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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D1014396 | (X3) Date Survey Completed 08/17/2023 |
| Name of Provider or Supplier Texas Mobile Health - American Medical Response | Street Address, City, State 4905 New York Ave, Arlington, 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 | <p>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 Samples 493.1250 Analytic Systems 493.1403 Laboratory Director, (moderate complexity). 493.1409 Technical Consultant 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.</p> |
| D2000 | <p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 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 and routine chemistry) to the date of the survey in 2023. Findings Included: 1. Review of laboratory policy, "Proficiency Testing" (Approved by the Laboratory Director on 11/17/2023) revealed the following: "The laboratory</p> |

will participate in an approved proficiency testing (PT) program to ensure high quality testing and to provide comparative data with other institutions, as required under the current Federal Regulations. If proficiency testing is unavailable for a limited number of tests, competency/comparison testing (split sampling) will be performed on these tests." 2. Review of CMS 116 form, submitted at time of survey, revealed the laboratory performed 1200 chemistry tests annually on the i-Stat analyzer (blood gas and routine chemistry). The laboratory began patient testing in January 2023. The tests performed are: Routine Chemistry a. Sodium b. Potassium c. Chloride d. Glucose e. Blood Urea Nitrogen Blood Gas f. pH g. pO2 h. pCO2 3. Review of the CASPER CMS 155 report, retrieved on 08/16/2023, revealed no proficiency testing scores for the routine chemistry analytes: Sodium, Potassium, Chloride, Glucose, Blood Urea Nitrogen and blood gas analytes: pH, PO2, and PCO2 in 2022 and 2023. 4. Review of laboratory documentation for 2023 revealed the laboratory failed to enroll in PT for the specialty of Chemistry, for 8 of 8 chemistry analytes performed on the i-STAT analyzer. 5. During an interview on 08/17/2023 at 11:05 a.m., in the facility laboratory with Testing Person 1 (TP-1), TP-1 confirmed the above findings. Word Key pH- potential of hydrogen PO2- oxygen partial pressure PCO2- carbon dioxide partial pressure

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 direct observation, review of laboratory policy, laboratory records, and staff interview, it was revealed the laboratory failed to meet analytic systems requirements, as evidenced by: 1. The laboratory failed to follow their own policy for enrollment /participation in proficiency testing in the specialty of chemistry for 2023. Refer to D5401 I. 2. The laboratory failed to follow their own policy for verifying 5 of 5 routine chemistry analytes reference ranges in the laboratory's studies in 2022. Refer to D5401 II. 3. The laboratory failed to follow their own policy for verifying 3 of 3 blood gas chemistry analytes reference ranges in the laboratory's studies in 2022. Refer to D5401 III. 4. The laboratory failed to follow their own policy for performing calibration verification for 2 of 2 cartridges tested (CG4+ and Chem 8) on the i-Stat analyzer every 6 months as required in July 2023. Refer to D5401 IV. 5. The laboratory failed to ensure the reference range for 5 of 5 routine chemistry analytes were verified by the laboratory's studies in 2022. Refer to D5421 I. 6. The laboratory failed to ensure the reference range for 3 of 3 blood gas chemistry analytes were verified by the laboratory's studies in 2022. Refer to D5421 II. 7. The laboratory failed to have documentation of performing calibration verification for 2 of 2 cartridges tested (CG4+ and Chem 8) on the i-Stat analyzer every 6 months as required in July 2023. Refer to D5439. 8. The laboratory failed to monitor the accuracy and precision of QC material over time on the i-Stat analyzer for 7 of 7 months in 2023 (01/2023-07 /2023) to ensure accurate and reliable test results. Refer to D5441. 9. The laboratory failed to include documentation of previous quality control (QC) testing to support the modification in QC for 1 of 1 cartridge (Chem 8) tested on the i-Stat analyzer in 2023.

