

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2013331	(X3) Date Survey Completed 02/09/2023
Name of Provider or Supplier Choctaw Regional Medical Center	Street Address, City, State 8613 Ms Hwy 12, Ackerman, MS	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by:</p> <ol style="list-style-type: none"> Based on review of the Abbott i-STAT System Manual, patient test results for blood gas testing with the Abbott i-STAT System from 8/23/2021 through 1/22/2023, and lack of documentation of the room temperature of the Respiratory Department where Abbott i-STAT testing was performed, the laboratory failed to follow manufacturer's instructions for the operating temperature of the Abbott i-STAT System from 8/23/2021 through 12/31/2021 when the room temperature was not monitored and documented. A total of 44 patient specimens were tested for pH, pCO₂, and pO₂ on the Abbot i-STAT System during this time frame. Findings include: The Abbott i-STAT System Manual states the operating temperature for i-STAT System testing is 16 to 30 degrees Celsius or 61 to 86 degrees Fahrenheit. On 2/8/2023, there was no documentation of the room temperature of the Respiratory Department, where Abbott i-STAT testing was performed from 8/23/2021 through 12/31/2021 to ensure manufacturer's instructions for operating temperature were followed. Review of patient test results for blood gas testing with the Abbott i-STAT System revealed a total of 44 patient specimens were tested for pH, pCO₂, and pO₂ between 8/23/2021 and 12/31/2021. Based on review of the Ortho Diagnostics MicroTyping System (MTS) Dispenser Instructions for Use, lack of documentation of MTS dispenser calibration checks and weekly cleaning, and interview with the technical consultant on 2/9/2023 at 10:25 a.m., the laboratory failed to follow manufacturer's instructions for performing calibration checks and weekly cleaning of the MTS Diluent 2 dispenser and the MTS Diluent 2 Plus dispenser, in use for patient

ABO/ Rh typing, antibody detection testing, and compatibility testing, since the last survey on 6/16/2021. Findings include: Ortho Diagnostics MTS Dispenser Instructions for Use state for Calibration Check: "A calibration check should be done as part of a routine laboratory quality control schedule and after each repair." The Instructions for Use state for Cleaning: "The dispenser should be cleaned on a weekly basis." There was no documentation on the day of the survey of calibration checks or weekly cleaning of the MTS Diluent 2 dispenser or MTS Diluent 2 Plus dispenser. In an interview on 2/9/2023 at 10:25 a.m., the technical consultant confirmed there was no documentation of calibration checks or weekly cleaning of the dispensers.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of printouts of patient test results from the Abbott i-STAT System since the last survey on 6/16/2021, interview on 2/8/2023 at 12:10 p.m. with the technical consultant, and lack of documentation of verification of performance specifications for pH, pCO₂, and pO₂ blood gas testing, the laboratory failed to verify the manufacturer's performance specifications for blood gas testing with the Abbott i-STAT CG8+ reagent cartridge before patient testing with this cartridge began on 8/23/2021. Findings include: Review of printouts of patient test results from the Abbott i-STAT System since 6/16/2021 revealed the CG8+ reagent cartridge was put in use for patient pH, pCO₂, and pO₂ testing on 8/23/2021. On 2/8/2023 there was no documentation of verification of performance specifications for pH, pCO₂, and pO₂ testing on the CG8+ reagent cartridge available for review, to include accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals for the laboratory's patient population. In an interview on 2/8/2023 at 12:10 p.m., the technical consultant confirmed verification of performance specifications were not performed for the Abbott i-STAT CG8+ reagent cartridge. A total of 164 patient specimens were tested for pH, pCO₂, and pO₂ blood gases with the CG8+ reagent cartridge from 8/23/2021 through 1/22/2023.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on review of the Abbott i-STAT System Manual, interview on 2/8/2023 at 1:30 p.m. with Respiratory Testing Personnel #1, listed on the Centers for Medicare and

Medicaid Services (CMS) 209 personnel form, and lack of documentation of thermal probe checks since the last survey on 6/16/2021, the laboratory failed to perform and document thermal probe checks every six months, as required by the manufacturer. Findings include: The Abbott i-STAT System Manual states to check the thermal probes on each analyzer every six months. There was no documentation available on 2/8/2023 of the performance of thermal probe checks on the i-STAT System since the last survey on 6/16/2021. In an interview on 2/8/2023 at 1:30 p.m., Respiratory Testing Personnel #1 confirmed there was no documentation of thermal probe checks on the Abbott i-STAT System.

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 calibration and calibration verification records for the Siemens Dimension EXL 200 chemistry analyzer since it was installed on 9/30/2021 and interview with the technical consultant on 2/9/2023 at 3:30 p.m., the laboratory failed to perform calibration verification at least once every six months for sodium, potassium, and chloride testing since 9/30/2021. Findings include: Review of calibration records for the Siemens Dimension EXL 200 chemistry analyzer since installation on 9/30/2021 revealed the sodium, potassium, and chloride tests have only two calibrators. There was no documentation available on 2/9/2023 of calibration verification performed on sodium, potassium, and chloride tests since the initial calibration verification on 9/30/2021. In an interview on 2/9/2023 at 3:30 p.m., the technical consultant confirmed calibration verification had not been performed on sodium, potassium, and chloride testing since the initial verification on 9/30/2021.

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 quality control (QC) records and patient test results for blood gas testing with the Abbott i-STAT System from 6/20/2021 through 1/22/2023, lack of documentation of an Individualized Quality Control Plan (IQCP) for testing with the Abbott i-STAT CG8+ reagent cartridge, and interview with the technical consultant on 2/8/2023 at 12:10 p.m., the laboratory failed to include a control each eight hours of patient testing from 8/23/2021 through 1/22/2023, when a total of 164 patient blood gas results were reported. Findings include: Review of QC records and patient test results for blood gas testing with the Abbott i-STAT System from 6/20/2021 through 1/22/2023 revealed blood gas results, which include pH, pCO₂, and pO₂, were reported for 164 patients during this time frame with no documentation of performance of a control each eight hours of patient testing. There was no documentation of establishment of an IQCP for Abbott i-Stat testing with the CG8+ reagent cartridge, which was put in use for patient testing on 8/23/2021. In an interview on 2/8/2023 at 12:10 p.m., the technical consultant confirmed an IQCP was not developed for blood gas testing with the Abbott i-STAT CG8+ reagent cartridge.