Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475237	11/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Muscogee (Creek) Nation Medical Center	1401 Morris Drive, Okmulgee, 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 11/01,02,03,04/2022. The laboratory was found out of compliance with the following CLIA Condition of Participation: 493.1409; D6033: Technical Consultant The findings were reviewed with the chief operating officer, administrator, quality improvement, laboratory director, director of laboratory services, and assistant director of laboratory services during an exit conference performed at the conclusion of the survey.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the director of laboratory services, the laboratory failed to ensure an adequate alarm system was in place for the blood bank refrigerator. Findings include: (1) On 11/01/2022 at 10:50 am, the director of laboratory services stated the laboratory routinely maintained 2 units of O negative and 2 units of O positive packed red blood cells in the blood bank refrigerator. The units were available for emergency patient transfusions; (2) The surveyor reviewed the laboratory's written policy for performing alarm checks on the refrigerator. The policy titled, "Blood Bank Refrigerator and Freezer Alarm Check" stated "Periodic alarm checks shall be performed at 3-month intervals to ensure proper functioning of temperature gauges"; (3) On 11/03/2022, a review of alarm check records during 2021 and to date in 2022 identified alarm checks had not been performed between 09/07/21 and 02/17/22; (4) The records were reviewed with the director of laboratory services who stated on 11/03/2022 at 11:42 am, the alarm checks had not been performed as required by policy.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the director of laboratory services, the laboratory failed to have a written policy to assess the competency of the technical consultant, general supervisor, and technical supervisor, based on the position responsibilities as listed in Subpart M. Findings include: (1) On 11/02/2022, a review of the competency assessment policy revealed there was no guidance, including the frequency, for assessing the competency of the technical consultant, general supervisor, and technical supervisor; (2) A review of personnel records for competency assessments performed during the review period of 2021 through the current date in 2022 revealed competencies, based on job responsibilities had not been performed as follows: (a) Technical Consultant - Not performed since 03/19/2021; (b) General Supervisor - Not performed during the review period; (c) Technical Supervisor - Not performed during the review period. (3) The findings were reviewed with the director of laboratory services who stated on 11 /03/2022 at 01:10 pm, a policy had not been written and competencies had not been performed for the positions as shown above.
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 records, policies and procedures and interview with the director of laboratory services, the laboratory failed to have written procedure for coagulation lot rollover studies. Findings include: (1) On 11/02/2022 at 11:00 am, the director of laboratory services stated the laboratory began using the ACL TOP 300 analyzer on 9 /19/21 to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing; (2) A review of manufacturer's instructions for reagent lot rollover studies identified the manufacturer stated to perform the normal patient mean studies following laboratory policy; (3) A review of laboratory policies and procedures identified no evidence of a coagulation reagent lot rollover procedure, including guidance for screening normal donors; (4) The findings were reviewed with the director of laboratory services who stated on 11/03/2022 at 03: 57 pm, the laboratory did not have a written procedure for performing coagulation lot rollover studies.
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 director of laboratory services, the laboratory failed to ensure the demonstrated reportable ranges were utilized for one of two new test systems introduced into the laboratory. Findings include: (1) On 11/01/2022 at 10:40 am, the director of laboratory services stated the laboratory began performing Troponin I testing using the Biosite Triage Meter Pro analyzer as a backup method to the Abbott Architect Plus ci4100 analyzer on 10/05/2022; (2) On 11/02/2022 a review of the performance specification records for the new test system identified the laboratory had demonstrated a reportable range of 0.06-26.7 ng/ml; (3) The manual titled, "Laboratory Testing Procedures" which contained the reportable ranges being used by the laboratory, was reviewed with the director of laboratory services. On 11/03/2022 at 11:04 am, the director of laboratory services stated the laboratory was using the reportable range of 0.05-30 ng/ml instead of the reportable range that had been demonstrated 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 director of laboratory services, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures on one of four analyzers reviewed. Findings include: (1) On 11/01/2022 at 10:45 am, the director of laboratory services stated CBC (Complete Blood Count) testing was performed using the Cell-Dyn Ruby analyzer; (2) On 11/03/2022, a review of the "Cell-Dyn Operator's Manual" in Section 9 titled "Scheduled Maintenance Procedures" required the following maintenance procedures: (a) Weekly - "Clean Loader Compartments" (b) Monthly - "Extended Auto-Clean" (3) A review of maintenance records from January 2022 through September 2022 identified the following: (a) The weekly Clean Loader Compartments procedure had not been documented as performed between 02/26/2022 and 03/08/2022; (b) The monthly Extended Auto-Clean procedure had not been documented as performed during January 2022. (4) The records were reviewed with the director of laboratory services who stated on 11/03/2022 at 11:30 am, the maintenance had not been documented as performed.
