

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472384	(X3) Date Survey Completed 10/06/2022
Name of Provider or Supplier Roger Mills Memorial Hospital	Street Address, City, State 501 South L L Males Avenue, Cheyenne, OK	
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	The recertification survey was performed on 10/04,05,06/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the CEO and laboratory manager during an exit conference performed at the conclusion of the survey.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the laboratory manager, the laboratory failed to ensure iSTAT cartridges had not exceeded their room temperature expiration date for one of four cartridge types observed. Findings include: (1) On 10/04/2022 at 11:30 am, the laboratory manger stated Blood Gas (pH, pCO₂, pO₂) testing was performed using the CG4+ cartridge and the iSTAT 1 analyzer; (2) Observation of the laboratory on 10/04/2022 at 11:35 am identified CG4+ cartridges stored at room temperature, with a date of 07/13/22 documented on the boxes: (a) Lot #D22116 - One box containing five cartridges and two boxes, each containing 25 cartridges. (3) Review of the manufacturer's storage requirements showed the following: (a) The cartridges were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The cartridges were stable at room temperature (18-30 degrees C) for two months. (4) Interview with the laboratory manager on 10/04/2022 at 11:42 am confirmed the cartridges had been placed at room temperature on 07/13/2022 and therefore, the cartridges had been stored at room temperature beyond the manufacturer's room temperature expiration date.</p>
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 a review of records and interview with the laboratory manager, the laboratory failed to ensure the demonstrated reportable ranges were utilized, and failed to ensure the performance specification data had been evaluated prior to implementing the new test for one of two new test methods introduced into the laboratory. Findings include: (1) On 10/04/2022 at 11:30 am, the laboratory manager stated the laboratory began performing D-dimer testing using the Biosite Triage Meter Pro analyzer on 05/11/2021; (2) On 10/05/2022, a review of the performance specification records for the new test system identified the following: (a) The laboratory had demonstrated a reportable range of 153-4900 ng/ml; (b) There was no evidence the data had been reviewed and evaluated by the laboratory. (3) The records were reviewed with the laboratory manager who stated the following on 10/05/2022 at 09:47 am: (a) The laboratory was using the manufacturer's reportable range of 100-5000 ng/ml instead of the reportable range of 153-4900 ng/ml that had been demonstrated by the laboratory; (c) There was no documentation to prove the data had been reviewed and evaluated by the laboratory.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for one of two analyzers reviewed. Findings include: (1) On 10/04/2022 at 11:43 am, the laboratory manager stated Albumin, Alcohol, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Amylase, AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), Calcium, CK (Creatine Kinase), Creatinine, Chloride, CO₂, Glucose, HDL (High Density Lipoprotein), Lactate, Magnesium, Potassium, Sodium, Total Bilirubin, Total Cholesterol, Total Protein, and Triglyceride testing were performed on the Ortho Vitros 350 analyzer; (2) On 10/05/2022, a review of the manufacturer's maintenance requirements, as stated on the manufacturer's maintenance log revealed the following requirements: (a) Weekly (i) Clean tray platform and transport arm (ii) Clean cup retainer (iii) Clean diluent bottles (iv) Clean tip locator assembly (v) Clean control unit screen (vi) Clean keypad cover (vii) Inspect, clean, and/or replace air filter (3) A review of maintenance logs from January 2022 through September 2022 identified the weekly maintenance had not been documented as performed between 08/29/2022 and 09/12/2022; (4) The

records were reviewed with the laboratory manager who stated on 10/05/2022 at 04:29 pm, the weekly maintenance had not been documented as performed as shown above.

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 a review of records and interview with the laboratory manager, the laboratory failed to perform calibration verification procedures at least once every six months for one of five test systems. Findings include: (1) On 10/04/2022 at 11:30 am, the laboratory manager stated the laboratory began performing D-dimer testing using the Biosite Triage Meter Pro analyzer on 05/11/2021; (2) Calibration verification records could not be located since the procedure had been performed during the implementation of the analyzer in 05/2021, and the laboratory manager was questioned. The laboratory manager stated on 10/04/2021 at 03:50 pm, calibration verification procedures had not been performed since 05/2021.

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 a review of records, quality control package inserts, and interview with the laboratory manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for Alkaline Phosphatase and Amylase testing for four of four months reviewed. Findings include: (1) On 10/04/2022 at 11:43 am, the laboratory manager stated Alkaline Phosphatase and Amylase testing were performed on the Ortho Vitros 350 analyzer; (2) On 10/05/2022 at 10:00 am, the laboratory manager stated the following: (a) Three levels of MAS ChemTRAK H Liquid Assayed QC (quality control) materials were performed each day of patient testing; (b) When new lot numbers of control materials were put into use, the laboratory established means for each analyte and utilized historic two SD (Standard Deviation) ranges; (c) The following lot numbers of control materials were currently in use: (i) Level 1 lot #CHA22101 (ii) Level 2 lot #CHA22102 (iii) Level 3 lot #CHA22103 (3) A review of the package insert for the QC materials identified the manufacturer's listed ranges were not listed as SD ranges and were listed as guideline ranges. The instructions stated under the heading "Control Ranges", "Instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges"; (4) A review of QC records (Levey-Jennings graphs and cumulative calculated data) from May 2022 through August 2022 (the current lot numbers were in use during the review period) identified the following: (a) Amylase - The laboratory was using ranges wider than the package insert guideline ranges for one of three levels of QC materials: (i) Level One - The laboratory was using a range of 49.2-96.28 from May through July and a range of 62.7-109.8 in August which was wider than the package insert guideline range of 61.9-92.9. (b) Alkaline Phosphatase - The laboratory was using ranges wider than the package insert guideline ranges for one of three levels of QC materials: (i) Level One - The laboratory was using a range of 29.32-58.86 during the review period which was wider than the package insert guideline range of 40-60. (5) The records were reviewed with the laboratory manager who stated on 10/06/2022 at 10:20 am, the laboratory was using ranges wider than the package insert guideline ranges and those ranges were currently being used to determine patient acceptability.