Refer to D5445 I. 10. The laboratory failed to include documentation of previous quality control (QC) testing to support the modification in QC for 1 of 1 cartridge (CG4+) tested on the i-Stat analyzer in 2023. Refer to D5445 II.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

I. Based on review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 116 form, CMS 155 report, and confirmed in staff interview, the laboratory failed to follow their own policy for enrollment/participation in proficiency testing in the specialty of chemistry in 2023. Findings Included: 1. Review of laboratory policy, "Proficiency Testing" (Approved by the Laboratory Director on 11/17/2023) revealed the following: "The laboratory will participate in an approved proficiency testing (PT) program to ensure high quality testing and to provide comparative data with other institutions, as required under the current Federal Regulations. If proficiency testing is unavailable for a limited number of tests, competency/comparison testing (split sampling) will be performed on these tests." 2. Review of CMS 116 form, provided at time of survey, revealed the laboratory performed 1200 chemistry tests annually on the i-Stat analyzer (blood gas and routine chemistry). The laboratory began patient testing in January 2023. The tests performed are: Routine Chemistry a. Sodium b. Potassium c. Chloride d. Glucose e. Blood Urea Nitrogen Blood Gas f. pH g. pO₂ h. pCO₂ 3. Review of the CASPER CMS 155 report, retrieved on 08/16/2023, revealed no proficiency testing scores for the routine chemistry analytes: Sodium, Potassium, Chloride, Glucose, Blood Urea Nitrogen and blood gas analytes: pH, PO₂, and PCO₂ in 2023. 4. Review of laboratory documentation for 2023 revealed the laboratory failed to enroll in PT for the specialty of Chemistry, for 8 of 8 chemistry analytes performed on the i-STAT analyzer. 5. During an interview on 08/17/2023 at 11:05 a. m., in the facility laboratory with TP-1, TP-1 confirmed the above findings. II. Based on review of laboratory policy, manufacturer's instructions for the i-Stat Chem 8 chemistry cartridge, laboratory verification studies, and confirmed in interview, the laboratory failed to follow their own policy for verifying 5 of 5 routine chemistry analytes reference ranges in the laboratory's studies in 2022. Findings Included: 1. Review of laboratory policy, "Method Validation Plan" (Approved by the Laboratory Director on 11/17/2022) revealed the following: "Procedure-Stepwise: ...Final Evaluation ...2. Compare with established reference range. Do a minimum of 20 comparisons over a wide analytical range. Draw a graph and look for the best fit. 3. Evaluate the reference interval by checking 10 patients expected to have normal results and 10 with abnormal results. If the analyzed values fall into or out of the reference range as expected, the reference interval is probably satisfactory." 2. Review of manufacturer's instructions for use, "i-Stat Chem 8+ Cartridge" (Rev. Date: 26-Feb-2020) revealed the following: "Reference Ranges Na mmol/L (mEq/L) 138-146 K mmol/L (mEq/L) 3.5-4.9 Cl mmol/L (mEq/L) 98-109 Glu mmol/L 70-105 BUN/Urea mg/dL 8-26 The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, sex and heritage, it is recommended that reference ranges be determined for the population being tested. Each facility

