Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D0475417	**(X3) Date Survey Completed** 01/08/2025
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 01/7,8/2025. The laboratory was found out of compliance with the following CLIA Conditions: 493.1210; D5016: Routine Chemistry 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant The findings were reviewed with the technical consultant, laboratory manager, chief executive officer, and human resource director during an exit conference performed on 01/09/2025.
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 and laboratory manager, the laboratory director failed to sign a proficiency testing attestation statement for one of five Immunohematology events reviewed in 2023 and 2024. Findings include: (1) On 01/07/2025, a review of 2023 and 2024 Immunohematology proficiency testing events identified the following for one of five events: (a) First 2024 Event - The attestation statement had not been signed by the

	laboratory director. (2) The findings were reviewed with the laboratory manager and technical consultant. Both stated on 01/07/2025 at 03:25 pm, the attestation statement had not been signed by the laboratory director.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on a review of records, nursing policy, and interview with the technical consultant and laboratory manager, the facility failed to ensure written policies were followed for preventing transfusion reactions for two of six units of packed red-blood cells transfused. Findings include: (1) On 01/07/2025 at 11:00 am, the technical consultant and laboratory manager stated blood transfusions were performed by nursing staff; (2) A review of the hospital policy titled, "Blood Transfusion" stated, "Check vital signs": (a) "Every 5 minutes for the first 15 minutes" (b) "Every 15 minutes for the first hour" (3) A review of transfusion records for six units transfused identified the policy had not been followed for two of the six units as follows: (a) Unit #W091023352269 - The transfusion started on 12/16/2023 at 09:50 am. The 15 minute vital signs had not been taken as follows: (i) Between 10:05 am and 10:35 am; (ii) Between 10:35 am and 11:05 am. (b) Unit #W091024135193 - The transfusion started on 03/01/2024 at 11:30 am. The 15 minute vital signs had not been taken as follows: (i) Between 12:00 pm and 12:30 pm. (4) The records were reviewed with the laboratory manager who stated on 01/07/2025 at 03:20 pm, the vital signs had not been documented according to policy.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure the requirements were met for the subspecialty of Routine Chemistry for Blood Gas testing on two of two iSTAT 1 analyzers. Findings include: (1) The laboratory failed to demonstrate the performance specifications for Blood Gas testing. Refer to D5421; (2) The laboratory failed to perform calibration verification procedures at least every six months. Refer to D5439; (3) The laboratory failed to have a system that evaluated and defined the relationship between two of two i-STAT 1 analyzers at least twice a year. Refer to D5775.
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 technical consultant, the laboratory failed to demonstrate the performance specifications for two of two replacement i-STAT handheld analyzers. Findings include: (1) On 01/07/2025 at 10:58 am, the technical consultant stated the laboratory performed arterial and venous blood gas (pH, pO2 and pCO2) testing using two i-STAT 1 handheld analyzers (serial #388665 and serial #386325) and the EG6+ cartridges; (2) Interview with the technical consultant on 01/07/2025 at 02:30 pm, confirmed the laboratory began using analyzer serial #388665 on 01/27/2024 and analyzer serial #386325 on 03/27/2024; (3) A review of records for the test systems identified no evidence the performance specifications (accuracy, precision, and reportable range) had been demonstrated; (4) Interview with the technical consultant on 01/07/2025 at 02:53 pm confirmed the performance specifications had not been demonstrated prior to putting the analyzers into use for patient testing; (5) A review of instrument printouts for blood gas testing performed from January through December 2024 confirmed 248 patients had been reported; (6) The following were examples of patient testing performed when the performance specifications had not been performed: (a) i-STAT 1 ANALYZER SERIAL #386325 (i) Patient # 82105 - testing performed on 03/27/2024 (ii)Patient # 65432 - testing performed on 04/15/2024 (iii) Patient # 84346 - testing performed on 04/19/2024 (iv) Patient # 84530 - testing performed on 04/21/2024 (v) Patient # 84694 - testing performed on 04/22/2024 (vi) Patient #85132 - testing