Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475237	08/31/2018
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 08/27/18 through 08/31/18. The findings were reviewed with the laboratory manager and Regional Medical Laboratory support staff during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1213; D5022: Toxicology 493.1271; D5026: Immunohematology 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director, Moderate Complexity 493.1409 D6033: Technical Consultant 493.1441; D6076: Laboratory Director, High Complexity
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 laboratory manager, the laboratory failed to enroll in a proficiency testing program for Chemistry testing. Findings include: (1) On the first day of survey, the surveyor reviewed proficiency testing records for 2017 and to date in 2018. There was no evidence the laboratory was enrolled in a proficiency program for the first 2018 Chemistry Core event (the analytes in the event include: Serum Acetone, Alcohol, CKTotal (Creatine Kinase), D-Dimer, Pro-BNP (B-Type Natriuretic Peptide), Troponin I, Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Amylase, AST (Aspartate

	Aminotransferase), Direct Bilirubin, Total Bilirubin, Total Calcium, Chloride, Cholesterol HDL, Total Cholesterol, CO2, Creatinine, Glucose, Lactic Acid, LDL Cholesterol, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides, Urea Nitrogen, Uric Acid, HCG (Human Chorionic Gonadotropin), Acetaminophen, Carbamazepine, Digoxin, Gentamicin, Lithium, Phenytoin, Salicylates, Valproic Acid, Vancomycin, Glycated Hemoglobin, pCO2, pH, PO2, Free Thyroxine and TSH (Thyroid Stimulating Hormone); (2) Following the survey on 10 /04/18, the surveyor called the laboratory manager to clarify the laboratory Proficiency Testing enrollment. The laboratory manager stated that the laboratory had submitted the invoice for payment. The hospital did not pay the bill until after the first event deadline.
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 and technical consultant, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following was identified for 3 of 21 testing events: (a) First 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (b) Second 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (c) Third 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (2) The findings were reviewed with the laboratory manager and technical consultant who stated the attestation had not been signed as indicated above.
D3035	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii) In addition, the laboratory must retain immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to maintain Blood Bank thermograph charts for at least 2 years. Findings include: (1) Later on the fourth day of the survey, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator

	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 Centigrade). Each chart monitored the temperature for a 7 day period; (2) The surveyor reviewed 52 refrigerator charts dated from 01/03/17 through 02/28/18. The review indicated that charts were not available for review between 10/25/17 through 12/18/17: (3) The surveyor asked the laboratory manager if the Blood Bank charts between 10/25/17 through 12/18/17 were available for review. The laboratory manager stated the thermograph charts could not be located for the above dates.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to ensure the requirements were met for the subspecialty of Toxicology. Findings include: (1) The laboratory failed to perform a negative and positive control each day of patient testing. Refer to D5449; (2) The laboratory failed to to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager and technical consultant, the laboratory failed to ensure the requirements were met for the specialty of Immunohematology. Findings include: (1) The laboratory failed to ensure reagents had not exceeded their expiration date. Refer to D5417; (2) The laboratory failed to ensure blood products were stored appropriately that included an adequate temperature alarm system that is regularly inspected. Refer to D5555; (3) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791.