should establish its own reference range to assure proper representation of specific populations." 3. Review of laboratory verification studies, performed in 12/2022, revealed the following reference ranges defined for the i-Stat Chem 8 cartridges: "Na mmol/L (mEq/L) 138-146 K mmol/L (mEq/L) 3.5-4.9 Cl mmol/L (mEq/L) 98-109 Glu mmol/L 70-105 BUN/Urea mg/dL 8-26" No documentation was provided referencing the 10 normal and 10 abnormal patients required in laboratory policy for the complete verification study. The laboratory failed to follow their own policy for verifying 5 of 5 routine chemistry analytes reference ranges in the laboratory's studies in 2022. 4. During an interview on 08/17/2023 at 11:35 a.m., in the facility laboratory with TP-1, TP-1 confirmed the above findings. III. Based on review of laboratory policy, manufacturer's instructions for the i-Stat CG4 blood gas cartridge, laboratory verification studies, and confirmed in interview, the laboratory failed to follow their own policy for verifying 3 of 3 blood gas chemistry analytes reference ranges in the laboratory's studies in 2022. Findings Included: 1. Review of laboratory policy, "Method Validation Plan" (Approved by the Laboratory Director on 11/17/2022) revealed the following: "Procedure-Stepwise: ...Final Evaluation ...2. Compare with established reference range. Do a minimum of 20 comparisons over a wide analytical range. Draw a graph and look for the best fit. 3. Evaluate the reference interval by checking 10 patients expected to have normal results and 10 with abnormal results. If the analyzed values fall into or out of the reference range as expected, the reference interval is probably satisfactory." 2. Review of manufacturer's instructions for use, "i-Stat CG4+ Cartridge" (Rev. Date: 07-Sep-2020) revealed the following: "Reference Ranges pH 7.35 - 7.45 PO2 mmHg 80 - 105 PCO2 mmHg 35 - 45 The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, sex and heritage, it is recommended that reference ranges be determined for the population being tested. Each facility should establish its own reference range to assure proper representation of specific populations." 3. Review of laboratory verification studies, performed in 12/2022, revealed the following reference ranges defined for the i-Stat CG4+ blood gas cartridges: "pH 7.35 - 7.45 PO2 mmHg 80 - 105 PCO2 mmHg 35 - 45" No documentation was provided referencing the 10 normal and 10 abnormal patients required in laboratory policy for the complete verification study. The laboratory failed to ensure the reference range for 3 of 3 blood gas chemistry analytes were verified by the laboratory's studies in 2022. 4. During an interview on 08/17/2023 at 11:35 a.m., in the facility laboratory with TP-1, TP-1 confirmed the above findings. IV. Based on direct observation, laboratory policy, review of laboratory records, and confirmed in interview, the laboratory failed to follow their own policy for performing calibration verification for 2 of 2 cartridges tested (CG4+ and Chem 8) on the i-Stat analyzer every 6 months as required in July 2023. Findings Included: 1. During a tour of the facility on 08/17/2023 at 10 a.m., the surveyor observed 3 i-Stat analyzers available for patient testing in the laboratory. (Serial Numbers: 21426331; 21426357; 21426337) 2. Review of laboratory policy, "Periodic Calibration, Calibration Verification (AMR) and Assay Correlations" (Approved by the Laboratory Director on 11/17/2022) revealed the following: "The Analytical Measuring Range (AMR) must be revalidated every 6 months. ...2. Verification of the Analytical Measuring Range (AMR) Calibration, calibration verification and validation of the analytical measurement range (AMR) require substantiating the continued accuracy of the test method. The CLIA-88 regulations use the term "calibration verification" to refer to both verification of correct method calibration and validation of the analytical measurement range." 3. Review of laboratory records revealed the laboratory began patient testing on the CG4+ and Chem 8 cartridges in January 2023. The laboratory was required to perform calibration verification by July 2023. No documentation of the laboratory performing

6-month calibration on the CG4+ and Chem 8 cartridges was provided. The laboratory failed to follow their own policy for performing calibration verification for 2 of 2 cartridges tested (CG4+ and Chem 8) on the i-Stat analyzer every 6 months as required in July 2023. 4. During an interview on 08/17/2023 at 11:45 a.m., in the facility laboratory with TP-1, TP-1 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:

I. Based on review of manufacturer's instructions for the i-Stat Chem 8 chemistry cartridge, laboratory policy, laboratory verification studies, and confirmed in interview, the laboratory failed to ensure the reference ranges for 5 of 5 routine chemistry analytes were verified by the laboratory's studies in 2022. Findings Included: 1. Review of manufacturer's instructions for use, "i-Stat Chem 8+ Cartridge" (Rev. Date: 26-Feb-2020) revealed the following: "Reference Ranges Na mmol/L (mEq/L) 138-146 K mmol/L (mEq/L) 3.5-4.9 Cl mmol/L (mEq/L) 98-109 Glu mmol/L 70-105 BUN/Urea mg/dL 8-26 The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, sex and heritage, it is recommended that reference ranges be determined for the population being tested. Each facility should establish its own reference range to assure proper representation of specific populations." 2. Review of laboratory policy, "Method Validation Plan" (Approved by the Laboratory Director on 11/17/2022) revealed the following: "Procedure-Stepwise: ...Final Evaluation ...2. Compare with established reference range. Do a minimum of 20 comparisons over a wide analytical range. Draw a graph and look for the best fit. 3. Evaluate the reference interval by checking 10 patients expected to have normal results and 10 with abnormal results. If the analyzed values fall into or out of the reference range as expected, the reference interval is probably satisfactory." 3. Review of laboratory verification studies, performed in 12/2022, revealed the following reference ranges defined for the i-Stat Chem 8 cartridges: "Na mmol/L (mEq/L) 138-146 K mmol/L (mEq/L) 3.5-4.9 Cl mmol/L (mEq/L) 98-109 Glu mmol/L 70-105 BUN/Urea mg/dL 8-26" No documentation was provided referencing the 10 normal and 10 abnormal patients required in laboratory policy for the complete verification study. The laboratory failed to ensure the reference ranges for 5 of 5 routine chemistry analytes were verified by the laboratory's studies in 2022. 4. During an interview on 08/17/2023 at 11:35 a.m., in the facility laboratory with TP-1, TP-1 confirmed the above findings. II. Based on review of manufacturer's instructions for the i-Stat CG4+ blood gas cartridge, laboratory policy, laboratory verification studies, and confirmed in interview, the laboratory failed to ensure the reference ranges for 3 of 3 blood gas chemistry analytes were verified by the laboratory's studies in 2022. Findings Included: 1. Review of manufacturer's instructions for use, "i-Stat CG4+ Cartridge" (Rev. Date: 07-Sep-2020) revealed the following: "Reference Ranges pH 7.35 - 7.45 PO2 mmHg 80 - 105 PCO2

