY CONTROL Daily Procedures Handheld Verification Verify the performance of each handheld in the i-STAT 1 System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, hematocrit, ACT, and PT/INR ... Integrity Testing* Verify the integrity of cartridges included in every shipment, upon receipt, by analyzing two levels of appropriate controls (see table below) along with a representative sample of each new lot and by comparing the results to the expected values published in the Value Assignment Sheets. Any analyzer that has passed the Electronic Simulator test may be used in the verification. *Note: the information in the above paragraph is not a manufacturer's system instruction. It is a suggestion to comply with regulatory requirements that may pertain to your laboratory." 2. Review of laboratory policies revealed the laboratory developed an Individualized Quality Control Plan (IQCP) to modify the quality control frequency from each day of patient testing to implement monthly quality control. The IQCP failed to support its reduction in frequency to every 30 days for the Na, K, iCa, Glu, Hct analytes tested on the i-Stat analyzer using the CG8+ cartridge. Refer to D5445. Review of the laboratory's policy "Blood Gas, Sodium, Potassium, Ionized Calcium (CG8+) using the iSTAT" revealed the following: "QUALITY CONTROL ... Frequency of Use: The staff verifies each new lot number and new shipment of cartridges using Level 1 and level 3 QC samples, prior to use for patient testing. The lab staff is responsible for completing the liquid quality control testing samples during the lab's designated monthly schedule." 3. A random sampling of patient records (response numbers) from February through August 2022, revealed the following dates QC was NOT performed and patients were tested and reported on the i-Stat analyzers for the Na, K, iCa, Glu, Hct analytes: a. i-Stat Serial #342346 02/14 /2022 Response #: 2096496 02/17/2022 Response #: 2096497 04/29/2022 Response #s: 2171764, 2180819 05/03/2022 Response #: 2180190 There was no documentation of QC ever being performed on the analyzer prior to the above dates. 05/27/2022 Response #: 2223921 Level 1 QC was last performed on 05/04/2022. There was no documentation of level 3 QC being performed on 05/04/2022. b. i-Stat Serial #347982 06/13/2022 Response #: 2248697 QC last performed on 06/02/2022 07/08/2022 Response #: 2286583 07/12/2022 Response #: 2292748 07/26/2022 Response #: 2297094 08/02/2022 Response #: 2323890 Level 1 QC was last performed on 07/06 /2022. There was no documentation of level 3 QC being performed on 07/06/2022. c. i-Stat Serial #373621 02/15/2022 Response #: 2097011 There was no documentation of QC ever being performed on the analyzer prior to the above date. 04/29/2022 Response #: 2184066 05/01/2022 Response #: 2187796 05/10/2022 Response #:

2199900 05/16/2022 Response #: 2217799 QC was last performed on 02/16/2022 d. i-Stat Serial #375370 05/22/2022 Response #: 2216645 05/25/2022 Response #: 2220505 There was no documentation of QC ever being performed on the analyzer prior to the above dates. 07/03/2022 Response #: 2279370 07/15/2022 Response #: 2297285 07/22/2022 Response #: 2307334 08/22/2022 Response #: 2352106 QC last performed on 06/09/2022 e. i-Stat Serial #398548 02/08/2022 Response #: 2070639 02 /18/2022 Response #: 2020642 02/22/2022 Response #: 2101022 03/03/2022 Response #: 2100405 There was no documentation of QC ever being performed on the analyzer prior to the above dates. f. i-Stat Serial #399238 02/05/2022 Response #: 2085840 02/07/2022 Response #: 2088442 02/22/2022 Response #: 2106104 03/13 /2022 Response #: 2128274 03/26/2022 Response #: 2123364 04/02/2022 Response #: 2151847 04/19/2022 Response #: 2155037 04/30/2022 Response #s: 2186566, 2187052 05/04/2022 Response #: 2191290 05/07/2022 Response #s: 2191299, 2196321 There was no documentation of QC ever being performed on the analyzer prior to the above dates. 07/15/2022 Response #: 2271664 Level 1 QC was last performed on 07/07/2022. There was no documentation of level 3 QC being performed on 07/07/2022. The laboratory failed to perform at least 2 levels of QC every day of patient testing. 4. During an interview on 08/29/2022 at 11:19 am, the Assistant Operations Manager confirmed the above findings. 