Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475908	10/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Creek Nation Community Hospital	1800 E Coplin Rd, Okemah, 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 10/15,16,17/2018. The laboratory was found out of compliance with the following CLIA regulations: 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant 493.1447; D6108: Technical Supervisor The findings were reviewed with the administrator, director of quality, quality improvement specialist, blood bank /coagulation department supervisor, hematology department supervisor, and urinalysis department supervisor during an exit conference performed at the conclusion of the survey.
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, written policies and procedures, manufacturer's instructions, and interview with technical consultant #2, the hematology department supervisor, blood bank/coagulation department supervisor, urinalysis department supervisor, and the chemistry department supervisor, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) The laboratory failed to have written procedures for manual differential and urine microscopic testing. Refer to D5401; (2) The laboratory failed to follow the manufacturer's instructions for establishing normal reference intervals for a new coagulation analyzer; and failed to follow the manufacturer's instructions to ensure flagged results were addressed for hematology. Refer to D5411; (3) The laboratory

	failed to demonstrate the performance specifications for new test methods; and failed to ensure the verified reportable ranges were used by the laboratory. Refer to D5421; (4) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (5) The laboratory failed to perform calibration verification procedures at least once every 6 months. Refer to D5439; (6) The laboratory failed to perform a negative and positive control material each day of patient Urine Drug Screen testing. Refer to D5449; (7) The laboratory failed to ensure units of blood were stored under appropriate conditions. Refer to D5555; (8) The laboratory failed to have an ongoing mechanism for performing effective 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 technical consultant #2, the hematology department supervisor and the urinalysis department supervisor, the laboratory failed to have written procedures for manual differential and urine microscopic testing. Findings include: MANUAL DIFFERENTIAL (1) On the first day of the survey, technical consultant #2 stated to the surveyor manual differential testing was performed in the laboratory; (2) On the third day of the survey, the surveyor requested the manual differential procedure from the hematology department supervisor; (3) The hematology department supervisor was unable to locate a written procedure for performing manual differential testing and stated to the surveyor a procedure had not been written. URINE MICROSCOPIC (1) On the first day of the survey, technical consultant #2 stated to the surveyor urine microscopic testing was performed in the laboratory; (2) On the third day of the survey, the surveyor requested the urine microscopic procedure from the urinalysis department supervisor; (3) The urinalysis department supervisor was unable to locate a written procedure for performing urine microscopic testing and stated to the surveyor a procedure had not been written.
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 technical consultant #2, the blood bank/coagulation department supervisor, and the hematology department supervisor, the laboratory failed to follow the manufacturer's instructions for establishing normal reference intervals for a new coagulation analyzer; and failed to follow the manufacturer's instructions to ensure flagged results

were addressed for hematology. Findings include: COAGULATION (1) On the first day of the survey, technical consultant #2 stated the following to the surveyor: (a) The hospital moved to a new location and the laboratory began patient testing in the new location on 05/10/18; (b) A new ACL TOP analyzer was put into use to perform PT /INR (Protime/International Normalized Ratio), PTT (Partial Thromboplastin Time) and D-dimer testing at the new location on 05/10/18. The laboratory had used the ACL Elite analyzer to perform PT/INR and PTT testing at the previous hospital location. (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions for establishing a normal reference interval which stated (the laboratory did not have the instructions, however, the surveyor had a copy of the instructions obtained from other laboratories using the same test system): (a) "You must decide before starting which type of study to perform. Will you perform a full reference interval study or will you be verifying a previous reference interval? Either 120 or 20 normal donors following these screening guidelines": (i) "Donors should be healthy and have no known pathological conditions. Don't use patients (they are at the hospital for a medical reason). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high dose aspirin, etc. Donors should span the adult age range. Pediatric ranges should be established separately. Donors should be equally divided between male/female". (b) In addition, the instructions stated, "If you choose to do a full reference interval study, test 120 donors. Ideally specimens will be analyzed over a number of days, resulting in values that represent average run-to-run variation. If you choose to verify a range, you may use a 20-donor study under specific conditions. The main conditions are as follows: The original site must have done a full reference range study The original site must have used the identical type of analytical system (method, instrument and reagents)". (3) To determine if the laboratory should perform a 20 or 120 sample study, the surveyor asked technical consultant #2 if the laboratory had ever performed a full reference interval study (120 sample study) on the ACL Elite analyzer. Technical consultant #2 verified there was no evidence to prove a 120 sample study had ever been performed. Based on the manufacturer's guidelines, the surveyor determined an initial 120 sample study was required, then subsequent studies may be performed using 20 samples due to the following: (a) There was no evidence a 120 sample study had been performed on the previous analyzer (ACL Elite). (4) The surveyor reviewed the implementation records for the analyzer. The following was identified for PT, PTT, and D-dimer: (a) The lot numbers that were in use when the analyzer was implemented were: (i) PT Reagent - RecombiPlasTin 2G lot #N1173928 (ii) PTT Reagent - SynthASil Lot #N1274655 (iii) D-dimer Reagent - lot #B30326 (b) The normal reference intervals had been established for each test performed on the analyzer as follows: (i) PT and PTT (aa) 21 donors had been utilized; (bb) There was no evidence of the health status (healthy with no pathological conditions) for the 21 donors; (cc) There was no evidence of the medication history for 6 of the donors; (dd) There was no evidence of the age and gender for 6 of the donors. (ii) D-dimer (aa) 23 donors had been utilized; (bb) There was no evidence the donors were healthy, with no pathological conditions; (cc) There was no evidence of the donors medication history; (dd) There was no evidence of the age and gender of the donors. (5) The surveyor reviewed the records with technical consultant #2 and the blood bank /coagulation department supervisor. Both stated the following: (a) The laboratory did not perform the 120 sample study; (b) The laboratory had not documented the health status and medication history for the donors as indicated above; (c) The laboratory had not documented the age and gender for the donors as indicated above. (6) The following were examples of patient testing performed when the normal reference intervals had not been established for the new analyzer as required: (a) Patient #19 - PT/INR testing performed on 05/10/18 (b) Patient #20 - D-dimer testing performed on

05/11/18 (c) Patient #21 - PT/INR, PTT, and D-dimer testing performed on 05/14/18 (d) Patient #22 - PT/INR testing performed on 05/16/18 (e) Patient #23 - PT/INR and PTT testing performed on 05/18/18 (f) Patient #24 - D-dimer testing performed on 05 /21/18 (g) Patient #25 - PT/INR testing performed on 05/24/18 (h) Patient #26 - PT /INR, PTT, and D-dimer testing performed on 05/26/18 (i) Patient #27 - PT/INR and PTT testing performed on 05/29/18 (j) Patient #28 - D-dimer testing performed on 0/7 /02/18 (k) Patient #29 - PT/INR and PTT testing performed on 07/05/18 (l) Patient #30 - PT/INR and PTT testing performed on 07/10/18 (m) Patient #31 - D-dimer testing performed on 07/10/18 (n) Patient #32 - PT/INR and PTT testing performed on 07/16/18 (o) Patient #33 - PT/INR testing performed on 07/17/18 (p) Patient #34 - PT /INR, PTT, and D-dimer testing performed on 07/20/18 (q) Patient #35 - PT/INR and PTT testing performed on 07/26/18 (r) Patient #36 - PT/INR and PTT testing performed on 07/27/18 (s) Patient #37 - PT/INR and PTT testing performed on 07/30 /18 (t) Patient #38 - PT/INR and PTT testing performed on 09/02/18 (u) Patient #39 - PT/INR testing performed on 09/04/18 (v) Patient #40 - PT/INR testing performed on 09/14/18 (w) Patient #41 - PT/INR testing performed on 09/19/18 (x) Patient #42 - PT /INR and PTT testing performed on 09/21/18 (y) Patient #43 - PT/INR and PTT testing performed on 09/22/18 (z) Patient #44 - PT/INR, PTT, and D-dimer testing performed on 09/24/18 (aa) Patient #45 - D-dimer testing performed on 09/26/18 HEMATOLOGY (1) On the first day of the survey, technical consultant #2 stated to the surveyor CBC (Complete Blood Count) testing, which included a 5 part automated differential, was performed on the Cell Dyn Ruby analyzer; (2) On the third day of the survey, the surveyor reviewed the manufacturer's instructions for verifying flags, and randomly reviewed CBC instrument printouts for testing performed in May 2018 and August 2018. With the assistance of the hematology department supervisor, the surveyor identified 11 patient records which contained flags. For 3 of the 11 patient records, the following was identified: (a) Patient #16 - RBC (Red Blood Cell) Morph flag obtained on 05/11/18 at 08:11 am (i) The manufacturer's instructions stated, "Review a stained smear for abnormal RBC or PLT morphology and