mmHg 35 - 45 The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, sex and heritage, it is recommended that reference ranges be determined for the population being tested. Each facility should establish its own reference range to assure proper representation of specific populations." 2. Review of laboratory policy, "Method Validation Plan" (Approved by the Laboratory Director on 11/17/2022) revealed the following: "Procedure-Stepwise: ...Final Evaluation ...2. Compare with established reference range. Do a minimum of 20 comparisons over a wide analytical range. Draw a graph and look for the best fit. 3. Evaluate the reference interval by checking 10 patients expected to have normal results and 10 with abnormal results. If the analyzed values fall into or out of the reference range as expected, the reference interval is probably satisfactory." 3. Review of laboratory verification studies, performed in 12/2022, revealed the following reference ranges defined for the i-Stat CG4+ blood gas cartridges: "pH 7.35 - 7.45 PO2 mmHg 80 - 105 PCO2 mmHg 35 - 45" No documentation was provided referencing the 10 normal and 10 abnormal patients required in laboratory policy for the complete verification study. The laboratory failed to ensure the reference ranges for 3 of 3 blood gas chemistry analytes were verified by the laboratory's studies in 2022. 4. During an interview on 08/17/2023 at 11:35 a.m., in the facility laboratory with TP-1, TP-1 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 direct observation, laboratory policy, review of laboratory records, and confirmed in interview, the laboratory failed to have documentation of performing calibration verification for 2 of 2 cartridges tested (CG4+ and Chem 8) on the i-Stat analyzer every 6 months as required in July 2023. Findings Included: 1. During a tour of the facility on 08/17/2023 at 10 a.m., the surveyor observed 3 i-Stat analyzers available for patient testing in the laboratory. (Serial Numbers: 21426331; 21426357; 21426337) 2. Review of laboratory policy, "Periodic Calibration, Calibration

Verification (AMR) and Assay Correlations" (Approved by the Laboratory Director on 11/17/2022) revealed the following: "The Analytical Measuring Range (AMR) must be revalidated every 6 months. ...2. Verification of the Analytical Measuring Range (AMR) Calibration, calibration verification and validation of the analytical measurement range (AMR) require substantiating the continued accuracy of the test method. The CLIA-88 regulations use the term "calibration verification" to refer to both verification of correct method calibration and validation of the analytical measurement range." 3. Review of laboratory records revealed the laboratory began patient testing on the CG4+ and Chem 8 cartridges in January 2023. The laboratory was required to perform calibration verification by July 2023. No documentation of the laboratory performing 6-month calibration on the CG4+ and Chem 8 cartridges was provided. The laboratory failed to have documentation of performing calibration verification for 2 of 2 cartridges tested (CG4+ and Chem 8) on the i-Stat analyzer every 6 months as required in July 2023. 4. During an interview on 08/17/2023 at 11:45 a.m., in the facility laboratory with TP-1, TP-1 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 direct observation, review of laboratory policies, quality control (QC) records, and confirmed in staff interview, the laboratory failed to monitor the accuracy and precision of QC material over time on the i-Stat analyzer (Chem 8 and CG4+ cartridges) for 7 of 7 months in 2023 (01/2023-07/2023) to ensure accurate and reliable test results. Findings Included: 1. During a tour of the facility on 08/17/2023 at 10 a.m., the surveyor observed 3 i-Stat analyzers available for patient testing on the Chem 8 and CG4+ cartridges in the laboratory. (Serial Numbers: 21426331; 21426357; 21426337) 2. Review of laboratory policies revealed no policy in place to monitor QC records over time, for the Chem 8 and CG4+ cartridges, to ensure accurate and reliable test results. 3. The laboratory was asked to provide documentation of monitoring Chem 8 and CG4+ cartridge QC over time in 2023. No documentation was provided. The laboratory failed to monitor the accuracy and precision of QC material over time on the i-Stat analyzer (Chem 8 and CG4+ cartridges) for 7 of 7 months in 2023 (01/2023-07/2023) to ensure accurate and reliable test results. 4. During an interview on 08/17/2023 at 11:45 a.m., in the facility laboratory with TP-1, TP-1 confirmed the above findings.