46891 II. Based on review of manufacturer's instructions, laboratory policy, Individualized Quality Control Plan (IQCP), quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to perform at least 2 levels of quality control each day of patient testing for the CHEM8+ cartridge on the Abbott i-STAT blood analyzer for 19 of 31 days in December 2020, 99 of 365 days in 2021, and 97 of 241 days in 2022. The findings include: 1. Review of the i-STAT User Guide revealed: "Verify the integrity of cartridges included in every shipment, upon receipt, by analyzing 2 levels of appropriate controls (see table below) along with a representative sample of each new lot and by comparing the results to the expected values published in the Value Assignment Sheets.* Any analyzer that has passed the Electronic Simulator test may be used in the verification. *This information is not a manufacturer's system instruction. It is a suggestion to comply with regulatory requirements that may pertain to your laboratory." 2. Review of the laboratory's policy titled "Chemistry Testing using the i-STAT, Chem8+, E3+, Crea Cartridge Types" revealed: "Frequency of use The staff verifies each new lot number and new shipment of cartridges using Level 1 and Level 3 QC samples, prior to use for patient testing. The lab staff is responsible for completing the liquid quality control testing samples during the lab's designated monthly scheduled date. If the quality control is not completed and evaluated as PASS, then cartridge-specific patient testing lockout engages until completed." 3. Review of the laboratory's IQCP, revealed the laboratory failed to support its reduction in QC frequency to every 30 days for the CHEM8+ cartridge on the Abbott i-STAT blood analyzer. Refer to D5445. 4. Review of QC and patient test records from 12/01/2020 through 08/29/2022 revealed the laboratory failed to perform at least 2 levels of QC every day of patient testing on the following days (random sampling): 12/01/2020 i-STAT serial number: 347982; patient ID: 40169 There was no record of QC being performed on this serial number. 12/04/2020 i-STAT serial number: 342346; patient ID: 418053 i-STAT serial number: 375370; patient ID: 237181 There was no record of QC being performed on these serial numbers. 12/10/2020 i-STAT serial number: 342346; patient ID: 429214 There was no record of QC being performed on this serial number. 12/13/2020 i-STAT serial number: 373621; patient ID: 429214 There was no record of QC being performed on this serial number. 12/14 /2020 i-STAT serial number: 342346; patient ID: 429186 i-STAT serial number: 398548; patient ID: 429214 There was no record of QC being performed on these serial numbers. 12/28/2020 i-STAT serial number: 399238; patient ID: 427653 i-

	STAT serial number: 342346; patient ID: 429186 There was no record of QC being performed on these serial numbers. 03/01/2021 i-STAT serial number: 398548; patient ID: 451954 There was no record of QC being performed on this serial number. 03/14/2021 i-STAT serial number: 375370; patient ID: 456699 There was no record of QC being performed on this serial number. 03/18/2021 i-STAT serial number: 347982; patient ID: 353055 i-STAT serial number: 375370; patient ID: 353055 There was no record of QC being performed on these serial numbers. 03/20/2021 i-STAT serial number: 373621; patient ID: 455586 There was no record of QC being performed on this serial number. 09/01/2021 i-STAT serial number: 375370; patient ID: 385635 There was no record of QC being performed on this serial number. 09/06 /2021 i-STAT serial number: 342346; patient ID: 456848 There was no record of QC being performed on this serial number. 09/17/2021 i-STAT serial number: 398548; patient ID: 507372 There was no record of QC being performed on this serial number. 09/18/2021 i-STAT serial number: 399238; patient ID: 424983 There was no record of QC being performed on this serial number. 09/28/2021 i-STAT serial number: 347982; patient ID: 509909 There was no record of QC being performed on this serial number. 07/02/2022 i-STAT serial number: 399238; patient ID: 479540 There was no record of QC being performed on this serial number. 07/06/2022 i-STAT serial number: 347982; patient ID: 467225 There was no record of QC being performed on this serial number. 07/08/2022 i-STAT serial number: 398548; patient ID: 604523 i-STAT serial number: 398548; patient ID: 604526 There was no record of QC being performed on these serial numbers. 