Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475417	06/16/2021
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 06/14,15,16/2021. The laboratory was found out of compliance with the following CLIA regulation: 493.801; D2000: Enrollment and Testing of Samples The findings were reviewed with the technical consultant, laboratory manager, testing person #2, chief nursing officer, and chief executive officer at the conclusion of the survey.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to enroll in a proficiency testing program for Uric Acid testing. Findings include: (1) On 06/14/2021 at 01:15 pm, the technical consultant stated to surveyor #1 the laboratory performed Uric Acid testing beginning 07/13/2020; (2) Surveyor #2 reviewed proficiency testing records for 2019, 2020, and 2021, but could not locate any evidence the laboratory had enrolled in an HHS approved proficiency testing program until the first 2021 Chemistry Core Event, which was tested in the laboratory on 01/30/2021 and 02/01/2021; (3) On 06/15/2021, surveyor #2 reviewed the findings with the technical consultant. On 06/15/2021 at 03:52 pm, the technical consultant stated the laboratory had not enrolled in a proficiency testing program as indicated above.

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 attestation statements were signed by the laboratory director or designee for one of 26 events. Findings include: (1) On 06/14/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing records, with the following identified: (a) First 2020 Hematology/Coagulation Event - The attestation statement had not been signed by the laboratory director or designee; (2) Surveyor #2 reviewed the records with the technical consultant. The technical consultant stated on 06/14/2021 at 03:40 pm the attestation statement had not been signed by the laboratory director or designee as indicated above.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results for one of 27 events. Findings include: (1) On 06/14/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing records and identified the following failures: (a) First 2020 Chemistry Core Event (i) ProBNP - The laboratory failed the results for one of 5 samples (CM-02). (2) Surveyor #2 could not locate evidence in the records proving the failures had been addressed; (3) Surveyor #2 reviewed the records with the technical consultant, and asked if corrective action had been taken and documented for the failures. The technical consultant stated on 06/14/2021 at 02:11 pm corrective action had not been documented.
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 procedure manuals and interview with the technical consultant, the laboratory failed to ensure written procedures had been approved, signed, and dated by the laboratory director. Findings include: (1) On 06/14/2021, surveyor #1 reviewed the following procedure manuals: (a) "Atoka County Medical Center Laboratory Blood Bank Policy & Procedure Manual" which contained the blood bank department policies and procedures; (b) "Atoka County Medical Center Laboratory Policy and Procedure Manual" which contained general laboratory policies and procedures. Examples of procedures contained in the manual were: (i) "Competency Assessments" (ii) "Quality Assurance Policy" (iii) "Sysmex XS-1000i Hematology Analyzer" (iv) "ACL Elite Pro" (v) "Preparation of blood collection for coagulation testing" (vi) "Blood Gas using EG6+" (2) There was no evidence the above manuals had been approved, signed, and dated by the current laboratory director; (3) Surveyor #1 reviewed the manual with the technical consultant who stated on 06/14/2021 at 03: 15 pm, the procedure manuals had not been signed and dated as approved by the laboratory director.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On 06/14 /2021 at 01:15 pm, the technical consultant stated to surveyor #1 the ACL Elite analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean); (2) On 06/15/2021 at 11:00 am, surveyor #1 observed the refrigerator where the testing reagents were maintained and identified the following reagents which appeared to be currently in use: (a) PT - HemosIL Recombiplastin reagent, lot #N0897673 (b) PTT - HemosIL Synthasil APTT reagent, lot #N0797526 (3) The technical consultant stated to surveyor #1 on 06/15/2021 at 11: 05 am, the above reagent lot numbers were currently in use, and had initially been put into use as follows: (a) HemosIL Recombiplastin reagent - 08/01/2020 (b) HemosIL Synthasil APTT reagent - 10/01/2020 (4) Surveyor #1 reviewed the manufacturer's instructions contained in the "Hemostasis Performance Verification Manual" for implementing new reagents, which stated, "When changing to a new lot number of reagent or a new reagent, it is important to establish a new normal reference interval, establish new assay control ranges, and perform a comparison study for all tests". In addition, the manufacturer required the following: (a) Section titled "Establishing a Normal Reference Interval" (i) "Reference Interval should be established whenever there is a change in: * Instrumentation and/or methodology. * Lot number of reagent. * Sample collection procedures. * At least once a year." (ii) "Reference Intervals should be established for each assay the lab performs."; (iii) "Reference Intervals should be established over several days, at different times of the day, including such variables as age of reagent, different vials of reagent, different operators."; (iv) "Donors should be healthy and have no known pathological conditions. Don't use samples from in-patients (due to medical conditions and treatment regiments). Donors

