Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0475417	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier Atoka County Medical Center	**Street Address, City, State** 1590 W Liberty Rd, Atoka, 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 11/27,28,29/18. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the hospital chief executive officer, chief nursing officer, technical consultant, and laboratory supervisor during an exit conference performed at the conclusion of the survey.
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 a review of records and interview with the technical consultant, the laboratory failed to ensure a proficiency testing attestation statement had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 Hematology proficiency testing records. The following was identified for 1 of 5 testing events: (a) Third 2017 Hematology Event - The attestation was not signed by the laboratory director or designee. (2) The findings were reviewed with the technical consultant who stated the attestation statement had not been signed.

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: Based on a review of a written policy, and interview with the technical consultant, the laboratory failed to follow a written policy. Findings include: (1) On the first day of the survey, the technical consultant stated the following to the surveyor: (a) PT/INR and PTT testing were performed on the ACL Elite analyzer; (b) The laboratory had a policy to ensure the specimens tested on the analyzer were platelet poor. (2) On the second day of the survey, the surveyor reviewed the policy titled, "Platelet Poor Plasma Procedure" which stated, "Twice annually the lab will validate that platelet poor plasma is being achieved. Routine patient samples will be collected and processed as described above. The processed plasma sample will be tested on the hematology instrument to determine the platelet count. At least 5 samples will be tested for each validation period. Platelet counts should be less than 10,000. If the test determines the plasma is not platelet poor, centrifuge speed/time will be adjusted. The validation will be recorded and maintained for at least 2 years"; (3) The surveyor then reviewed records for 2017 and 2018 and identified the platelet-poor plasma checks had not been performed twice annually as required by policy, instead, the checks had been performed on an annual basis (the checks had been performed on 11/07/17 and 11/13/18: (4) The surveyor reviewed the records and policy with the technical consultant who stated the laboratory had not followed their written policy.
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 technical consultant, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor *CMP, *Lipid Profile, Amylase, PBNP (Pro B-type Natriuretic Peptide), CK, Phosphorus, Lipase, Magnesium, Uric Acid, CKMB, Troponin I, Hemoglobin A1c, TSH (Thyroid Stimulating Hormone), Acetaminophen, Alcohol, and Salicylate testing were performed on the Siemens Dimension EXL 200 analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements were as follows: (a) Weekly (i) Clean Outside of R2 Probe (ii) Clean Outside of HM Wash Probes (b) Monthly (i) Replace IMT Pump Tubing (ii) Clean IMT System (iii) Replace/Clean Air Filters (iv) Stylette HM Wash Probes (v) Replace HM Pump Heads (vi) Clean R2 Drain (3) The surveyor then reviewed maintenance records for the analyzer from May 2017 through October 2018. The following was identified: (a) Weekly - Not

	documented as performed between: (i) 07/18/17 and 08/01/17 (ii) 08/24/17 and 09/25 /17 (iii) 05/24/18 and 06/06/18 (iv) 08/20/18 and 09/06/18 (b) Monthly - The following had not been documented as performed for 3 of 18 months: (i) May 2017 - Replace IMT Pump Tubing, Clean IMT System, Replace HM Pump Heads, and Clean R2 Drain; (ii) September 2017 - Replace IMT Pump Tubing, Clean IMT System, Replace/Clean Air Filters, Stylette HM Wash Probes, Replace HM Pump Heads, and Clean R2 Drain; (iii) March 2018 - Replace/Clean Air Filters and Clean R2 Drain. (3) The surveyor reviewed the records with the technical consultant who stated the above maintenance procedures had not been documented as being performed as required. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein *Lipid Profile - Cholesterol, HDL Cholesterol, Triglyceride
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 technical consultant, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor Chloride, Potassium, Sodium testing were performed using the Siemens Dimension EXL 200 analyzer; (2) On the second day of the survey, the surveyor reviewed calibration verification records for Chloride, Potassium, and Sodium (since routine calibration procedures were performed using less than three calibrators for the above analytes, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). There was no evidence calibration verification procedures had been performed prior to or after 02/06 /18; (3) The surveyor reviewed the records with the technical consultant who stated calibration verification had not been performed every 6 months during 2017 and to date in 2018.

