Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475237	12/11/2020
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 12/08,09,10,11/2020. The findings were reviewed with laboratory director, laboratory manager, laboratory support specialists, quality manager, and chief operating officer administration during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
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 laboratory manager, the laboratory failed to ensure attestation statements were signed by the laboratory director or designee for one of 28 events; and failed to ensure proficiency testing records were maintained for a minimum of two years for four of 28 events. Findings include: ATTESTATION (1) On 12/08/2020, the surveyor reviewed 2019 and 2020 proficiency testing records, with the following identified: (a) Second 2020 Microbiology Event - The attestation statement had not been signed by the laboratory director or designee. (2) The surveyor reviewed the records with the laboratory

	manager. The laboratory manager stated on 12/08/2020 at 04:05 pm the attestation statement had not been signed by the laboratory director as indicated above. GRADED EVALUATIONS (1) On 12/08/2020, the surveyor reviewed 2019 and 2020 proficiency testing records, with the following identified: (a) Graded evaluations could not be located for four of the events (i) First 2019 Hematology/Coagulation Event (ii) First 2019 Microbiology Event (iii) Second 2019 Microbiology Event (iv) First 2020 Hematology/Coagulation Event (2) The surveyor asked the laboratory manager if the graded evaluations from the proficiency testing provider were available. The laboratory manager stated on 12/08/2020 at 04:10 pm, performance evaluations were not available during the survey.
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 laboratory manager, the laboratory failed to review and evaluate proficiency testing results for three of 28 events. Findings include: FAILURE (1) On 12/08/2020, the surveyor reviewed 2019 and 2020 proficiency testing records and identified the following failure: (a) Third 2019 Chemistry Core Event (i) BUN (Blood Urea Nitrogen) - The laboratory failed the result for 1 of 5 samples (CH-14); (2) The surveyor could not locate evidence in the records proving the failure had been addressed; (3) The surveyor reviewed the records with the laboratory manager and asked if corrective action had been taken and documented for the failure. The laboratory manager stated on 12/08/2020 at 04:11 pm corrective action had not been taken. BIASES (1) On 12/08/2020, the surveyor reviewed 2019 and 2020 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Third 2019 Chemistry Core Event (i) Phenytoin - four of five results exhibited a negative bias (aa) Sample CH-01- SDI of -2.0 (bb) Sample CH-02 - SDI of -2.2 (cc) Sample CH-03 - SDI of -2.4 (dd) Sample CH-04 - SDI of -2.2 (b) First 2020 Chemistry Core Event (i) Chloride - three of five results exhibited a negative bias (aa) Sample CH-02- SDI of -2.1 (bb) Sample CH-04 - SDI of -2.0 (cc) Sample CH-05 - SDI of -2.2 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager. The laboratory manager stated on 12/08/2020 at 12:50 pm the biases had not been addressed.
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, and interview with laboratory manager, the laboratory failed to follow the manufacturer's instructions for

	implementing one of one coagulation reagent. Findings include: (1) On 12/08/2020 at 10:20 am, the laboratory manager stated to the surveyor the laboratory performed PT (Prothrombin Time) testing on the Sysmex CA-620 analyzer; (2) On 12/09/2020 at 11: 00 am, the laboratory manager stated to the surveyor the following reagent were put into use on 11/20/2020: (a) PT - Innovin PT reagent lot 549771A (3) The surveyor reviewed the manufacturer's instructions for implementing new reagents, which stated, "The following recommendations should be used as a guideline when converting to new lots of reagents for Hemostasis analyzers. These procedures should be followed each year before new lots of reagents are put into use on the existing Hemostasis system". In addition, the manufacturer required the following: (a) Section titled, "Quality Control" (i) "Assay new lot number of QC material with the new lot of reagent in PTN and APTTN protocols"; (ii) Collect a minimum of 30 data points over multiple days and stability limits of control"; (iii) Calculate the mean, 2 SD and 3 SD range". (4) The surveyor reviewed the records for the changes with the following identified: (a) Siemens Ci-Trol control level 1 lot #548057A (i) The records showed the laboratory had assayed the new lot of quality control material using 25 data points instead of 30 data points as required. (b) Siemens Ci-Trol control level 3 lot #548489 (i) The records showed the laboratory had assayed the new lot of quality control material using 25 data points instead of 30 data points as required. (5) The surveyor reviewed the records and the findings with the laboratory manager, who stated the following to the surveyor on 12/09/2020 at 04:50 pm: (a) The laboratory had utilized 25 data points to assay the new lots of quality control materials for level 1 and level 3, instead of 30 data points; (b) The laboratory had not followed the manufacturer's instructions for implementing the coagulation reagents.