follow your laboratory's review criteria"; (ii) There was no evidence in the records the laboratory reviewed a stained smear as required. (b) Patient #17 - The RBC result exceeded the linearity of the analyzer and displayed as ">>>>" on 05/11/18 at 01:53 pm (i) The manufacturer's instructions stated, "Specimens with results that exceed the linearity should be diluted with Diluent/Sheath according to the laboratory's procedure and repeated. (Be sure to correct the results for the dilution factor used.)"; (ii) Although the laboratory performed a dilution on the sample to obtain a result for RBC, there was no indication in the records that the result had been obtained by dilution, and there was no procedure available for the surveyor's review to determine if the appropriate diluent was used and the dilution factor that was used. (c) Patient #18 - A "Sampling Error" flag was obtained on 08/03/18 at 05:07 pm, indicated by an asterisk (*) for each analyte (WBC (White Blood Cell), RBC, Hemoglobin, Hematocrit, MCV (Mean Corpuscular Volume), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), Platelet, Neutrophil-% and absolute, Lymphocyte-% and absolute, Monocyte-% and absolute, Eosinophil-% and absolute, and Basophil-% and absolute) (i) The manufacturer's instructions stated, "The following summarizes all of the parameters marked with an asterisk (*) requiring further result validation". Listed in the table under the heading, "Instrument and Data Invalidating Alerts" was "Sampling Error"; (ii) There was no evidence in the records the laboratory had identified the Sampling Error message and attempted to further validate each analyte marked with an asterisk. (3) The surveyor reviewed the records with the hematology department supervisor who printed the final CBC reports for each patient above for further review. The hematology department supervisor stated the laboratory did not follow the manufacturer's instructions as indicated above, and

	stated the following to the surveyor: (a) For patient #16, the results were reported without a slide review to verify the RBC Morph flag; (b) For patient #17, the laboratory had performed a dilution to obtain a result for the analyte RBC. The laboratory did not have a written procedure for performing dilutions for results that exceed the linearity of the analyzer; (c) For patient #18, the results were reported with the sampling error and with each parameter marked with an asterisk, and no further action was taken.
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, written procedure, and interview with technical consultant #2, the urinalysis department supervisor, and the hematology department supervisor, the laboratory failed to demonstrate the performance specifications for new test methods; and failed to ensure the verified reportable ranges were used by the laboratory. Findings include: URINE DRUG TEST KIT (1) On the second day of the survey, technical consultant #2 stated to the surveyor the laboratory began using the Bio-Rad TOX/See Drug Screen Test kit to perform patient Urine Drug Screen testing on 10/05/17; (2) The surveyor requested documentation from technical consultant #2 to substantiate the performance specifications (i.e., accuracy, precision) had been demonstrated for the test kit before it had been put into use; (3) Technical consultant #2 stated to the surveyor, the performance specifications had not been demonstrated for the test kit; (4) The following were examples of patient Urine Drug Screen testing performed when the performance specifications had not been demonstrated prior to beginning patient testing: (a) Patient #1 - testing performed on 10/05/17 (b) Patient #2 - testing performed on 10/13/17 (c) Patient #3 - testing performed on 10/25/17 (d) Patient #4 - testing performed on 11/07/17 (e) Patient #5 - testing performed on 11/18 /17 (f) Patient #6 - testing performed on 11/28/17 (g) Patient #7 - testing performed on 11/30/17 (h) Patient #8 - testing performed on 05/16/18 (i) Patient #9 - testing performed on 05/21/18 (j) Patient #10 - testing performed on 05/25/18 (k) Patient #11 - testing performed on 05/28/18 (l) Patient #12 - testing performed on 07/02/18 (m) Patient #13 - testing performed on 07/17/18 (n) Patient #14 - testing performed on 09 /06/18 (o) Patient #15 - testing performed on 09/18/18 CLINITEK ADVANTUS (1) On the first day of the survey, technical consultant #2 stated the following to the surveyor: (a) The hospital moved to a new location and the laboratory began patient testing in the new location on 05/10/18; (b) A new Clinitek Advantus analyzer was put into use to perform Urinalysis testing (for the analysis of Leukocytes, Nitrites, Protein, Blood, Glucose, Ketones, Bilirubin, Urobilinogen, pH, Specific Gravity, and Creatinine in patient urine specimens) on 05/10/18. (2) On the second day of the survey, the surveyor requested records from the urinalysis department supervisor to substantiate the performance specifications (i.e., accuracy, precision, reportable range, and reference range) had been demonstrated for the new test system before it had been put into use; (3) The urinalysis department supervisor stated to the surveyor the