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. Findings include:

	(1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program: (a) Second 2017 Chemistry Core Event (i) Chloride - 5 of 5 results exhibited a negative bias (aa) Sample CH-06 - SDI of -3.1 (bb) Sample CH-07 - SDI of -2.0 (cc) Sample CH-08 - SDI of -2.4 (dd) Sample CH-09 - SDI of -2.5 (ee) Sample CH-10 - SDI of -2.6 (ii) Cholesterol, Total - 4 of 5 results exhibited a positive bias (aa) Sample CH-06 - SDI of 2.4 (bb) Sample CH-07 - SDI of 2.1 (cc) Sample CH-08 - SDI of 2.5 (dd) Sample CH-09 - SDI of 2.3 (iii) Triglycerides - 5 of 5 results exhibited a positive bias (aa) Sample CH-06 - SDI of 2.6 (bb) Sample CH-07 - SDI of 2.5 (cc) Sample CH-08 - SDI of 2.1 (dd) Sample CH-09 - SDI of 2.1 (ee) Sample CH-10 - SDI of 2.6 (b) Third 2017 Chemistry Core Event (ii) Cholesterol, Total - 3 of 5 results exhibited a positive bias (aa) Sample CH-13 - SDI of 2.6 (bb) Sample CH-14 - SDI of 2.6 (cc) Sample CH-15 - SDI of 2.7 (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 who stated the biases had not been addressed.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on a review of records and an interview with the laboratory manager, the laboratory failed to provide written instructions to clients collecting and referring hematology and chemistry specimens. Findings include: (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing using the Cell-Dyn Ruby analyzer; (i) Hematology specimens were transported to the laboratory from outside home health agencies. (b) The laboratory performed routine chemistry testing using the Abbott Architect analyzer; (i) Routine chemistry specimens were transported to the laboratory from outside home health agencies. (2) The surveyor asked the laboratory manager if instructions (e.g., client service manual) had been written and provided to the home health agencies which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The laboratory manager stated specimen handling instructions had not been written and provided to the clients.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies and procedures and interview with the laboratory manager, testing person #1/hematology supervisor and technical consultant, the laboratory failed to monitor and evaluate the overall quality of analytic systems for each specialty and subspecialty of testing performed. Findings include: (1) The laboratory failed to follow written policies. Refer to D5401; (2) The laboratory failed to follow the manufacturer's instructions for verifying flagged results. Refer to D5411; (3) The laboratory failed to perform a negative and positive control each day of patient testing. Refer to D5449; (4) The laboratory failed to use control materials of a similar matrix to that of patient specimens. Refer to D5465; (5) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the laboratory manager and testing person #1/hematology supervisor, the laboratory failed to follow written policies. Findings include: HEMATOLOGY - CELL-DYN RUBY (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) CBC (Complete Blood Count) was performed using the Abbott Cell-Dyn Ruby analyzer; (b) The laboratory had a policy to ensure the verification of new hematology quality control material. (2) On the third day of the survey, the surveyor reviewed the policy titled, "Complete Blood Count Abbott Cell-dyn Ruby" which stated, "Each lab will establish a mean and an acceptable range for each new lot of control material that is used. The mean however, should fall within the manufacturer's listed mean range. Verify the new control lot by running each level of control 3 times in its respective file to ensure that the mean of all 3 runs is within the range shown on the assay sheet. Run the new control twice a day for 5 days. Use the mean of 10 runs to verify that the new lot yields expected results."; (3) The surveyor then reviewed records for 3 QC (Quality Control) lot numbers and identified the following: (a) For 1 (Lot# 8057 - low, normal and high) of 3 QC lot numbers (i) The QC material was ran one time before put into use on 03/16/18. (4) The surveyor reviewed the records and policy with the laboratory manager and testing person #1/hematology supervisor who stated the laboratory had not followed their written policy for ensuring the verification of new hematology QC materials. CHEMISTRY - ABBOTT ARCHITECT (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) Routine Chemistry testing was performed using the Abbott Architect analyzer; (b) The laboratory had a quality control (QC) policy to ensure acceptable control results. (2) On the third day of the survey, the surveyor reviewed the policy titled, "Chemistry Policy" which stated, "C. Modified Westgard Rules will be used where applicable to interpret Quality Control (QC) results and determine when a method is considered acceptable control for each run and whether or not patient results can be released for reporting. 1. For each level of control a QC value may exceed the mean by +/- 2 Standard Deviation (SD) but be within +/- 3 SD range. If the QC Value exceeds the 2SD for a second consecutive day, corrective action must be taken 2. On day 1, if two

	levels of controls exceed the +/-2SD for the same parameter, corrective action must be taken. 3. When only one QC value exceeds the mean by +/- 3SD, corrective action must be taken." (3) The surveyor then reviewed records for 3 QC lot numbers and identified the following: (a) Chloride (Lot# 47931 - Level 1) (i) 07/14/18 - The QC result (79) exceeded -3 SD and no evidence of corrective action (b) Total Protein (Lot# 47931 - Level 1) (ii) 07/19/18 - The QC result (3.7) exceeded -3 SD and no evidence of corrective action (iii) 07/20/18 - The QC result (3.7) exceeded -3 SD and no evidence of corrective action (c) Total Protein (Lot# 47933 - Level 3) (ii) 07/31/18 - The QC result (7.1) exceeded -3 SD and no evidence of corrective action (d) Total Bilirubin (Lot# 47933 - Level 3) (i) 07/18/18 - The QC result (8.0) exceeded 3 SD and no evidence of corrective action (e) Vitamin D (Lot# 60233 - Level 3) (i) 07/09/18 - The QC result (34.8) exceeded -3 SD and no evidence of corrective action (f) BNP (Lot# 23672 - Level 2) (i) 07/02/18 - The QC result (259.3) exceeded -3 SD and no evidence of corrective action (g) Troponin I (Lot# 23672 - Level 2) (i) 07/18/18 - The QC result (7.192) exceeded 3 SD and no evidence of corrective action (4) The surveyor reviewed the records and policy with the laboratory manager who stated the laboratory had not followed their written policy for ensuring acceptable control runs. NOTE: D5401 was cited on the recertification survey performed on 11/29/16 through 12/01/16.