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 technical consultant and laboratory supervisor, the laboratory failed to perform a negative and positive control material each day of patient testing. Findings include: SERUM PREGNANCY TESTING (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory performed Serum Pregnancy testing using the Quidel QuickVue One Step hCG test kit; (2) The surveyor asked the technical consultant if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The technical consultant stated to the surveyor at 1:25 pm that an IQCP had not been developed. Therefore, the surveyor determined negative and positive QC (quality control) materials must be performed each day of patient testing; (3) The surveyor reviewed QC and patient testing records from January 2018 through the first day of the survey. The review indicated negative and positive QC materials had not been performed 9 of 9 days of patient testing reviewed. The specific days were 02/22/18, 03 /28/18, 04/04/18, 05/10/18, 06/26/18, 07/04/18, 08/09/18, 08/27/18, and 10/16/18; (4) The surveyor reviewed the records with the technical consultant, who stated negative and positive QC materials had not been performed each day of patient testing. SERUM KETONE TESTING (1) On the first day of the survey, the technical consultant stated to the surveyor Serum Ketone testing was performed using the Germaine Laboratories Aim Tab Ketone tablets; (2) The laboratory supervisor stated to the surveyor at 1:47 pm that negative and positive QC materials were not performed each day of patient testing; (3) The surveyor requested serum Ketone test records from January 2018 through the first day of the survey. For 2 of 2 days of patient testing, a negative and positive control had not been performed. The specific days were 02/14/18 and 08/05/18: (4) The surveyor reviewed the findings with the technical consultant and laboratory supervisor. Both stated an IQCP (Individualized Quality Control Plan) had not been developed for the test system.
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, policies and procedures, and interview with the technical consultant, the laboratory failed to ensure that blood products were stored under appropriate conditions. Findings include: (1) On the first day of the survey, the

	technical consultant stated to the surveyor units of packed red blood cells, which were stored in the blood bank refrigerator, were used for patient transfusions; (2) The surveyor reviewed the "Blood Bank Procedure Manual" and identified a procedure titled, "Blood Bank Alarm Checks" which stated, "The alarm on the refrigerator used to store blood is checked quarterly for proper functioning. The high and low temperatures of activation are checked and results recorded. AABB Standards require the alarm setting to activate at a temperature that will allow intervention before the blood or components reach an undesirable temperature. The acceptable range is 1 to 6 degrees Celsius. The alarm is set to sound at 2 degrees Celsius for low alarm and 5.5 degrees Celsius for the high alarm"; (2) The surveyor reviewed alarm check records from January 2017 through the first day of the survey, with the following identified: (a) The alarm checks had not been performed on a quarterly basis (every 3 months) as follows: (i) 2017 - Alarm checks had not been performed during the second quarter (not performed between 03/02/17 and 08/09/17). (b) The high alarm check result sounded at a temperature warmer than 6.0 degrees C-Centigrade (the warmest allowable temperature for blood products) as follows: (i) 2018 - The temperature for the alarm check performed on 07/03/18 sounded at 6.7 degrees C. (3) The surveyor reviewed the records with the technical consultant who stated the alarm checks had not been performed on a quarterly basis in 2017, and the high alarm had sounded at a temperature beyond the acceptable storage for the products as indicated above.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed using Sysmex XS 1000i analyzer; (2) On the second day of the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult male patient with the testing performed on 11/27/17 at 07:49 am; the second report was for an adult female patient with the testing performed on 10/31/18 at 09:31 am; (3) Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell) and Hemoglobin which were: (a) RBC - 4.69 - 6.13 10^6/L (b) Hemoglobin - 14.1 - 18.1 g/dL (4) The surveyor viewed the findings with the technical consultant who stated the patient reports did not include gender specific reference ranges for RBC and Hemoglobin. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
D6054	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 annually, after the first year.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to ensure evaluations included all moderate complexity testing performed. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor wet prep analysis was performed in the laboratory: (2) The surveyor then reviewed personnel records for 2 persons performing wet prep analysis in the laboratory (the laboratory supervisor/testing person #1 and testing person #2) The records verified that evaluations had been performed as follows: (a) Laboratory Supervisor/Testing Person #1 - Performed on 08/09/17 and 08/29/18 (b) Testing Person #2- Performed on 08/24/17 and 08/29/18 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of Wet Prep analysis; (4) The surveyor reviewed the findings with the technical consultant, who stated the above evaluations did not include Wet Prep analysis.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the technical consultant and laboratory supervisor, testing personnel failed to follow the laboratory's policy for performing patient testing. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor manual differential testing was performed in the laboratory; (2) On the second day of the survey, the surveyor reviewed the manual differential policy. Under the heading "Differential Count" it stated, "The number of cells counted depends on the leukocyte count. 100 cells should be counted when the leudocyte count is normal"; (3) The surveyor randomly reviewed patient records that included manual differential results, for testing performed in February, April, July, and October 2018, and identified testing personnel had not followed the policy for 1 patient: (a) The patient specimen had been tested on 10/31/18 and met the laboratory criteria for performing a 100 cell count manual differential. The reported WBC (White Blood Cell) count from the manual differential testing did not equal 100, instead the WBC count from the manual differential was reported as 102; (4) The surveyor reviewed the report with the technical consultant and laboratory supervisor. Both stated testing personnel did not follow the laboratory policy for the patient.