07/11/2022 i-STAT serial number: 373621; patient ID: 605794 i-STAT serial number: 373621; patient ID: 604526 i-STAT serial number: 398548; patient ID: 592259 There was no record of QC being performed on these serial numbers. 07/22/2022 i-STAT serial number: 375370; patient ID: 576328 There was no record of QC being performed on this serial number. 07/26/2022 i-STAT serial number: 342346; patient ID: 516437 There was no record of QC being performed on this serial number. 08/02/2022 i-STAT serial number: 347982; patient ID: 609320 i-STAT serial number: 399238; patient ID: 612638 There was no record of QC being performed on these serial numbers. 08/04/2022 i-STAT serial number: 373621; patient ID: 544458 i-STAT serial number: 399238; patient ID: 613230 There was no record of QC being performed on these serial numbers. 08/08/2022 i-STAT serial number: 398548; patient ID: 604526 There was no record of QC being performed on this serial number. 08/10/2022 i-STAT serial number: 375370; patient ID: 615345 There was no record of QC being performed on this serial number. 08/29 /2022 i-STAT serial number: 398548; patient ID: 604526 There was no record of QC being performed on this serial number. Review of QC logs revealed no QC was performed prior to patient testing for the dates above. The laboratory failed to perform at least 2 levels of QC every day of patient testing. 5. During an interview on 08/29 /2022 at 11:15 a.m., the Assistant Operations Manager confirmed the above findings.
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 review of laboratory policies, Abbott i-STAT quality control (QC) records, and staff interview, it was revealed the laboratory failed to verify the criteria for acceptability of all control materials for 11 of 11 lots used in 2020, 2021 and 2022. Findings include: 1. A review of laboratory policies revealed the laboratory did NOT have a policy for verifying the criteria for acceptability of all control materials. 2. Review of the Tri- Control quality control reports from 2020, 2021 and 2022 revealed the following quality control lot numbers were placed into service and the laboratory failed to cross-check the new quality control lot against the old quality control lot for levels 1 and 3: Level 1; Lot # 301141; expiration date 09/30/2022 Level 3; Lot # 321141; expiration date 09/30/2022 Level 1; Lot # 301145; expiration date 01/31 /2023 Level 3; Lot # 321146; expiration date 02/28/2023 Level 1; Lot # 301136; expiration date 04/30/2022 Level 3; Lot # 321139; expiration date 04/30/2022 Level 1; Lot # 301128; expiration date 08/31/2021 Level 3; Lot # 321128; expiration date 08 /31/2021 Level 1; Lot # 301123; expiration date 03/31/2021 Level 3; Lot # 321133; expiration date 01/31/2022 Level 1; Lot # 301132; expiration date 12/31/2021 Level 3; Lot # 321146; expiration date 02/28/2023 3. During an interview on 08/29/2022 at 11:40 am, the Assistant Operations Manager confirmed the laboratory failed to verify the criteria for acceptability of the control material.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that included both low and high values on each day of testing on the six i-STAT analyzers for the CG8+ blood gas cartridge containing the pH, pO2 (oxygen partial pressure), pCO2 (carbon dioxide partial pressure) analytes for 34 of 34 days in 2022 (random sampling 02/2022-08/2022). Findings include: 1. Review of the manufacturer's Procedure Manual (revision date 29-Mar-19) for the i-STAT System revealed: "QUALITY CONTROL Daily Procedures Handheld Verification Verify the performance of each handheld in the i-STAT 1 System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, hematocrit, ACT, and PT/INR ... Integrity Testing* Verify the integrity of cartridges included in every shipment, upon receipt, by analyzing two levels of appropriate controls (see table below) along with a representative sample of each new lot and by comparing the results to the expected values published in the Value Assignment Sheets. Any analyzer that has passed the Electronic Simulator test may be used in the verification. *Note: the information in the above paragraph is not a manufacturer's system

