Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475417	02/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Atoka County Medical Center	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 02/06,07,08/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief operating officer, compliance, technical consultant, and laboratory manager 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 director failed to sign a proficiency testing attestation statement for one of five Immunohematology proficiency testing events reviewed. Findings include: (1) On 02/06/2023, a review of the 2021 and 2022 Immunohematology proficiency testing records identified the following for one of five events: (a) Second 2021 Immunology/Immunohematology Event - The attestation statement had not been signed by the laboratory director. (2) The findings were reviewed with the technical consultant who stated on 02/07/2023 at 10:00 am the attestation statement had not been signed by the laboratory director.

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 written policies and procedures and interview with the technical consultant, the laboratory failed to have a written procedure for Post Vasectomy Qualitative Semen Analysis (presence or absence). Findings include: (1) On 02/06 /2023 at 10:00 am, the technical consultant stated the laboratory performed Post Vasectomy Qualitative Semen Analysis; (2) A review of the test volume list completed for the survey identified the laboratory performed approximately one Post Vasectomy Qualitative Semen Analysis annually; (3) A review of the manual titled "Laboratory Policy and Procedure Manual" identified no evidence of a written procedure for Post Vasectomy Qualitative Semen Analysis; (4) The findings were reviewed with the technical consultant who stated on 02/06/2023 at 10:10 am, the laboratory did not have a written procedure for performing the analysis.
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 a review of policies and procedures and interview with the technical consultant and laboratory manager, laboratory failed to have step by step procedures for two of five procedures reviewed. Findings include: QUALITATIVE SERUM PREGNANCY (1) On 02/06/2023 at 01:45 pm, the laboratory manager stated qualitative serum pregnancy testing was performed using the Quidel QuickVue One-Step hCG Combo test and serum samples; (2) A review of the test volume list completed for the survey identified the laboratory performed approximately seven qualitative serum pregnancy tests annually; (3) The technical consultant provided the

	manufacturer's package insert for the test kit and stated on 02/06/2023 at 02:00 pm that the package insert served as the procedure for the testing; (4) A review of the package insert identified it did not include the following: (a) Quality control procedures including identity, number and frequency of testing controls; (b) The laboratory's system for entering results in the patient record and reporting patient results. (5) The findings were reviewed with the technical consultant and laboratory manager. Both stated on 02/06/2023 at 02:33 pm, the procedure did not include the information as stated above. URINE MICROSCOPIC (1) On 02/06/2023 at 10:45 am, the technical consultant stated the following: (a) Urine microscopic testing was performed in the laboratory; (b) Specimens were processed in the Drucker Model 514V centrifuge at a speed of 1500 rpm (revolutions per minute) for five minutes. (2) A review of the test volume list completed for the survey identified the laboratory performed approximately 1220 urine microscopic tests annually; (3) A review of the urine microscopic procedure titled, "Routine Urinalysis Multistix" did not specify the speed and time to process the specimens in the centrifuge for microscopic examination of the sediment, and instructed the reader to use the Urofuge centrifuge instead of the centrifuge currently in use (Drucker Model 514V centrifuge); (4) The procedure was reviewed with the technical consultant who stated on 02/06/2023 at 10: 14 am, the procedure did not include the speed and time the urines were to be processed and did not include instructions for using the current centrifuge.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the technical consultant and laboratory manager, the laboratory failed to ensure a procedure had been approved, signed, and dated by the laboratory director. Findings include: (1) On 02/06/2023 at 01:45 pm, the laboratory manager stated qualitative serum pregnancy testing was performed using the Quidel QuickVue One-Step hCG Combo test and serum samples; (2) A review of the manual titled, "Laboratory Policy and Procedure Manual" identified no evidence of a written procedure for qualitative serum pregnancy testing; (3) The technical consultant provided the manufacturer's package insert for the test kit and stated on 02/06/2023 at 02:00 pm that the package insert served as the procedure for the testing but was maintained in a notebook containing package inserts, and was not included in the laboratory policy and procedure manual; (4) A review of the package insert identified no evidence it had been approved, signed, and dated by the laboratory director; (5) The findings were reviewed with the laboratory manager and technical consultant. Both stated on 01/06/2023 at 02:33 pm, the package insert had not been approved, signed, and dated by the laboratory director.