	performance specifications had not been demonstrated for the test system; (4) The following were examples of patient Urinalysis testing performed when the performance specifications had not been demonstrated prior to beginning patient testing: (a) Patient #46 - testing performed on 05/10/18 (b) Patient #47 - testing performed on 05/14/18 (c) Patient #48 - testing performed on 05/18/18 (d) Patient #49 - testing performed on 05/28/18 (e) Patient #50 - testing performed on 07/05/18 (f) Patient #51 - testing performed on 07/11/18 (g) Patient #52 - testing performed on 07 /19/18 (h) Patient #53 - testing performed on 07/25/18 (i) Patient #54 - testing performed on 07/30/18 (j) Patient #55 - testing performed on 09/10/18 (k) Patient #56 - testing performed on 09/16/18 (l) Patient #57 - testing performed on 09/23/18 (m) Patient #58 - testing performed on 09/26/18 (n) Patient #59 - testing performed on 09 /30/18 CELL DYN RUBY (1) On the first day of the survey, technical consultant #2 stated to the surveyor, a new Cell Dyn Ruby analyzer was put into use to perform patient *CBC (Complete Blood Count) testing on 05/10/18 when the laboratory moved to their new location; (2) On the second day of the survey, the surveyor reviewed validation records for the analyzer and identified the reportable ranges had been verified for WBC (White Blood Cell) and Platelet as follows: (a) WBC - 0.76-90.28 (b) Platelet - 8.0-2041.25 (3) On the third day of the survey, the surveyor reviewed the procedure titled, "Complete Blood Count Abbott Cell-Dyn Ruby". Under the heading "XVI. Limitation", the procedure defined the reportable ranges as follows: (a) WBC - 0.68-230.0 (b) Platelet - 0.90-2175 (4) The surveyor reviewed the findings with the hematology department supervisor who stated the laboratory was not using the reportable ranges that had been verified by the laboratory for WBC and Platelet; (5) The following were examples of patient CBC testing performed when the laboratory was not using the verified reportable ranges for the analytes WBC and Platelet: (a) Patient #46 - testing performed on 05/10/18 (b) Patient #47 - testing performed on 05/14/18 (c) Patient #48 - testing performed on 05/18/18 (d) Patient #49 - testing performed on 05/28/18 (e) Patient #50 - testing performed on 07/05/18 (f) Patient #51 - testing performed on 07/11/18 (g) Patient #53 - testing performed on 07 /25/18 (h) Patient #54 - testing performed on 07/30/18 (i) Patient #55 - testing performed on 09/10/18 (m) Patient #56 - testing performed on 09/16/18 (n) Patient #57 - testing performed on 09/23/18 (o) Patient #58 - testing performed on 09/26/18 (p) Patient #59 - testing performed on 09/30/18 *CBC consists of the analytes WBC, RBC (Red Blood Cell), Hemoglobin, Hematocrit, Platelet, MCV (Mean Corpuscular Volume), MCH (Mean Corpuscular Hemoglobin), and MCHC (Mean Corpuscular Hemoglobin Concentration)
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 technical consultant #2 and the chemistry department supervisor, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, technical consultant #2 stated the following to the surveyor: (a) *CMP, Amylase, Ammonia, Direct Bilirubin, BNP (B-Type Natriuretic Peptide), CK (Creatine Kinase), CKMB (Creatine Kinase Iso-enzyme), CRP (C-Reative Protein), Hemoglobin A1C, HDL (High Density

	Lipoprotein), Lactic Acid, Lipase, Magnesium, Phosphorus, PSA (Prostate Specific Antigen), Triglycerides, Troponin I, Uric Acid, Ferritin, Folate, Vitamin B12, TSH (Thyroid Stimulating Hormone), Free T4, HCG (Human Chorionic Gonadotropin), Acetaminophen, Carbamazepine, Ethanol, Lithium, Dilantin, Salicylate, Theophylline, Urine Drug Screen, Valproic Acid, and Vancomycin testing were performed on the Abbott Architect Plus Ci4100 analyzer; (b) The analyzer was installed in the new hospital location in November 2017, however, patient testing did not begin at the new location until 05/10/18. (2) On the third day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements were as follows: (a) Weekly (i) Check ICT Components (ii) Clean Mixers (iii) Clean Sample/Reagent Probes (iv) Clean Cuvettes with Detergent (v) Check HC Waste Pump Tubing (3) The surveyor then reviewed maintenance records for the analyzer from May 2018 through the third day of the survey. The following was identified: (a) Check ICT Components not documented as performed between: (i) 06/22/18 and 07/02/18 (ii) 09/28/18 and 10/10 /18 (b) Clean Mixers not documented as performed between: (i) 06/22/18 and 07/02 /18 (ii) 09/28/18 and 10/10/18 (c) Clean Sample/Reagent Probes not documented as performed between: (i) 06/22/18 and 07/02/18 (ii) 05/28/18 and 06/08/18 (iii) 09/28 /18 and 10/10/18 (d) Clean Cuvettes with Detergent not documented as performed between: (i) 06/22/18 and 07/02/18 (ii) 09/28/18 and 10/10/18 (e) Check HC Waste Pump Tubing not documented as performed between: (i) 06/22/18 and 07/02/18 (ii) 09 /28/18 and 10/10/18 (3) The surveyor reviewed the records with the chemistry department supervisor who stated the above maintenance procedures had not been documented as being performed as required. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein NOTE: D5429 was cited on the previous recertification survey performed 04/03/17-04/05/17.