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:

I. Based on review of the laboratory's quality control documentation (January 2023-July 2023), i-Stat Chem 8 IQCP (Individual Quality Control Plan), and staff interview, it was revealed the laboratory failed to include documentation of previous quality control (QC) testing to support the modification in QC for 1 of 1 cartridge (Chem 8) tested on the i-Stat analyzer in 2023. Findings Included: 1. Review of laboratory's QC documentation revealed the laboratory only performed QC once a month or every new lot/shipment. Chem 8 QC Performed: January 15, 2023 Lot Number: H22262 February 17, 2023 Lot Number: H22262 March 23, 2023 Lot Number: H23007A No QC results for April 2023. May 4, 2023 Lot Number: H23050 June 4, 2023 Lot Number: H23050 July 28, 2023 Lot Number: H23094 2. Review of laboratory's IQCP (Signed by the Technical Consultant on 11/17/2022) revealed the laboratory failed to include any supporting QC data in the QC section of the IQCP. The Laboratory Director did not sign/approve the IQCP. The laboratory failed to include documentation of previous QC to support the modification in QC to once a month or every new lot/shipment for 1 of 1 cartridge (Chem 8) tested on the i-Stat analyzer. 3. Further review of the laboratory's IQCP revealed the following in the Quality Assurance section, "Data to be included with basic paperwork for IQCP: Validation studies, Historical QC data, Biannual Calibration Verification, QC run on new shipments/lots, Patient data over time". No historical QC data, biannual calibration verification or patient data over time was included in the IQCP. The laboratory failed to include any supporting data in the Quality Assurance section of the IQCP. 4. During an interview on 08/17/2023 at 11:45 a.m., in the facility laboratory with TP-1, TP-1 confirmed the above findings. II. Based on review of the laboratory's quality control documentation (January 2023-July 2023), i-Stat CG4+ IQCP (Individual Quality Control Plan), and staff interview, it was revealed the laboratory failed to include documentation of previous quality control (QC) testing to support the modification in QC for 1 of 1 cartridge (CG4+) tested on the i-Stat analyzer in 2023. Findings Included: 1. Review of laboratory's QC documentation revealed the laboratory only performed QC once a month or every new lot/shipment. CG4+ QC Performed: January 15, 2023 Lot Number: D22271A February 17, 2023 Lot Number: D222312 March 23, 2023 Lot Number: D22294A No QC results for April 2023. May 4, 2023 Lot Number: D22294A June 4, 2023 Lot Number: D22294A July 28, 2023 Lot Number: D23068 2. Review of laboratory's IQCP (Signed by the Technical Consultant on 11/17/2022) revealed the laboratory failed to include any supporting QC data in the QC section of the IQCP. The Laboratory Director did not sign/approve the IQCP. The laboratory failed to include documentation of previous QC testing to support the modification in QC to once a month or every new lot /shipment for 1 of 1 cartridge (CG4+) tested on the i-Stat analyzer. 3. Further review of the laboratory's IQCP revealed the following in the Quality Assurance section, "Data to be included with basic paperwork for IQCP: Validation studies, Historical QC data, Biannual Calibration Verification, QC run on new shipments/lots, Patient data over time". No historical QC data, biannual calibration verification or patient data over time was included in the IQCP. The laboratory failed to include any