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to ensure an analyzer was stored as required by the manufacturer for two of two months. Findings include: (1) On 12/08/2020 at 10: 20 am, the laboratory manager stated to the surveyor, Coagulation testing was performed on the Sysmex CA-620 analyzer; (2) On 12/09/2020, the surveyor reviewed the manufacturer's environmental requirements for the analyzer, which required a relative humidity range of 30 - 85%; (3) The surveyor reviewed laboratory humidity records from January 2019 through February 2019 and identified the following for two months of two months: (a) January 2019 - 18 of 31 days were documented less than 30% (i) Days 26,29,30,31 the humidity was documented at 25% (ii) Days 20,21,24,25,27,28 the humidity was documented at 26% (iii) Days 9,10,19, 23 the humidity was documented at 27% (iv) Days 11,14,15 the humidity was documented at 28% (v) Day 13 the humidity was documented at 29% (b) February 2019 - 16 of 28 days were documented less than 30% (i) Day 19 the humidity was documented at 23% (ii) Days 7,20,21 the humidity was documented at 24% (iii) Days

	17,18,24 the humidity was documented at 25% (iv) Days 8,9,12 the humidity was documented at 26% (v) Days 10,16 the humidity was documented at 27% (vi) Days 11,13 the humidity was documented at 28% (vii) Days 15,23 the humidity was documented at 29% (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated on 12/09/2020 at 05:12 pm the laboratory failed to ensure the analyzer was stored as required by the manufacturer as indicated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure blood bank materials had not exceeded their expiration date. Findings include: (1) On 12/08/2020 at 10:45 am, the laboratory manager stated the following to the surveyor: (a) ABO Typing, Antibody Screen, and Compatibility testing were performed using the Ortho ID-MTS gel system. (2) On 12/10/2020, the surveyor reviewed the package inserts for the following reagents: (a) Anti-IgG Card - used for detection of antigens to red blood cells; (b) Buffered Gel Card - used for the detection of antibodies to red blood cells. (3) The surveyor reviewed quality control (QC) and patient testing records between 11/02/2020 through 12/10/2020 (fourth day of the survey) with the following identified: (a) Anti-IgG Card lot #01222001-03, expiration 11/21/2020 had been used to perform QC and patient testing as follows: (i) Patient #37-20-327-0015 - 11/22/2020. (b) Buffered Gel Card lot #022420004-01, expiration 12/04/2020 had been used to perform patient testing as follows: (a) Patient #37-20-342-0102 - 12/07/2020 (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated on 12/10/2020 at 04:00 pm expired reagents had been used as indicated above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the laboratory manager, the laboratory failed to follow written quality control policies for three of three test systems. Findings include: (1) On 12/08/2020 at 11:45 am, the laboratory manager stated to the surveyor: (a) CKMB, Troponin I, and D-Dimer testing were performed using the Alere Triage Meter; (b) IQCPs (Individualized Quality Control

	Plans) had been developed for the above test systems. (2) The surveyor reviewed the IQCP that had been developed for each test system. The QCP (Quality Control Plan) portion of the IQCP required 2 levels of external quality control materials be tested once every 30 days; (3) The surveyor reviewed QC (quality control) records for 23 months (January 2019 through November 2020) and identified the laboratory failed to follow the written QCP of performing quality control testing every 30 days. Quality control testing had not been performed as follows: (a) CKMB (i) Between 01/31/2019 and 04/27/2019 (b) Troponin I (i) Between 01/31/2019 and 04/27/2019 (c) D-Dimer (i) Between 08/03/2020 and 10/01/2020 (4) The findings were reviewed with the laboratory manager who stated on 12/09/2020 at 04:55 pm, the laboratory had not performed quality control testing as required by the QCP.