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 manager, the laboratory failed to perform a negative and positive control material four of seven days of patient qualitative serum pregnancy testing reviewed from June 2021 through the current date. Findings include: (1) On 02/06/2023 at 01: 45 pm, the laboratory manager stated the following: (a) Qualitative serum pregnancy testing was performed using the Quidel QuickVue One-Step hCG Combo test and serum samples; (b) Negative and positive QC (quality control) materials were performed each day of patient testing. (2) A review of the test volume list completed for the survey identified the laboratory performed approximately seven qualitative serum pregnancy tests annually; (3) A review of QC and patient testing records for testing performed from June 2021 through the current date identified negative and positive QC materials had not been documented as performed each day of patient testing for four of seven days. The specific days of patient testing were 07/23/2022, 07 /24/2022, 08/24/2022, and 11/22/2022; (4) The records were reviewed with the technical consultant who stated on 02/06/2023 at 02:33 pm, negative and positive QC materials had not been documented as performed as stated above.
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: Based on a review of records and interview with the technical consultant, the laboratory failed to have a system that evaluated and defined the relationship between two of two iSTAT 1 analyzers at least twice a year during the review period of 07/01 /2021 through the current date. Findings include: (1) On 02/06/2023 at 10:30 am, the technical consultant stated Blood Gas (pH, pCO2, pO2) testing was performed using two iSTAT 1 analyzers (Serial Numbers 386131 and 385556); (2) On 02/07/2023 a review of records for the testing from 07/01/2021 through the current date identified no evidence the relationship between the test results using the two analyzers had been evaluated at least twice annually; (3) The findings were discussed with the technical consultant who stated on 02/07/2023 at 01:10 pm, the relationship between the analyzers had not been evaluated.
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 for two of two patient reports reviewed. Findings include: (1) On 02/06/2023 at 10:50 am, the technical consultant stated the laboratory began using the Sysmex XN-550 analyzer on 07/01/22 to perform patient CBC (Complete Blood Count) testing; (2) On 02/07/2022 two patient CBC reports were reviewed - the first report was for an adult male patient with the testing performed on 10/12/2022 at 10:25 am; the second report was for an adult female patient with the testing performed on 02/02/2023 at 02:01 pm. Both reports included the same reference intervals for the following CBC parameters: (a) RBC (red blood cell) count - 4.69-6.13 M/ul (b) Hemoglobin - 14.1-18.1 g/dl (3) The reports were reviewed with the technical consultant who stated on 02/08/2023 at 10:26 am, the patient reports did not include gender specific reference ranges for RBC and Hemoglobin.
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 and laboratory manager, the technical consultant failed to ensure competency evaluations included all moderate complexity testing for four of four persons receiving annual competencies in 2021 and 2022. Findings include: (1) On 02/06/2023 at 01:45 pm, the laboratory manager stated qualitative serum pregnancy testing was performed using the Quidel QuickVue One-Step hCG Combo test and serum samples; (2) A review of personnel records for four persons identified that annual evaluations performed in 2021 and 2022 did not include an assessment of qualitative serum pregnancy testing for four of four persons: (a) Laboratory Manger/Testing Person #1- Performed on 07 /19/2021 and 08/16/2022 (b) Testing Person #2 - Performed on 07/19/2021 and 08/16 /2022 (c) Testing Person #3 - Performed on 07/19/2021 and 08/16/2022 (d) Testing Person #5 - Performed on 07/19/2021 and 08/16/2022 (3) The findings were reviewed with the technical consultant who stated on 02/06/2023 at at 03:15 pm the above evaluations did not include an assessment of qualitative serum pregnancy testing.