supporting data in the Quality Assurance section of the IQCP. 4. During an interview on 08/17/2023 at 11:45 a.m., in the facility laboratory with TP-1, TP-1 confirmed the above findings.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of laboratory's procedure manual, laboratory records, and quality control data, the laboratory failed to have an effective QA (quality assessment) system in place to identify and correct problems for the analytical phase of testing as evidenced by: 1. The laboratory failed to ensure the reference range for 5 of 5 routine chemistry analytes were verified by the laboratory's studies in 2022. Refer to D5421 I. 2. The laboratory failed to ensure the reference range for 3 of 3 blood gas chemistry analytes were verified by the laboratory's studies in 2022. Refer to D5421 II. 3. The laboratory failed to have documentation of performing calibration verification for 2 of 2 cartridges tested (CG4+ and Chem 8) on the i-Stat analyzer every 6 months as required in July 2023. Refer to D5439. 4. The laboratory failed to monitor the accuracy and precision of QC material over time on the i-Stat analyzer (Chem 8 and CG4+ cartridges) for 7 of 7 months in 2023 (01/2023-07/2023) to ensure accurate and reliable test results. Refer to D5441. 5. The laboratory failed to include documentation of previous quality control (QC) testing to support the modification in QC for 1 of 1 cartridge (Chem 8) tested on the i-Stat analyzer in 2023. Refer to D5445 I. 6. The laboratory failed to include documentation of previous quality control (QC) testing to support the modification in QC for 1 of 1 cartridge (CG4+) tested on the i-Stat analyzer in 2023. Refer to D5445 II.

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 direct observations, review of laboratory policies, laboratory records, patient records, CMS 209 form, and confirmed in interview, it was revealed the laboratory director failed to provide overall management and direction in accordance with 493.1403 of this subpart, as evidenced by:

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 laboratory policy and confirmed in staff interview, the Laboratory Director failed to ensure laboratory overall operations and test systems were in compliance with regulations as evidenced by: 1. The laboratory failed to meet the requirements of participating in proficiency testing for the specialty of Chemistry (blood gas and routine chemistry) to the date of the survey for in 2023. Refer to D2000. 2. The laboratory failed to ensure the reference range for 5 of 5 routine chemistry analytes were verified by the laboratory's studies in 2022. Refer to D5421 I. 3. The laboratory failed to ensure the reference range for 3 of 3 blood gas chemistry analytes were verified by the laboratory's studies in 2022. Refer to D5421 II. 4. The laboratory failed to have documentation of performing calibration verification for 2 of 2 cartridges tested (CG4+ and Chem 8) on the i-Stat analyzer every 6 months as required in July 2023. Refer to D5439. 5. The laboratory failed to monitor the accuracy and precision of QC material over time on the i-Stat analyzer (Chem 8 and CG4+ cartridges) for 7 of 7 months in 2023 (01/2023-07/2023) to ensure accurate and reliable test results. Refer to D5441. 6. The laboratory failed to include documentation of previous quality control (QC) testing to support the modification in QC for 1 of 1 cartridge (Chem 8) tested on the i-Stat analyzer in 2023. Refer to D5445 I. 7. The laboratory failed to include documentation of previous quality control (QC) testing to support the modification in QC for 1 of 1 cartridge (CG4+) tested on the i-Stat analyzer in 2023. Refer to D5445 II. 8. The technical consultant failed to perform initial and semi-annual competency assessments of 9 of 9 testing personnel in 2022 and 2023. Refer to D6046.