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 laboratory manager, the laboratory failed to perform negative and positive control materials four of four days of patient qualitative serum ketone testing; and failed to perform negative and positive control materials five of 17 days of patient qualitative serum pregnancy testing. Findings include: (1) On 12/08/2020 at 10:25 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed qualitative serum ketone testing using the AimTab tablets; (b) The laboratory performed qualitative serum pregnancy testing using the Quidel QuickVue hCG Combo test kit; (c) Positive and negative serum quality control (QC) materials were performed each day of patient testing for both test systems. (2) The surveyor reviewed QC and serum ketone patient testing records between 08/04/2019 through 08/29/2019 and QC and serum pregnancy testing records between 11/01/2020 through 11/30/2020. The review showed that negative and positive QC materials had not been performed as follows: (a) Serum Ketone (i) For four of four days of patient testing reviewed. The specific days were 08 /04/2019, 08/17/2019, 08/18/2019, and 08/29/2019. (b) Serum Pregnancy (i) For five of 17 days of patient testing reviewed. The specific days were 11/03/2020, 11/09 /2020, 11/15/2020, 11/16/2020, and 11/25/2020. (3) The surveyor reviewed the records with the laboratory manager who stated on 12/09/2020 at 03:55 pm, negative and positive QC materials had not been performed as indicated above.
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 and interview with the laboratory manager, the laboratory failed to ensure units of blood were stored under appropriate conditions for one of five refrigerator temperature charts. Findings include: (1) On 12/08/2020 at 10: 45 am, the laboratory manager stated the following to the surveyor: (a) The laboratory stored units of packed red blood cells in the blood bank refrigerator; (b) The above units were to be used for patient transfusions. (2) On 12/10/2020 at 11:00 am, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. It had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees (C) Centigrade. Each chart monitored the temperature for a 7 day period; (3) On 12/10/2020, the surveyor reviewed five refrigerator charts dated from 11/05/2020 through 12/13/2020. The review showed that one of five refrigerator charts had not been changed by the 7th day of usage as follows: (a) Chart #5 - The chart was put into use on 12/03/2020 and removed on 12/13/2020 (10 days). (4) The surveyor reviewed the charts with the manager who stated on 12/10/2020 at 03:00 pm, the charts had not been changed by the 7th day as stated above.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 written policies and interview with the laboratory manager, the laboratory failed to ensure that written policies provided safety for individuals being transfused for four of nine units of packed red blood cells. Findings include: (1) On 12 /08/2020 at 10:55 am, the laboratory manager stated to the surveyor the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 12/10/2020, the surveyor reviewed the hospital policy titled, "Administration of Blood & Blood Products" under the section titled, "Procedure", stated: (a) "N. Document vital signs 15 minutes after transfusion begins, then 30 minutes and every one hour thereafter; to include one hour post transfusion". (3) On 12/10/2020, the surveyor then reviewed records for nine units of PRBCs (Packed Red Blood Cells) that had been transfused between 02/08/2019 through 06/20/2020 for three patients, and identified the following: (a) One hour post transfusion vitals signs (i) Patient #80073457 - Transfused with one unit PRBC (unit #W091019109228) on 03/01/2019. The transfusion ended at 06:05 pm. No one hour post vitals were documented; (ii) Patient #80073457 - Transfused with one unit PRBC (unit #W091019160493) on 05/16/2019. The transfusion ended at 01:30 pm. No one hour post vitals were documented; (iii) Patient #80069252 - Transfused with one unit PRBC (unit #W091019109228) on 04/25/2020. The transfusion ended at 12:30 pm.

	No one hour post vitals were documented; (iv) Patient #80131094 - Transfused with one unit PRBC (unit #W091020200604) on 06/03/2020. The transfusion ended at 07: 00 pm. No one hour post vitals were documented. (4) The surveyor reviewed the findings with the laboratory manager. The laboratory manager stated on 12/10/2020 at 04:25 pm the written policy and procedure for blood administration had not been followed as indicated 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 laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different analyzers. Findings include: (1) On 12/08/2020, the laboratory manager stated to the surveyor CKMB (CK Isoenzyme), and Troponin testing were performed on two analyzers as follows: (a) The Abbott Architect analyzer was the primary analyzer; (b) The Triage Meter Plus analyzer was the back-up analyzer. (2) On 12/10/2020 the surveyor reviewed the comparison data for the analyzers for testing performed from January 2019 through the fourth day of the survey (12/10/2020). There was no evidence the relationship between the analyzers had been evaluated twice in 2019 and to date in 2020; (3) The surveyor reviewed the records with the laboratory manager who stated on 12/10/2020 at 03:05 pm, the relationship between the analyzers had not been evaluated as indicated above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP's for one of two years. Findings include: (1) On 12/08/2020 at 11:45 am, the laboratory manager stated to the surveyor: (a) Clostridium difficile testing was performed using the QuikChek complete kit; (i) IQCP (Individualized Quality Control Plan) had been developed for the test system. (b) CKMB, Troponin, and D-Dimer testing were performed using the Alere Triage Meter; (i) IQCP's (Individualized Quality Control Plan) had been developed for the test systems. (c) Urine Drug testing was performed using the Tox See analyzer; (i) IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCPs for the above test systems. The QA (Quality Assessment) portion of the IQCPs included a schedule for evaluating the QCP (Quality Control Plan) annually to ensure they continued to

	provide accurate and reliable results; (3) The surveyor reviewed 2019 and 2020 records and could not locate the QA review for 2019; (4) The surveyor reviewed the records with the laboratory manager, who stated on 12/09/2020 at 04:40 pm, the 2019 QA review had not documented as performed.