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 director of laboratory services, the laboratory failed to perform calibration verification procedures at least once every 6 months for 14 of 25 analyte reviewed on the Abbott Architect Plus ci4100 analyzer. Findings include: (1) On 11/01/2022 at 11:00 am, the director of laboratory services stated ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Alkaline Phosphatase, Total Bilirubin, Direct Bilirubin, Amylase CK (Creatine Kinase), Uric Acid, Hemoglobin A1c, Acetaminophen, Salicylate, TSH (Thyroid Simulating Hormone), LDL (Low Density Lipoprotein), and HDL (High Density Lipoprotein) testing were performed on the Abbott Architect Plus ci4100 analyzer; (2) A review of 2022 calibration records revealed the calibration procedures for the above analytes were performed with less than three levels of calibrators therefore, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of records for 2021 and to date in 2022 identified calibration verification had not been performed at least once every six months as follows: (a) ALT not performed prior to 01/26/2022 (b) AST not performed prior to 01/26/2022 (c) Alkaline Phosphatase not performed prior to 01/26/2022 (d) Total Bilirubin not performed between 03/29/2021 and 04/06/2022 (e) Direct Bilirubin not performed between 03/29/2021 and 04/06 /2022 (f) Amylase not performed prior to 01/26/2022 (g) CK not performed prior to 01 /26/2022 (h) Uric Acid not performed prior to 04/06/2022 (i) Hemoglobin A1c not performed during the review period (j) Acetaminophen not performed between 01/25 /2022 and 10/16/2022 (k) Salicylate not performed between 01/26/2022 and 10/16 /2022 (l) TSH not performed between 06/13/2021 and 10/24/2022 (m) LDL not performed between 03/31/2021 and 04/06/2022 (n) HDL not performed between 03/31 /2021 and 04/06/2022 (4) The records were reviewed with the director of laboratory services who stated on 11/04/2022 at 10:25 am, calibration verification procedures had not been performed every six months.
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 director of laboratory services, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different methods for one of two analytes. Findings include: (1) On 11/01/2022 at 10:45 am, the director of laboratory services stated the laboratory performed Lactate testing as follows: (a) Using the Abbott Architect Plus ci4100 analyzer as the primary method; (b) Using the IL GEM 4000 analyzer as the backup method. (2) On 11/03/2022, records were requested to prove the relationship between the testing performed using the different test methods had been evaluated twice annually during the review period of January 2021 through the current date; (3) The director of laboratory services stated on 11/03/2022 at 11:42 am, there was no documentation to show the relationship between the testing using the two methods had been evaluated twice annually during the review period.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records, Bio-Rad TOX/See Drug Screen test package insert, and interview with the director of laboratory services, the laboratory failed to ensure test reports for Urine Drug Screen testing included information required for interpretation for one of one patient report. Findings include: (1) On 11/01/2022 at 10:42 am, the director of laboratory services stated Urine Drug Screen testing was performed using the Bio-Rad TOX/See Drug Screen test; (2) On 11/03/2022, a review of the Bio-Rad TOX/See Drug Screen test package insert stated, "This test provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used"; (3) A review of one patient report with Urine Drug Screen test results reported on 11/02/2022 identified the report did not include a disclaimer with the manufacturer's statement that the results were preliminary and guidance on obtaining a confirmed analytical result; (4) The findings were discussed with the director of laboratory services who stated on 11/03/2022 at 03: 51 pm the patient report did not include the disclaimer.
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 director of laboratory services, the technical consultant failed to provide technical supervision in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the director of laboratory services, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for one of 22

	competency evaluations. Findings include: (1) On 11/01/2022, a review of records for seven persons performing moderate complexity testing in 2021 and to date in 20221 revealed the following for one of 13 testing persons: (a) Directory of Laboratory Services/Testing Person #14 - The 05/31/2022 evaluation had been performed by an individual who did not meet the regulatory requirements of a technical consultant. (2) The records were reviewed with the director of laboratory services who stated on 11 /01/2022 at 03:00 pm, the evaluation had been performed by an individual who did not meet the qualifications of a technical consultant.