	instruction. It is a suggestion to comply with regulatory requirements that may pertain to your laboratory." 2. Review of laboratory policies revealed the laboratory developed an Individualized Quality Control Plan (IQCP) to modify the quality control frequency from each day of patient testing to implement monthly quality control. The IQCP failed to support its reduction in frequency to every 30 days for the pH, pO2, pCO2 blood gas analytes tested on the i-Stat analyzer using the CG8+ cartridge. Refer to D5445. Review of the laboratory's policy "Blood Gas, Sodium, Potassium, Ionized Calcium (CG8+) using the iSTAT" revealed the following: "QUALITY CONTROL ... Frequency of Use: The staff verifies each new lot number and new shipment of cartridges using Level 1 and level 3 QC samples, prior to use for patient testing. The lab staff is responsible for completing the liquid quality control testing samples during the lab's designated monthly schedule." 3. A random sampling of patient records from February through August 2022, revealed the following dates QC was NOT performed and patients were tested and reported on the i-Stat analyzers for the pH, pO2, pCO2 blood gas analytes: a. i-Stat Serial #342346 02/14/2022 Response #: 2096496 02/17/2022 Response #: 2096497 04/29/2022 Response #s: 2171764, 2180819 05/03/2022 Response #: 2180190 There was no documentation of QC ever being performed on the analyzer prior to the above dates. 05/27/2022 Response #: 2223921 Level 1 QC was last performed on 05/04/2022. There was no documentation of level 3 QC being performed on 05/04/2022. b. i-Stat Serial #347982 06/13/2022 Response #: 2248697 QC last performed on 06/02/2022 07/08/2022 Response #: 2286583 07/12/2022 Response #: 2292748 07/26/2022 Response #: 2297094 08/02/2022 Response #: 2323890 Level 1 QC was last performed on 07/06 /2022. There was no documentation of level 3 QC being performed on 07/06/2022. c. i-Stat Serial #373621 02/15/2022 Response #: 2097011 There was no documentation of QC ever being performed on the analyzer prior to the above date. 04/29/2022 Response #: 2184066 05/01/2022 Response #: 2187796 05/10/2022 Response #: 2199900 05/16/2022 Response #: 2217799 QC was last performed on 02/16/2022 d. i-Stat Serial #375370 05/22/2022 Response #: 2216645 05/25/2022 Response #: 2220505 There was no documentation of QC ever being performed on the analyzer prior to the above dates. 07/03/2022 Response #: 2279370 07/15/2022 Response #: 2297285 07/22/2022 Response #: 2307334 08/22/2022 Response #: 2352106 QC last performed on 06/09/2022 e. i-Stat Serial #398548 02/08/2022 Response #: 2070639 02 /18/2022 Response #: 2020642 02/22/2022 Response #: 2101022 03/03/2022 Response #: 2100405 There was no documentation of QC ever being performed on the analyzer prior to the above dates. f. i-Stat Serial #399238 02/05/2022 Response #: 2085840 02/07/2022 Response #: 2088442 02/22/2022 Response #: 2106104 03/13 /2022 Response #: 2128274 03/26/2022 Response #: 2123364 04/02/2022 Response #: 2151847 04/19/2022 Response #: 2155037 04/30/2022 Response #s: 2186566, 2187052 05/04/2022 Response #: 2191290 05/07/2022 Response #s: 2191299, 2196321 There was no documentation of QC ever being performed on the analyzer prior to the above dates. 07/15/2022 Response #: 2271664 Level 1 QC was last performed on 07/07/2022. There was no documentation of level 3 QC being performed on 07/07/2022. The laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that included both low and high values on each day of testing . 4. During an interview on 08/29/2022 at 11:19 am, the Assistant Operations Manager confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must

	have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, laboratory records, CMS 116 form, and confirmed in interview, the laboratory failed to verify at least twice annually the accuracy of 13 of 13 analytes in 2021 and 2022 for the chemistry and hematology analytes tested on the i-STAT analyzers. Findings include: 1. Review of laboratory policies revealed the laboratory did not have a policy for performing instrument comparisons for the i-STAT analyzers. 2. Review of laboratory records revealed the laboratory performed testing of the CHEM8+ and CG8+ cartridges on 6 i-STAT analyzers (S#s: 347982, 373621, 342346, 375370, 398548, 399238). 