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:

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 the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for the specialty of chemistry in 2023, as evidenced by: 1. Review of laboratory policy, "Proficiency Testing" (Approved by the Laboratory Director on 11/17/2023) revealed the following: "The laboratory will participate in an approved proficiency testing (PT) program to ensure high quality testing and to provide comparative data with other institutions, as required under the current Federal Regulations. If proficiency testing is unavailable for a limited number of tests, competency /comparison testing (split sampling) will be performed on these tests." 2. Review of CMS 116 form revealed the laboratory performed 1200 chemistry tests annually on the i-Stat analyzer (blood gas and routine chemistry). The laboratory began patient testing in October 2022. The tests performed are: Routine Chemistry a. Sodium b. Potassium c. Chloride d. Glucose e. Blood Urea Nitrogen Blood Gas f. pH g. pO2 h. pCO2 3. Review of the CMS 155 report revealed no proficiency testing scores for the routine chemistry analytes: Sodium, Potassium, Chloride, Glucose, Blood Urea Nitrogen and blood gas analytes: pH, PO2, and PCO2. 4. Review of laboratory documentation for 2022 and 2023 revealed the laboratory failed to enroll in PT for the specialty of Chemistry, for 8 of 8 chemistry analytes performed on the i-STAT analyzer. 5. During an interview on 08/17/2023 at 11:05 a.m., in the facility laboratory with TP-1, TP-1 confirmed the above findings. Word Key pH- potential of hydrogen PO2- oxygen partial pressure PCO2- carbon dioxide partial pressure

D6022

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 and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on direct observation, review of laboratory records, patient test results, and manufacturer's instructions, the Laboratory Director failed to ensure that QA (quality assessment) and QC (quality control) programs were monitored and maintained, as evidenced by: 1. The laboratory failed to ensure an effective QA (quality assessment) system was in place to monitor, assess, and correct problems in the laboratory. Refer to D5793

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on direct observation, review of laboratory policies, testing personnel competencies, and confirmed in interview, the Technical Consultant failed to provide technical oversight, as evidenced by: The Technical Consultant failed to provide technical and scientific oversight. Refer to D6036.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on direct observation, review of laboratory policies, testing personnel competencies, and confirmed in interview, the Technical Consultant failed to provide technical oversight, as evidenced by: 1. The technical consultant failed to perform initial and semi-annual competency assessments of 9 of 9 testing personnel in 2022 and 2023. Refer to D6046.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy, the CMS Form 209 Laboratory Personnel Report, review of the laboratory's personnel records, and interview with facility personnel, the technical consultant failed to perform initial and semi-annual competency assessments of 9 of 9 testing personnel in 2022 and 2023. Findings Included: 1. Review of laboratory policy, "Personnel Responsibilities" (Approved by the Laboratory Director on 11/17/2022) revealed the following: "Technical Consultant /Supervisor 1. Must be accessible to the laboratory to provide on-site, telephone or electronic consultation. 2. Responsible for: ...Evaluation of each employee and documentation, semiannually the first year and annually thereafter, that the individual tests patient specimens competently." 2. Review of CMS-209 Form revealed the laboratory employed 9 testing personnel (TP-1, TP-2, TP-3, TP-4, TP-5, TP-6, TP-7, TP-8 and TP-9), who performed moderate complexity testing on the i-Stat analyzer, and 1 technical consultant (TC-1). 3. Review of laboratory's personnel records revealed TC-1 failed to perform initial and 6-month competency on the following testing personnel: a. TP-1 Initial competency performed: 10/13/22 6-Month competency performed: 04/13/23 Both competencies performed by TP-1. b. TP-2 Initial competency performed: 10/13/22 6-Month competency performed: 04/13/23 Both competencies performed by TP-1. c. TP-3 Initial competency performed: 10/14/22 6-Month competency performed: 04/14/23 Both competencies performed by TP-1. d. TP-4 Initial competency performed: 10/14/22 6-Month competency performed: 04/14/23 Both competencies performed by TP-1. e. TP-5 Initial competency performed: 10/14/22 6-Month competency performed: 04/14/23 Both competencies performed by

TP-1. f. TP-6 Initial competency performed: 11/17/22 6-Month competency performed: 08/15/2023 Both competencies performed by TP-1. g. TP-7 Initial competency performed: 02/10/2023 Competency performed by TP-1. h. TP-8 Initial competency performed: 02/09/2023 6-Month competency performed: 08/09/2023 Both competencies performed by TP-1. i. TP-9 Initial competency performed: 02/05/2023 6-Month competency performed: 08/14/2023 Both competencies performed by TP-1. The technical consultant failed to perform initial and semi-annual competency assessments of 9 of 9 testing personnel in 2022 and 2023. 4. During an interview on 08/17/2023 at 11:15 a.m., in the facility laboratory with TP-1, TP-1 confirmed the above findings.