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 the laboratory manager, the laboratory failed to follow the manufacturer's instructions for verifying flagged results. Findings include: (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) CBC (Complete Blood Count) testing, which included a 5 part automated differential, was performed on the Cell Dyn Ruby analyzer; (2) The surveyor reviewed the manufacturer's operator's manual for information regarding flagged results. The following was identified: (a) For RBC MORPH flags, the instructions stated, "Review a stained smear for abnormal RBC or PLT morphology and follow your laboratory's review criteria"; (3) The surveyor asked the laboratory manager if the laboratory had a policy for addressing flagged results. The laboratory manager obtained the policy for the surveyors. The policy stated, "A manual differential or slide review is indicated when any parameter results, such are NRBC, DFLT, LRI, URI, Band, Blast, Var Lym, or RBC MORPH are displayed" In addition, the policy stated, "Refer to Section 3 of the Operator's Manual for a complete listing of the Operational Messages and Data Flagging as well as the suggested actions"; (4) The surveyor then reviewed 26 patient records containing flags. For 1 of 26 records, laboratory did not follow manufacturer's instruction when a flag was obtained as follows: (a) Patient #6 - RBC MORPH flag obtained and reported on 06/24/18 at 02:20 pm. (5) The findings were reviewed with the laboratory manager who stated the laboratory did not follow manufacturer's instructions when a RBC Morphology flag was obtained. NOTE: D5411 was cited on the recertification survey performed on 11/29/16 through 12/01/16.

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 reagents had not exceeded their expiration date. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor Crossmatch testing was performed in the laboratory which included: (a) ABO Typing and Antibody Screen using the Ortho ID-MTS gel system (2) On the fourth day of the survey, the laboratory manager provided the package inserts to the surveyor which explained the use of the following reagents: (a) Ortho Confidence System -used for QC testing to confirm the reactivity of anti-A, anti-B, anti-A,B anti-D and the anti-IgG component of anti-human globulin, as well as reverse grouping cells and reagent red blood cells used for antibody detection; (b) Ortho Selectogen - used for Antibody Screen testing; (c) Ortho Affirmagen - used for ABO serum grouping; (d) Ortho Diluent 2 - used for patient cell suspense for ABO grouping; and donor cell suspension for crossmatching. (3) The surveyor reviewed quality control (QC) and patient testing records for 20 months (January 2017 through August 2018). It was identified that expired Confidence, Selectogen, Affirmagen and Diluent 2 had been used during 2 of 20 months reviewed: (a) Confidence lot #CN7054, expiration date of 04/11/17 and Selectogen lot #VS008, expiration date of 04/11/17 had been used to perform QC and patient testing on the following days: (i) Patient #45 - 04/12 /17 (ii) Patient #46 - 04/12/17 (iii) Patient #47 - 04/13/17 (iv) Patient #48 - 04/14/17 (b) Affirmagen lot# 8A702, expiration date of 11/07/17 had been used to perform patient testing on the following day: (i) Patient #49 - 11/08/17 (c) Affirmagen lot# 8A702, expiration date of 11/07/17 and Diluent 2 lot# MD100, expiration date 11/08 /17 had been used to perform patient testing on the following days: (i) Patient #50 - 11 /13/17 (ii) Patient #51 - 11/13/17 (iii) Patient #52 - 11/15/17 (iv) Patient #53 - 11/28 /17 (3) The surveyor reviewed the records with the laboratory manager who stated expired reagents had been used as indicated 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 laboratory manager, the laboratory failed to perform a negative and positive control each day of patient testing. Findings include: (HIV) HUMAN IMMUNODEFICIENCY VIRUS (1) On the first day of the survey, the laboratory manager stated to the surveyor qualitative HIV - 1/2 Antigen/Antibody combination testing was performed using the Alere Determine HIV-1/2 Ag/Ab Combo Kit Lot#160707 and serum specimens; (2) On the fourth day of the

survey, the laboratory manager stated to the surveyor negative and positive QC (Quality Control) testing were performed with each new test kit lot; (3) The surveyor asked the laboratory manager if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory manager stated an IQCP had not been developed. Therefore, the surveyor determined negative and positive QC testing must be performed each day of patient testing; (4) The surveyor reviewed QC and patient testing records from April 2017 through the July 2018. The review indicated negative and positive QC testing had not been performed 1 of 9 days of patient testing; (5) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated a positive and negative serum HIV-1/2 Ag/Ab QC materials had not been tested each day of patient testing; (6) The following patient HIV-1/2 Ag/Ab testing had occurred when QC testing had not been performed: (a) Patient #1 - testing performed on 02/10/18 SERUM HCG PREGNANCY TESTING (1) On