3. During an interview on 08/29/2022 at 9:20 am, the Assistant Operations Manager stated the facility had 6 i-STAT analyzers that performed testing on the CHEM8+ and CG8+ cartridges. The analytes tested on the CHEM8+ cartridge included: Na (sodium), K (potassium), Cl (chloride), iCa (ionized calcium), Glu (glucose), BUN/Urea (blood urea nitrogen), Crea (creatinine), TCO2 (total carbon dioxide). The analytes tested on the CG8+ cartridge included: Na (sodium), K (potassium), iCa (ionized calcium), Glu (glucose), Hct (hematocrit), pH, PO2 (oxygen partial pressure), PCO2 (carbon dioxide patrial pressure). The laboratory was asked to provide twice annual instrument comparisons for the 6 i-STAT analyzers, and none were provided. The laboratory failed to perform twice annual instrument comparisons on the 6 i-STAT analyzers in 2021 and 2022. 4. A review of the laboratory's submitted CMS 116 application revealed an annual test volume of 4742 tests performed. 5. During an interview on 08 /29/2022 at 1:45 pm, the Assistant Operations Manager confirmed the above findings. Word Key: S#s: serial numbers CMS: Center for Medicare & Medicaid Services II. Based on review of laboratory policy, laboratory records, and confirmed in interview, the laboratory failed to verify at least twice annually the accuracy of 4 of 4 analytes in 2022 for the chemistry analytes tested on the CHEM8+ and CG8+ cartridges. Findings include: 1. Review of laboratory policies revealed the laboratory did not have a policy for performing instrument comparisons for the i-STAT analyzers. 2. Review of laboratory records revealed the laboratory performed testing of the CHEM8+ and CG8+ cartridges on 6 i-STAT analyzers (S#s: 347982, 373621, 342346, 375370, 398548, 399238). 3. During an interview on 08/29/2022 at 9:20 am, the Assistant Operations Manager stated the facility had 6 i-STAT analyzers that performed testing on the CHEM8+ and CG8+ cartridges. The analytes tested on both the CHEM8+ and CG8+ cartridges included: Na (sodium), K (potassium), iCa (ionized calcium), Glu (glucose). The laboratory was asked to provide twice annual cartridge comparisons for the CHEM8+ and CG8+ cartridges and none were provided. The laboratory failed to perform twice annual cartridge comparisons on the CHEM8+ and CG8+ cartridges tested on the i-STAT analyzers in 2022. 4. During an interview on 08/29/2022 at 1:45 pm, the Assistant Operations Manager confirmed the above findings. Word Key: S#s: serial numbers
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that

	perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the operator's guide, laboratory environmental logs, corrective action reports, and confirmed in interview, the laboratory failed to document corrective action for out-of-range temperatures on the Abbott i-STAT blood analyzer for 1 of 31 days in December 2020, 1 of 31 days in March 2021, 1 of 30 days in September 2021, and 2 of 61 days in 2022 (June, July). The findings include: 1. Review of the Abbott i-STAT blood analyzer system manual revealed: "Specifications ... Operating Temperature 16-30C (61-86F) for i-STAT cartridge testing Transport Temperature 10-46C (14-115F)" 2. Review of the laboratory's environmental logs revealed the following out-of-range temperatures: 12/10/2020 i-STAT Serial Number: 375370 0.1C 0.1C 03/30/2021 i-STAT Serial Number: 399238 602C 09/21/2021 i-STAT Serial Number: 375370 96.9F 96.9F 06/24/2022 i-STAT Serial Number: 398548 221C 07/13/2022 i-STAT Serial Number: 375370 1.5C 1.5C 3. Review of the laboratory's corrective action reports revealed no corrective action documentation for the out-of-range temperatures on the dates above. 4. During an interview on 08/29 /2022 at 12:00 p.m., the Assistant Operations Manager confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies, manufacturer's instructions, laboratory records, laboratory's CMS 116 form, i STAT data log, quality control (QC) records, patient records, laboratory's Individualized Quality Control Plan (IQCP), corrective action reports, and confirmed in interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems, as evidenced by: 1. The laboratory failed to have policies in place that included all required components for laboratory tests. Refer to D5403. 