	should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-does aspirin, etc."; (v) "Donors should span the adult age range. Pediatric ranges should be established separately."; (vi) "Donors should be equally divided between male/female."; (vii) "If the INR system is utilized to report PT's, note the geometric mean value of the PT normal reference interval in seconds and use along with the lot-specific ISI value in the INR setup calculation page". (b) Section titled "Comparison Study" (i) "Collect and handle specimens according to accepted laboratory practice for the assay being performed" (ii) "Include diseases/treatments known to affect the assay being performed" (iii) "At least 50% of the samples should be outside of the laboratory normal reference interval, if possible" (iv) "At least 40 specimens should be analyzed. More samples will improve the confidence in the data" (v) "Evaluate the new instrument or reagent over clinically meaningful range including data below and above the expected reference range" (vi) "For a given specimen, analysis by the comparative and new methods or reagents should be accomplished within 1 hour of each other to avoid possible degradation of the samples" (vii) "Analyze each patient sample using the new method (or reagents) and the comparative method" (viii) "Examine the results after each run. If an isolated specimen's results for the new and comparative methods differ more than observed for other specimens, retest that specimen in duplicate on both methods. If the difference has been resolved use the repeat data" (ix) "Record data on the data sheets provided" (x) "The analysis of the comparison data can be as simple as a visual comparison, calculation of the difference (delta) between the two methods, or as involved as a regression analysis. The comparison will depend on the types of specimen, instruments and methodologies chosen. The more similarities among those items, the closer will be the comparison results" (5) Surveyor #1 reviewed the implementation records for Recombiplastin reagent lot #N0897673 and APTT reagent lot #N0797526, with the following identified: (a) Recombiplastin lot #N0897673 (i) Although the laboratory had used 20 donors, there was no evidence of the age and health status of the donors; (ii) The comparison study included 18 abnormal specimens instead of 20. (b) APTT reagent lot #N0797526 (i) Although the laboratory had used 20 donors, there was no evidence of the age, health status, and medication history of the donors; (ii) The comparison study included 15 abnormal specimens instead of 20. (6) Surveyor #1 reviewed the findings with the technical consultant who stated on 06/15/2021 at 12:42 pm, the manufacturer's instructions had not been followed for the reagent lot changes as specified above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. 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 ensure the urine centrifuge was

	functioning properly for 9 of 9 function checks. Findings include: (1) On 06/14/2021 at 01:00 pm, stated the following to surveyor #1: (a) Urine sediment examinations were performed in the laboratory; (b) The specimens were processed in the Drucker Company 614V centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes. (2) Surveyor #1 reviewed the centrifuge maintenance records for 2019, 2020 and to date in 2021. The speed had not been checked at the speed the urine specimens were processed, to ensure the centrifuge was functioning properly at that speed, for 9 of 9 checks performed as follows: (a) 01/30/2019 - The speed had been checked at 2431 rpm; (b) 04/10/2019 - The speed had been checked at 2471 rpm; (c) 07/31/2019 - The speed had been checked at 2403 rpm; (d) 10/30/2019 - The speed had been checked at 2851 rpm; (e) 01/30/2020 - The speed had been checked at 2885 rpm; (f) 07/29/2020 - The speed had been checked at 2879 rpm; (g) 10/28/2020 - The speed had been checked at 2604 rpm; (h) 01/19/2021 - The speed had been checked at 2814 rpm; (i) 04/21/2021 - The speed had been checked at 2787 rpm. (3) The surveyor reviewed the findings with the technical consultant, who stated on 06/14/2021 at 03: 20 pm, the centrifuge speed had not been checked at the speed used to process urine specimens.
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 make appropriate reference ranges available. Findings include: (1) On 06/14/2021 at 01:15 pm, the technical consultant stated to surveyor #1 the ACL Elite analyzer was used to perform PTT (Partial Thromboplastin Time) testing; (2) On 06/15/2021, surveyor #1 reviewed the implementation records for the current lot number of reagent and identified the following: (a) HemosIL Synthasil APTT reagent, lot #N0797526 was put into use on 10/01/2020; (b) The laboratory had verified a normal reference range of 23.6-37.4 (3) Surveyor #1 then reviewed a patient PTT report with testing performed on 06/13/2021. The reference range on the patient report was 25.4-38.4; (4) Surveyor #1 reviewed the findings with the technical consultant who stated on 06/15/2021 at 02:05 pm, the normal reference range that had been verified by the laboratory for PTT was not included on the patient report.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; 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 attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for three of 27 events. Findings include: (1) On 06/14/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing records. It was identified for three of 27 events, the attestation statements had been signed approximately 3-14 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Immunology First Event of 2020 - The samples had been tested on 04/14/2020 and the attestation statement had not been signed by the laboratory director until 06/10 /2021; (b) Immunology Second Event of 2020 - The samples had been tested on 05/29 /2020 and the attestation statement had not been signed by the laboratory director until 08/09/2020; (c) Immunology Third Event of 2020 - The samples had been tested on 12 /16/2020 and the attestation statement had not been signed by the laboratory director until 06/10/2021; (2) Surveyor #2 reviewed the findings with the technical consultant on 06/14/2021 at 03:42 pm and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.