performed on 04/26/2024 (vii) Patient # 88009 - testing performed on 05/19/2024 (viii)Patient # 88323 - testing performed on 05/22/2024 (ix) Patient # 10128226 - testing performed on 06/09/2024 (x) Patient # 91487 - testing performed on 06/15/2024 (xi) Patient # 96784 - testing performed on 07/28/2027 (xii) Patient # 99144 - testing performed on 08/16/2024 (xiii) Patient # 99306 - testing performed on 08/18/2024 (xiv) Patient # 99450 - testing performed on 08/19/2024 (xv) Patient # 3488 - testing performed on 09/19/2024 (xvi) Patient # 03814 - testing performed on 09/22/2024 (xvii) Patient # 6208 - testing performed on 10/11/2024 (xviii) Patient # 6502 - testing performed on 10/14/2024 (xix) Patient # 7471 - testing performed on 10/21/2024 (xx) Patient # 1234 - testing performed on 10/25/2024 (xxi) Patient # 8227 - testing performed on 10/26/2024 (xxii) Patient # 8671 - testing performed on 10/30/2024 (xxiii) Patient # 8821 - testing performed on 10/31/2024 (xxiv) Patient # 8913 - testing performed on 11/01/2024 (xxv) Patient # 9348 - testing performed on 11/05/2024 (xxvi) Patient # 9643 - testing performed on 11/08/2024 (xxvii) Patient # 10405 - testing performed on 11/14/2024 (xxviii) Patient # 10486 - testing performed on 11/15/2024 (xxix) Patient # 12004 - testing performed on 11/30/2024 (xxx) Patient # 12230 - testing performed on 12/02/2024 (xxxi) Patient # 13954 - testing performed on 12/14/2024 (xxxii) Patient # 15381 - testing performed on 12/27/2024 (b) i-STAT 1 ANALYZER SERIAL #388665 (i) Patient # 74794 - testing performed on 01/26/2024 (ii) Patient # 74958 - testing performed on 01/27/2024 (iii) Patient # 75695 - testing performed on 02/01/2024 (vi) Patient # 76322 - testing performed on 02/07/2024 (v) Patient # 77237 - testing performed on 02/14/2024 (vi) Patient # 77292 - testing performed on 02/15/2024 (vii) Patient # 78492 - testing performed on 02/23/2024 (viii) Patient # 78851 - testing performed on 02/26/2024 (ix) Patient # 10125828 - testing performed on 03/02

	/2024 (x) Patient # 10125851 - testing performed on 03/03/2024 (xi) Patient # 80032 - testing performed on 03/08/2024 (xii) Patient # 80232 - testing performed on 03/10 /2024 (xiii) Patient # 80028 - testing performed on 03/14/2024 (xiv) Patient # 81949 - testing performed on 03/26/2024 (xv) Patient # 83196 - testing performed on 04/09 /2024 (xvi) Patient # 83313 - testing performed on 04/10/2024 (xvii) Patient # 83551 - testing performed on 04/12/2024 (xviii) Patient # 83648 - testing performed on 04/13 /2024 (xix) Patient # 83680 - testing performed on 04/14/2024 (xx) Patient # 83807 - testing performed on 04/15/2024 (xxi) Patient # 84089 - testing performed on 04/17 /2024 (xxii) Patient # 9999 - testing performed on 04/22/2024 (xxiii) Patient # 85849 - testing performed on 05/03/2024 (xxiv) Patient # 86326 - testing performed on 05/08 /2024 (xxv) Patient # 86769 - testing performed on 05/10/2024 (xxvi) Patient # 87026 - testing performed on 05/12/2024 (xxvii) Patient # 87826 - testing performed on 05/17 /2024 (xxviii) Patient # 88015 - testing performed on 05/19/2024 (xxix) Patient # 88646 - testing performed on 05/23/2024 (xxx) Patient # 89234 - testing performed on 05/28/2024 (xxxi) Patient # 89437 - testing performed on 05/29/2024 (xxxii) Patient # 90123 - testing performed on 06/05/2024 (xxxiii) Patient # 90456 - testing performed on 06/08/2024 (xxxiv) Patient # 91216 - testing performed on 06/13/2024 (xxxv) Patient # 91468 - testing performed on 06/15/2024 (xxxvi) Patient # 91548 - testing performed on 06/16/2024 (xxxvii) Patient # 94727 - testing performed on 07/11/2024 (xxxviii) Patient # 94863 - testing performed on 07/12/2024 (xxxix) Patient # 95794 - testing performed on 07/20/2024 (xl) Patient # 95969 - testing performed on 07/22 /2024 (xli) Patient # 97195 - testing performed on 07/31/2024 (xlii) Patient # 97441 - testing performed on 08/02/2024 (xliii) Patient # 97587 - testing performed on 08/04 /2024 (xliv) Patient # 98277 - testing performed on 08/09/2024 (xlv) Patient # 98521 - testing performed on 08/12/2024 (xlvi) Patient # 98656 - testing performed on 08/13 /2024 (xlvii) Patient # 99553 - testing performed on 08/19/2024 (xlviii) Patient # 15 - testing performed on 08/23/2024 (xlix) Patient # 363 - testing performed on 08/26 /2024 (l) Patient # 554 - testing performed on 08/27/2024 (li) Patient # 01596 - testing performed on 09/06/2024 (lii) Patient # 1901 - testing performed on 09/09/2024 (liii) Patient # 2693 - testing performed on 09/14/2024 (liv) Patient # 2977 - testing performed on 09/16/2024 (lv) Patient # 3499 - testing performed on 09/19/2024 (lvi) Patient # 3607 - testing performed on 09/20/2024 (lvii) Patient # 3927 - testing performed on 