2. The laboratory failed to monitor relative humidity for the Abbott i STAT blood analyzer for 1 of 1 months in 2020 (December), 12 of 12 months in 2021, and 7 of 7 months in 2022 (January-July). Refer to D5413, I. 3. The laboratory failed to monitor temperature for the Abbott i STAT blood analyzer when stored in the facility (not in use) for 1 of 1 months in 2020 (December), 12 of 12 months in 2021, and 7 of 7 months in 2022 (January-July). Refer to D5413, II. 4. The laboratory failed to perform verification studies for the i STAT analyzer prior to reporting patient test results. Refer to D5421. 5. The laboratory failed to have documentation of performing calibration verification every six months for testing using 2 of 2 Abbott i STAT test cartridges (CHEM8+ and CG8+) in 2020, 2021, and 2022. Refer to D5439. 6. The laboratory failed to monitor the accuracy and precision of Tri Control QC material over time for analytes tested on

	the i STAT analyzer using the CHEM8+ and CG8+ cartridges for 21 of 21 months from 12/2020 through 08/2022 to ensure accurate and reliable test results. Refer to D5441. 7. The laboratory failed to have a complete IQCP to include a Quality Control Plan (QCP) with data to support its reduction in QC frequency to every 30 days and failed to have a Quality Assessment (QA) for the CHEM8+ and CG8+ cartridges tested on the i STAT analyzer. Refer to D5445. 8. The laboratory failed to perform two levels of control each day of patient testing on the six i STAT analyzers for the CG8+ cartridge containing the sodium (Na), potassium (K), ionized calcium (iCa), glucose (Glu), hematocrit (Hct) analytes for 34 of 34 days in 2022 (random sampling 02/2022 08/2022). Refer to D5447, I. 9. The laboratory failed to perform at least 2 levels of quality control each day of patient testing for the CHEM8+ cartridge on the Abbott i STAT blood analyzer for 19 of 31 days in December 2020, 99 of 365 days in 2021, and 97 of 241 days in 2022. Refer to D5447, II. 10. The laboratory failed to verify the criteria for acceptability of all control materials for 11 of 11 lots used in 2020, 2021 and 2022. Refer to D5469. 11. The laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that included both low and high values on each day of testing on the six i STAT analyzers for the CG8+ blood gas cartridge containing the pH, pO2 (oxygen partial pressure), pCO2 (carbon dioxide partial pressure) analytes for 34 of 34 days in 2022. Refer to D5537. 12. The laboratory failed to verify at least twice annually the accuracy of 13 of 13 analytes in 2021 and 2022 for the chemistry and hematology analytes tested on the i STAT analyzers. Refer to D5775, I. 13. The laboratory failed to verify at least twice annually the accuracy of 4 of 4 analytes in 2022 for the chemistry analytes tested on the CHEM8+ and CG8+ cartridges. Refer to D5775, II. 14. The laboratory failed to document corrective action for out of range temperatures on the Abbott i STAT blood analyzer for 1 of 31 days in December 2020, 1 of 31 days in March 2021, 1 of 30 days in September 2021, and 2 of 61 days in 2022 (June, July). Refer to D5781.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies, manufacturer's instructions, laboratory records, laboratory's CMS 116 & 209 forms, i STAT data log, quality control (QC) records, patient records, laboratory's Individualized Quality Control Plan (IQCP), corrective action reports, and confirmed in interview, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure laboratory overall operations and test systems were in compliance with regulations. Refer to D6004. 2. The laboratory director failed to ensure analytic systems provided quality results. Refer to D6007. 3. The laboratory director failed to perform establishment/verification studies for the i-STAT analyzer prior to reporting patient test results. Refer to D6013. 4. The laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for each specialty (chemistry-blood gases) for which it seeks certification. Refer to D6015. 5. The laboratory director failed to ensure a quality control program was developed and followed to provide quality laboratory services. Refer to D6020. 6. The laboratory director failed to establish and follow written policies and procedures for an ongoing mechanism to