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 laboratory manager, the laboratory failed to make appropriate reference ranges available for one of one Prothrombin Time test report and for one of one Wet Prep test report. Findings include: PROTHROMBIN TIME NORMAL REFERENCE RANGE (1) On 12/08 /2020 at 10:20 am, the laboratory manager stated to the surveyor the laboratory performed PT (Prothrombin Time) testing on the Sysmex CA-620 analyzer. In addition the following reagent was put into use on 03/07/2021: (a) Innovin PT reagent lot 549771A (2) On 12/10/2020, the surveyor reviewed the PT reagent implementation records and identified the laboratory had verified a PT normal reference interval of 9.2 - 11.0 seconds; (3) On 12/11/2020, the surveyor then reviewed a patient PT report dated 12/11/2020 at 08:25 am with a normal reference range of 9.2 - 11.3 seconds; (4) The surveyor surveyor reviewed the findings with the laboratory manager. On 12/11/2020 at 02:14 pm, the laboratory manager stated that although the laboratory had established a PT normal reference interval with the PT reagent lot change, the laboratory had not implemented the change into the laboratory's computer information system. WET PREP NORMAL REFERENCE RANGE Findings include: (1) On 12/08/2020 at 10:12 am, the laboratory manager stated to the surveyor Wet Prep testing was performed in the laboratory; (2) On 12/09 /2020, the surveyor reviewed one Wet Prep report for a patient tested on 11/21/2020 at 01:28 am. The report did not include a normal reference range for Clue Cells, Bacteria, Epithelial Cells, White Blood Cells, Red Blood Cells, Yeast, and Trichomonas; (3) The surveyor reviewed the report with the laboratory manager, who stated on 12/09/2020 at 06:15 pm, Wet Prep reports did not include a normal reference range as indicated above.
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 laboratory manager, 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 four of 28 events. Findings include: (1) On 12/08/2020, the surveyor reviewed 2019 and 2020 proficiency testing events. For four of 28 events, the attestation statements had been signed approximately three to eight 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) First 2019 Microbiology Event - The sample testing had been completed on 03/01 /2019, and the attestation statement had not been signed by the laboratory director /designee until 12/10/2020; (b) Third 2019 Microbiology Event - The sample testing had been completed on 09/26/2019, and the attestation statement had not been signed by the laboratory director/designee until 12/10/2020; (c) First 2019 Immunohematology Event - The sample testing had been completed on 04/12/2019, and the attestation statement had not been signed by the laboratory director/designee until 07/30/2019; (d) Second 2020 Microbiology Event - The sample testing had been completed on 06/23/2020, and the attestation statement had not been signed by the laboratory director/designee until 12/10/2020. (2) The surveyor reviewed the findings with the laboratory manager who stated on 12/08/2020 at 04:00 pm the attestations had been signed approximately three to eight months after the proficiency samples had been tested. The surveyor 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.
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 laboratory manager, 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 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 laboratory manager, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for one of eight competency evaluations performed. Findings include: (1) On 12/08/2020, the surveyor reviewed records for eight persons performing moderate complexity testing in 2019 and 2020. The records showed the evaluation for one of eight persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #11 - The 05/14/2020 evaluation had been performed by testing person #6 (this person had earned an associate's degree in a clinical laboratory science). (2) The surveyor explained to the laboratory manager that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a masters degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 1 year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory manager stated to the surveyor on 12/08/2021 at 04: 15 pm, the evaluation had been performed by an individual who did not meet the years of experience of a technical consultant.