the first day of the survey, the laboratory manager stated to the surveyor qualitative serum HCG pregnancy testing was performed using the Quidel Quickvue Serum HCG test kit; (2) On the fourth day of the survey, the laboratory manager stated to the surveyor negative and positive QC testing were performed with each day of patient testing; (3) The surveyor reviewed QC and patient testing records from January 2017 through the July 2018. The review indicated negative and positive QC testing had not been performed 2 of 43 days of patient testing; (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated a positive and negative HCG serum pregnancy QC materials had not been tested each day of patient testing; (5) The following patients HCG serum pregnancy testing had occurred when QC testing had not been performed: (a) Patient #2 - testing performed on 04/03/18 (b) Patient #3 - testing performed on 05/26/18 SERUM KETONE TESTING (1) On the first day of the survey, the laboratory manager stated to the surveyor qualitative serum ketone testing was performed using the AimTab Ketone Tablets test kit; (2) On the fourth day of the survey, the laboratory manager stated to the surveyor negative and positive QC testing were performed with each day of patient testing; (3) The surveyor reviewed QC and patient testing records from July 2018 through the fourth day of the survey (08/30/18). The review indicated negative and positive QC testing had not been performed 2 of 40 days of patient testing. (QC material that was used was urine matrix refer to D5465); (5) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated a positive and negative serum Ketone QC materials had not been tested each day of patient testing; (6) The following patient serum Ketone testing had occurred when QC testing had not been performed: (a) Patient #4 - testing performed on 07/21/18 (b) Patient #5 - testing performed on 08/22/18 URINE DRUG SCREEN (1) On the first day of the survey, the laboratory manager stated to the surveyor qualitative urine drug screen testing was performed using the BIO/RAD Tox See kit test; (2) On the third day of the survey, the laboratory manager stated to the surveyor negative and positive QC testing were performed with each day of patient testing; (3) The surveyor asked the laboratory manager and technical consultant if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory manager stated an IQCP had not been developed and approved by the laboratory director. Therefore, the surveyor determined negative and positive QC testing must be performed each day of patient testing; (4) The surveyor reviewed QC and patient testing records from March 2018 through July 2018. The review indicated negative and positive QC testing had not been performed 37 of 37 days of patient testing; (5) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated a positive and negative urine drug screen quality control materials had not been tested each day of patient testing; (6) The following patients urine drug screen testing had occurred when QC testing had not been performed: (a) Patient #7 - testing performed on 03/02/18 (b)

	Patient #8 - testing performed on 03/05/18 (c) Patient #9 - testing performed on 03/08 /18 (d) Patient #10 - testing performed on 03/09/18 (e) Patient #11 - testing performed on 03/11/18 (f) Patient #12 - testing performed on 03/16/18 (g) Patient #13 - testing performed on 03/19/18 (h) Patient #14 - testing performed on 03/21/18 (i) Patient #15 - testing performed on 03/26/18 (j) Patient #16 - testing performed on 03/30/18 (k) Patient #17 - testing performed on 04/03/18 (l) Patient #18 - testing performed on 04 /04/18 (m) Patient #19 - testing performed on 04/10/18 (n) Patient #20 - testing performed on 04/12/18 (o) Patient #21 - testing performed on 04/15/18 (p) Patient #22 - testing performed on 04/18/18 (q) Patient #23 - testing performed on 04/21/18 (r) Patient #24 - testing performed on 04/24/18 (s) Patient #25 - testing performed on 04 /30/18 (t) Patient #26 - testing performed on 05/03/18 (u) Patient #27 - testing performed on 05/08/18 (v) Patient #28 - testing performed on 05/11/18 (w) Patient #29 - testing performed on 05/16/18 (x) Patient #30 - testing performed on 05/19/18 (y) Patient #31 - testing performed on 05/23/18 (z) Patient #32 - testing performed on 05/31/18 (aa) Patient #33 - testing performed on 05/29/18 (bb) Patient #34 - testing performed on 06/03/18 (cc) Patient #35 - testing performed on 06/08/18 (dd) Patient #36 - testing performed on 06/11/18 (ee) Patient #37 - testing performed on 06/14/18 (ff) Patient #38 - testing performed on 06/19/18 (gg) Patient #39 - testing performed on 06/25/18 (hh) Patient #40 - testing performed on 07/03/18 (ii) Patient #41 - testing performed on 07/09/18 (jj) Patient #42 - testing performed on 07/15/18 (kk) Patient #43 - testing performed on 07/23/18 (ll) Patient #44 - testing performed on 07/31/18