09/23/2024 (lviii) Patient # 4377 - testing performed on 09/26/2024 (lix) Patient # 4645 - testing performed on 09/29/2024 (lx) Patient # 5402 - testing performed on 10/05/2024 (lxi) Patient # 0000 - testing performed on 10/15/2024 (lxii) Patient # 7471 - testing performed on 10/21/2024 (lxiii) Patient # 10131564 - testing performed on 10/22/2024 (lxiv) Patient # 8155 - testing performed on 10/25/2024 (lxv) Patient # 8227 - testing performed on 10/26/2024 (lxvi) Patient # 10133119 - testing performed on 12/14/2024 (lxvii) Patient # 14036 - testing performed on 12/15 /2024 (lxviii) Patient # 14293 - testing performed on 12/16/2024 (lxix) Patient # 14568 - testing performed on 12/18/2024 (lxx) Patient # 14815 - testing performed on 12/21/2024 (lxxi) Patient # 15298 - testing performed on 12/27/2024 (lxxii) Patient # 15576 - testing performed on 12/29/2024 (lxxiii) Patient # 15634 - testing performed on 12/30/2024
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, the laboratory failed to define a written function check protocol to ensure the urine centrifuge was functioning properly during the review period of February 2023 through the current date. Findings include: (1) On 01/07/2025 at 11:15 am, the laboratory manager stated the laboratory performed urine microscopic testing and urine specimens were processed at a speed of 1500 rpm (revolutions per minute) for 5 minutes using the Drucker Company model 614V centrifuge; (2) A function check protocol that defined the frequency of the urine centrifuge speed and timer checks and the acceptable limits for the checks could not be located; (3) Interview with the technical consultant on 01/07/2025 at 02:59 pm confirmed the laboratory did not have a written function check protocol but the centrifuge was checked semi-annually; (4) A review of centrifuge records from February 2023 through the current date identified the following: (a) 02/21/2023 - Although the speed had been documented as checked at 1500 rpm, there was no documentation the timer had been checked; (b) 02/21/2024 - Although the speed had been documented as checked at 1500 rpm, there was no documentation the timer had been checked; (c) 08/21/2024 - Although there was a record for this date, the actual speed and time obtained had not been recorded. (5) The findings were reviewed with the technical consultant who stated on 01/07/2025 at 02: 59 pm, the laboratory did not have a written function check protocol for the urine centrifuge and the checks 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 technical consultant, the

	laboratory failed to perform calibration verification procedures at least once every six months for two of two i-STAT 1 test systems during the review period of January 2024 through the current date. Findings include: (1) On 01/07/2025 at 10:58 am, the technical consultant stated the laboratory performed arterial and venous blood gas (pH, pO2 and pCO2) testing on two i-STAT 1 analyzers (serial #388665 and serial #386325) using the EG6+ cartridges; (2) A review of records from January 2024 through the current date identified no evidence the calibration verification procedures had been performed for the test systems prior to 12/09/2024; (3) The findings were reviewed with the technical consultant, who stated on 01/07/2025 at 03:02 pm, the calibration verification procedures had not been performed every six months 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 technical consultant, the laboratory failed to perform positive and negative control materials for one of two days of patient serum pregnancy testing reviewed from January through December 2024. Findings include: (1) On 01/07/2025 at 11:00 am, the technical consultant stated the laboratory performed qualitative pregnancy testing using the Quidel QuickVue One Step Combo test kit on serum samples; (2) A review of QC (Quality Control) and patient testing records for testing performed from January through December 2024 identified positive and negative QC materials had not been performed one of two days of patient testing (12/29/2024); (3) The records were reviewed with the technical consultant who stated on 01/07/2025 at 12:30 pm, QC materials had not been performed each day of patient testing.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (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 technical consultant and laboratory manager, the laboratory failed to comply with 21 CFR 606.160(b)(3)(v). The laboratory failed to ensure that emergency release of blood forms had been signed by the physician for two of eight emergency release forms reviewed. Findings include: (1) On 01/07/2025 at 11:00 am, the technical consultant and laboratory manager stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for patient transfusions; (2) A review of "Emergency