	monitor, assess and when indicated, correct problems identified in the analytic systems. Refer to D6021. 7. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. Refer to D6023. 8. The laboratory director failed to ensure remedial actions were taken and documented when deviations from the laboratory's test systems were identified. Refer to D6024. 9. The laboratory director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 19 of 19 Testing Persons (TP1 through TP19) performing moderate complexity testing. Refer to D6030. 10. The laboratory director failed to establish a procedure manual available for all testing procedures. Refer to D6031.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, laboratory records, CMS 116 form, and confirmed in interview, the laboratory failed to ensure laboratory overall operations and test systems were in compliance with regulations as evidenced by: 1. The laboratory failed to have documentation of performing calibration verification every six months for testing using 2 of 2 Abbott i STAT test cartridges (CHEM8+ and CG8+) in 2020, 2021, and 2022. Refer to D5439. 2. The laboratory failed to verify at least twice annually the accuracy of 13 of 13 analytes in 2021 and 2022 for the chemistry and hematology analytes tested on the i STAT analyzers. Refer to D5775, I. 3. The laboratory failed to verify at least twice annually the accuracy of 4 of 4 analytes in 2022 for the chemistry analytes tested on the CHEM8+ and CG8+ cartridges. Refer to D5775, II.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of the operator's guide, laboratory environmental logs, and

	confirmed in interview, the laboratory failed to ensure analytic systems provided quality results. Refer to D5413, I and D5413, II.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the laboratory's CMS 116 form, i STAT data log, and confirmed in interview, the laboratory failed to perform establishment/verification studies for the i-STAT analyzer prior to reporting patient test results. Refer to D5421.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, CMS 116 form, CMS 155 report, and confirmed in staff interview, the laboratory failed to ensure the laboratory was enrolled in a proficiency testing program for each specialty (chemistry-blood gases) for which it seeks certification. Refer to D2000.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory policies, manufacturer's instructions, laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) patient records, and confirmed in staff interview laboratory failed to ensure a quality control program was developed and followed to provide quality laboratory services as evidenced by: 1. The

	laboratory failed to monitor the accuracy and precision of Tri Control QC material over time for analytes tested on the i STAT analyzer using the CHEM8+ and CG8+ cartridges for 21 of 21 months from 12/2020 through 08/2022 to ensure accurate and reliable test results. Refer to D5441. 2. The laboratory failed to have a complete IQCP to include a Quality Control Plan (QCP) with data to support its reduction in QC frequency to every 30 days and failed to have a Quality Assessment (QA) for the CHEM8+ and CG8+ cartridges tested on the i STAT analyzer. Refer to D5445. 3. The laboratory failed to perform two levels of control each day of patient testing on the six i STAT analyzers for the CG8+ cartridge containing the sodium (Na), potassium (K), ionized calcium (iCa), glucose (Glu), hematocrit (Hct) analytes for 34 of 34 days in 2022 (random sampling 2/2022 08/2022). Refer to D5447, I. 4. The laboratory failed to perform at least 2 levels of quality control each day of patient testing for the CHEM8+ cartridge on the Abbott i STAT blood analyzer for 19 of 31 days in December 2020, 99 of 365 days in 2021, and 97 of 241 days in 2022. Refer to D5447, II. 5. The laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that included both low and high values on each day of testing on the six i STAT analyzers for the CG8+ blood gas cartridge containing the pH, pO2 (oxygen partial pressure), pCO2 (carbon dioxide partial pressure) analytes for 34 of 34 days in 2022 (random sampling 02/2022 08 /2022). Refer to D5537.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory policies, manufacturer's instructions, laboratory records, laboratory's CMS 116 form, i STAT data log, quality control (QC) records, patient records, laboratory's Individualized Quality Control Plan (IQCP), corrective action reports, and confirmed in interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems. Refer to D5791.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by:

	Based on review of laboratory policies, Abbott i STAT quality control (QC) records, and staff interview, the laboratory failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. Refer to D5469.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of the operator's guide, laboratory environmental logs, corrective action reports, and confirmed in interview the laboratory failed to ensure remedial actions were taken and documented when deviations from the laboratory's test systems were identified. Refer to D5781.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) 209 form, laboratory policy, and confirmed in interview, the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 19 of 19 Testing Persons (TP1 through TP19) performing moderate complexity testing. The findings include: 1. Review of the CMS 209 form revealed 19 Testing Persons (TP1 through TP19) performing moderate complexity testing. 2. Review of the laboratory's policy binder revealed there was no policy for competency assessment for personnel performing moderate complexity testing. The laboratory was asked to provide a copy of the competency assessment policy. None was provided. 3. During an interview on 08/29/2022 at 10:36 a.m., the Assistant Operations Manager confirmed the above findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory policies and confirmed in interview, the laboratory failed to establish a procedure manual available for all testing procedures. Refer to D5403.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) 209 form, personnel records, and confirmed in interview, the Technical Consultant failed to evaluate and document semi-annual competency at least twice during the first year of patient testing for 19 of 19 testing persons (TP1 through TP19) in 2021 and 2022. The findings include: 1. Review of the CMS-209 form revealed TP1 through TP19 listed to perform moderate complexity testing. 2. Review of personnel records revealed 19 of 19 testing persons had competency assessed by Assistant Operations Manager/TP8, who was not delegated as a Technical Consultant. There was no documentation of the Technical Consultant performing semi- annual competency assessments for the following 5 testing persons (random sampling): TP3 Initial training: 11/23/2020 Competency #1 ("6-month"): 10/13/2021 Competency #2 ("Annual"): 05/02/2022 Competencies were not signed by the Technical Consultant. TP7 Initial training: 12/01 /2020 Competency #1 ("6-month"): 10/13/2021 Competency #2 ("Annual"): 05/02 /2022 Competencies were not signed by the Technical Consultant. TP8 Initial training: 11/20/2020 Competency #1 ("6-month"): 10/13/2021 Competency #2 ("Annual"): 04/20/2022 Competencies were not signed by the Technical Consultant. TP12 Initial training: 12/2/2020 Competency #1 ("6-month"): 10/13/2021 Competency #2 ("Annual"): 05/10/2022 Competencies were not signed by the Technical Consultant. TP13 Initial training: 05/1/2022 Competency #1 ("6-month"): 08/11/2022 Competency was not signed by Technical Consultant. The Technical Consultant failed to assess and document semi-annual competencies. 3. During an interview on 08/29/2022 at 10:36 a.m., the Assistant Operations Manager/TP8 confirmed they were responsible for assessing and documenting semi-annual competencies and no semi-annual competencies were assessed and documented by the Technical Consultant.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.

	1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and confirmed in interview, the laboratory failed to have documentation that 3 of 19 testing persons (TP1, TP3, and TP6) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and confirmed in interview, the laboratory failed to have documentation that 3 of 19 testing persons (TP1, TP3, and TP6) met the qualifications required to perform moderate complexity testing prior to performing patient testing. The findings include: 1. Review of the CMS-209 form revealed TP1 through TP19 listed to perform moderate complexity testing. 2. Review of personnel records revealed the laboratory did not have documentation to ensure the following testing persons were qualified to perform moderate complexity testing: TP1; No education documents provided TP3; No education documents provided TP6; No education documents provided 3. During an interview on 08/29/2022 at 10:36 a.m., the Assistant Operations Manager confirmed there was no educational documentation for TP1, TP3, and TP6.