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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--Test control materials in the same manner as patient specimens. (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 use control materials of a similar matrix to that of patient specimens. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor blood (serum, plasma) Ketone testing was performed using the AimTab Ketone tablets; (2) On the fourth day of the survey, the laboratory manager stated to the surveyor that when quality control testing was performed on the tablets, a negative and a positive urine control was performed instead of blood based (serum/plasma) controls. The manager verified the QC materials used were Bio-Rad Liquichek Urinalysis Control Levels 1 & 2; (3) The surveyor reviewed July 2018 through the fourth day of the survey (08/30/18) quality control and patient Ketone records which verified that, patient testing had been performed on 22 days. Quality control testing had been performed on the days of patient testing (07/01/18, 07/06/18, 07/08/18, 07/11/18, 07/13/18, 07/14/18, 07/15/18, 07/16/18, 07/18/18, 07/19/18, 07/20 /18, 07/23/18, 07/24/18, 07/25/18, 07/26/18, 07/27/18, 07/28/18, 07/30/18, 07/31/18, 08/10/18, 08/21/18, 08/24/18) using negative and positive urine control specimens; (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated urine controls were used instead of serum controls as indicated above. NOTE: The interpretive guidelines at D5465 (493.1256) state "Control materials of a similar, matrix to that of patient specimens should be utilized, if available, and the control materials must be treated in the same manner as patient specimens and go through all analytic test phases."

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, policies and procedures, and interview with the laboratory manager, the laboratory failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected. Findings include: ALARM CHECKS (1) At the beginning of the survey, the laboratory manager stated to the surveyor that units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On the fourth day of the survey, the laboratory manager stated to the surveyor Blood Bank alarms were checked quarterly for high/low activation; (3) The surveyor reviewed the refrigerator alarm check records for 2017 through the fourth day of the survey (08/30/18). The records indicated the alarm checks had not been performed quarterly. They had not been performed between 12/01/16 and 08/21/18; (4) The surveyor reviewed the records with the laboratory manager who stated the alarm checks had not been performed quarterly as required. UNMONITORED REFRIGERATOR (1) On the fourth day of the survey, the laboratory manager stated the following to the surveyor: (a) The blood bank refrigerator had been out of service between 04/16/17 through 05/03/17; (b) The laboratory manager instructed the staff to move the blood units to an unmonitored refrigerator and manually observe and document the temperature every 4 hours. (2) The surveyor requested manual temperature records between 04/16/17 through 05/03/17. The laboratory manager was not able to locate the records. Therefore, the surveyor could not verify the temperatures had not been observed and documented as required; (3) The laboratory manager stated the records could not be located to prove the laboratory monitored the temperature in the refrigerator as specified 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 and technical consultant, the laboratory failed to have a policies for monitoring the effectiveness of their IQCP'S; and failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: IQCP FOR CLOSTRIDIUM DIFFICILE (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) The laboratory performed C. Diff (Clostridium difficile) testing using the Wampole C. Diff Quik Chek Complete test kit; (b) An IQCP

	(Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as effective 12/30/15). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continued to provide accurate and reliable test results. There was no evidence of QA reviews for the IQCP since the effective date; (3) The surveyor reviewed the records with the laboratory manager and technical consultant and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if a QA review had been performed since 12/30/15. The laboratory manager and technical consultant stated a policy had not been written and a QA review had not been performed. IQCP FOR D-DIMER TESTING (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) The laboratory performed D-Dimer testing using the Biosite Triage Meter Plus analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as effective 12/30/15). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continued to provide accurate and reliable test results. There was no evidence of QA reviews for the IQCP since the effective date; (3) The surveyor reviewed the records with the laboratory manager and technical consultant and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if a QA review had been performed since 12/30/15. The laboratory manager and technical consultant stated a policy had not been written and a QA review had not been performed. ANALYTIC QUALITY ASSESSMENT (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow written policies. Refer to D5401; (b) The laboratory failed to follow the manufacturer's instructions for verifying flagged results. Refer to D5411; (c) The laboratory failed to ensure reagents had not exceeded their expiration date. Refer to D5417; (d) The laboratory failed to perform a negative and positive control each day of patient testing. Refer to D5449; (e) The laboratory failed to use control materials of a similar matrix to that of patient specimens. Refer to D5465; (f) The laboratory failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected.Refer to D5555.