	Request for Uncrossmatched Blood Products" forms dated 09/21/2023 through 10/09/2024 identified two of eight forms had not been signed by a physician for the following: (a) One unit of O negative packed red blood cells had been released to a patient on 09/21/2023; (b) One unit of O negative packed red blood cells had been released to a patient on 10/09/2024. (3) The documentation was reviewed with the laboratory manager who stated on 01/07/2024 at 02:45 pm, the emergency releases as stated above, had not been signed by a physician.
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 i-STAT 1 analyzers at least twice a year during the review period of January 2024 through the current date. Findings include: (1) On 01/07/2025 at 10:58 am, the technical consultant stated the laboratory performed arterial and venous blood gas (pH, pO2 and pCO2) testing using two i-STAT 1 handheld analyzers (serial #388665 and serial #386325) and the EG6+ cartridges; (2) On 01/08/2025 a review of records for the testing from January 2024 through the current date identified no evidence the relationship between the test results using the two analyzers had been evaluated at least twice annually prior to 12/09/2024; (3) The findings were reviewed with the technical consultant, who stated on 01/08/2025 at 10:52 am, the relationship between the analyzers had not been evaluated as stated above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to provide overall management and direction during the review period of January 2024 through the current date. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services during the review period of January 2024 through the current date. Refer to D6020.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; 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 ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the laboratory demonstrated performance specifications for two of two replacement i-STAT handheld analyzers. Refer to D5421.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. 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 ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure calibration verification procedures were performed at least once every six months for two of two i-STAT 1 test systems. Refer to D5439; (2) The laboratory director failed to ensure a system was in place that evaluated and defined the relationship between two of two i-STAT 1 test systems. Refer to D5775.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Refer to D6040; (2) The technical consultant failed to ensure the laboratory participated in a proficiency testing program commensurate with the services offered for Hemoglobin A1c testing. Refer to D6041; (3) The technical consultant failed to

	establish a quality control program which ensured the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. 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 that verification procedures were adequate to determine the performance characteristics. Findings include: (1) The technical consultant failed to ensure the laboratory demonstrated performance specifications for two of two replacement i-STAT handheld analyzers. Refer to D5421.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to participate in a proficiency testing program commensurate with the services offered for Hemoglobin A1c testing for five of five events reviewed in 2023 and 2024. Findings include: (1) On 01/07/2025 at 11:45 am, the technical consultant stated Hemoglobin A1c testing was performed using the Beckman Coulter AU 480 analyzer; (2) A review of Chemistry Core proficiency testing records for 2023 (second and third events) and 2024 (first, second, and third events) identified for five of five events, the laboratory had participated using the method code for the Siemens Dimension analyzer instead of the Beckman Coulter AU 480 analyzer; (3) The records were reviewed with the technical consultant who stated on 01/07/2025 at 12:15 pm, the laboratory had participated in proficiency testing using the incorrect method code for Hemoglobin A1c testing.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; 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 establish a quality control program which ensured the

	establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure calibration verification procedures were performed at least once every six months for two of two i-STAT1 test systems. Refer to D5439; (2) The technical consultant failed to ensure a system was in place that evaluated and defined the relationship between two of two i-STAT 1 test systems at least twice a year prior. Refer to D5775.