D5447

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the laboratory manager, the laboratory failed to perform two levels of quality control materials each day of patient Troponin I testing for two of eight days reviewed. Findings include: (1) On 10/04 /2022 at 11:30 am, the laboratory manger stated the following: (a) Troponin I testing was performed using the TPNI cartridge and the iSTAT 1 analyzer; (b) Two levels of iSTAT quality control (QC) materials were performed each 24 hours of patient testing. (2) On 10/05/2022, a review of QC and patient testing records in August 2022

identified two levels of QC testing had not been performed each 24 hours of patient testing reviewed for two of eight days as follows: (a) 08/09/2022 - Patient testing had been performed at 02:01 pm. There was no documentation QC testing had been performed in the previous 24 hour time period. QC had not been performed until 03:38 pm; (b) 08/28/2022 - Patient testing had been performed at 10:58 am. There was no documentation QC testing had been performed in the previous 24 hour time period. QC had not been performed until 12:23 pm. (3) The records were reviewed with the laboratory manager who stated on 10/05/2022 at 10:33 am, the laboratory had not performed two levels of QC testing each 24 hours of patient testing as stated above.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager, the laboratory failed to perform positive control procedures each day of blood bank testing for six of 12 days of patient testing reviewed. Findings include: (1) On 10/04/2022 at 11:40 am, the laboratory manager stated the laboratory performed Crossmatch Testing, which consisted of ABO Group testing, using the tube method; (2) On 10/05/2022, a review of records for blood bank testing performed from February 2022 through September 2022 identified positive QC (quality control) for the A-Antisera, B-Antisera, and A,B Antisera had not been performed for six of 12 days of patient testing (only negative QC testing had been performed). The specific days were 02/11/2022, 03/09/2022, 03/24/2022, 09/05/2022, 09/08/2022, and 09/24/2022; (3) The records were reviewed with the laboratory manager who stated on 10/05/2022 at 01:05 pm, positive QC had not been documented as performed for the antisera used for ABO Group testing as stated above.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager, the laboratory failed to perform two levels of quality control materials each eight hours of D-dimer testing 15 of 15 days of patient testing reviewed. Findings include: (1) On 10/04/2022 at 11:30 am, the laboratory manager stated the following: (a) The laboratory began performing D-dimer testing using the Biosite Triage Meter Pro analyzer on 05/11/2021; (b) Two levels of QC (Quality Control) materials were performed with new lot numbers of test devices; (c) An IQCP (Individualized Quality Control Plan) had not been developed for the test system. (2) Since an IQCP had not been developed for

the test system, it was determined two levels of QC materials must be performed each eight hours of patient testing; (3) On 10/05/2022, a review of QC and patient testing records for testing performed during March and August 2022 identified two levels of QC materials had not been performed each 8 hours of patient testing (QC had not been performed on the days of testing) for 15 of 15 days with the specific days as follows: (a) March 2022 - 03/06, 03/07, 03/08, 03/12, 03/18 (b) August 2022 - 08/01, 08/02, 08/04, 08/08, 08/09, 08/14, 08/16, 08/22, 08/28, 08/30 (4) The records were reviewed with the laboratory manager who stated on 10/05/2022 at 11:15 am, two levels of QC materials had not been performed each eight hours of patient testing.

D5555

IMMUNOHEMATOLOGY
CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure units of blood were stored under appropriate conditions for five of 27 blood bank refrigerator temperature charts. Findings include: (1) On 10/04 /2022 at 11:40 am, the laboratory manager stated units of packed red blood cells were stored in the Helmer blood bank refrigerator with a recorder connected to it to continuously record the temperature on thermograph charts, which monitored the temperature for a seven day period: (2) A review of 27 refrigerator charts dated from 12/27/2021 through 07/05/2022 identified that five of 27 charts had not been changed by the seventh day as follows: (a) Chart #1 - The chart had been put into use on 02/14 /2022 and removed on 02/23/2022 (9 days); (b) Chart #2 - The chart had been put into use on 03/21/2022 and removed on 03/29/2022 (8 days); (c) Chart #3 - The chart had been put into use on 05/02/2022 and removed on 05/10/2022 (8 days); (d) Chart #4 - The chart had been put into use on 05/23/2022 and removed on 05/31/2022 (8 days); (e) Chart #5 - The chart had been put into use on 06/27/2022 and removed on 07/05 /2022 (8 days). (3) The charts were reviewed with the laboratory manager who stated on 10/05/2022 at 02:10 pm, the above charts had not been changed by the 7th day.