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, manufacturer's instructions, written policies and procedures, and interview with the laboratory manager and testing person #1 /hematology supervisor, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure personnel performed testing as required for accurate and reliable results. Refer to D6014; (2) The laboratory director failed to ensure that proficiency testing samples were tested as required. Refer to D6016; (3) The laboratory director failed to ensure that quality control programs were established and maintained. Refer to D6020; (4) The

	laboratory director failed to ensure that a quality assessment program had been established and maintained. Refer to D6021; (5) The laboratory director failed to ensure the written policies were followed. Refer to D6031.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. 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 director failed to ensure test methods were performed as required for accurate and reliable results. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for verifying flagged results. Refer to D5411.
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 laboratory manager and 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. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. It was identified for 1 of 21 events, the attestation statements had been signed approximately 2 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 2017 Hematology/Coagulation Event - The samples had been tested on 03/29/17 and the attestation statement had not been signed by the laboratory director until 05/31 /17; (2) The surveyor reviewed the findings with laboratory manager and technical consultant 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.
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 laboratory manager, the laboratory director failed to ensure a quality control program was maintained to ensure quality laboratory services were provided. Findings include: (1) The laboratory director failed to ensure negative and positive controls were performed each day of patient testing. Refer to D5449; (2) The laboratory director failed to ensure control materials of a similar matrix to that of patient specimens. Refer to D5465.
D6021	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 quality assessment programs are 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 laboratory manager and technical consultant, the laboratory director failed to ensure that a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure there was an effective mechanism for performing quality assessment. Refer to D5791.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the laboratory manager and testing person #1/hematology supervisor, the laboratory director failed to ensure policies and procedures had been written and followed by personnel. (1) The laboratory director failed to ensure policies and procedures had been followed. Refer to D5401.
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, manufacturer's instructions 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 establish a quality control program that ensured acceptable levels of analytic performance. Refer to D6042.
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, manufacturer's instructions and interview with the laboratory manager, 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 the manufacturer's instructions were followed for verifying flagged results. Refer to D5411; (2) The technical consultant failed to ensure a negative and positive control was performed each day of patient testing. Refer to D5449; (3) The technical consultant failed to ensure the use of control materials of a similar matrix to that of patient specimens. Refer to D5465.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, written policies and procedures and interview with laboratory manager, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure that quality control programs were established and maintained. Refer to D6093; (2) The laboratory director failed to ensure that a quality assessment program had been established and maintained. Refer to D6094.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory director failed to ensure quality control programs were established and maintained. Findings include: (1) The laboratory director failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected. Refer to D5555; (2) The laboratory director failed to ensure reagents had not exceeded their expiration date. Refer to D5417.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory director failed to ensure that a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure there was an effective mechanism for performing quality assessment. Refer to D5791.