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 technical consultant #2 and the chemistry department supervisor, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: ABBOTT ARCHITECT (1) On the first day of the survey, technical consultant #2 stated the following to the surveyor: (a) The laboratory performed Acetaminophen, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Ammonia, Amylase, AST (Aspartate Aminotransferase), Chloride, CK (Creatine Kinase), Hemoglobin A1c, HDL (High Density Lipoprotein), Lipase, Lithium, LDH (Lactate Dehydrogenase), LDL (Low Density Lipoprotein), Potassium, Salicylate, and Sodium testing using the Abbott Architect Plus ci4100 analyzer; (b) The analyzer was installed in the new hospital location in November 2017, however, patient testing did not begin at the new location until 05/10/18. (2) On the third day of the survey, the chemistry department supervisor stated to the surveyor (and provided records to substantiate) quality control materials were tested each day and maintenance procedures were performed until the laboratory began patient testing on 05/10/18; (3) The surveyor reviewed 2018 calibration records and identified that calibration procedures for the above analytes had been performed with one or two levels of calibrators. Since the calibration procedures included only one or two levels, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (4) The surveyor could not locate records to verify calibration verification procedures had been performed for the above analytes since the analyzer was installed in 11/2017 (due 5/2018); (5) The surveyor asked the chemistry department supervisor if calibration verification procedures had been performed since 11/2017. The chemistry department supervisor stated calibration verification procedures had not been performed since the analyzer was installed in 11/2017; (6) The following were examples of patient testing performed when calibration verification procedures had not been performed (NOTE: CMP testing includes the analytes Alkaline Phosphatase, ALT, AST, Chloride, Potassium, and Sodium): (a) Patient #20 - CMP and CK testing performed on 05/11/18 (b) Patient #10 - CMP, CK, and Hemoglobin A1c testing performed on 05/25/18 (c) Patient #11 - CMP and CK testing performed on 05/28/18 (d) Patient #60 - CMP, HDL, and LDL testing performed on 07/02/18 (e) Patient #29 - CMP and CK testing performed on 07/05/18 (f) Patient #30 - CMP and Hemoglobin A1c testing performed on 07/10/18 (g) Patient #33 - CMP testing performed on 07/17 /18 (h) Patient #35 - CMP and CK testing performed on 07/26/18 (i) Patient #14 - Amylase and CMP testing performed on 09/06/18 (j) Patient #15 - Ammonia and CMP testing performed on 09/18/18 (k) Patient #61 - CMP, Hemoglobin A1c, HDL, and LDL testing performed on 09/21/18 (l) Patient #45 - CMP testing performed on 09 /26/18 (m) Patient #59 - CMP and Amylase testing performed on 09/30/18 BIOSITE TRIAGE (1) On the first day of the survey technical consultant #2 stated to the surveyor the laboratory performed CKMB and Troponin I testing using the Biosite Triage Meter Plus analyzer as the back-up method (the primary method was the Abbott Architect); (2) On the second day of the survey, technical consultant #2 stated to the surveyor, the laboratory moved the analyzer from the previous location to the new location, therefore, the analyzer had been in use since the previous recertification survey; (3) The surveyor reviewed calibration verification records for 2017 and to date in 2018 (since calibration procedures were not routinely performed, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). There was no evidence calibration verification procedures had been performed after 02/07/18 (due in August 2018); (3) The surveyor reviewed the records with technical consultant #2 who stated calibration verification procedures had not been performed every six months for CKMB and Troponin I since 02/07/18; (4) The following were examples of patient CKMB and Troponin I testing performed

	when calibration verification had not been performed every six months: (a) Patient #62 - testing performed on 03/16/18 (b) Patient #63 - testing performed on 03/17/18 (c) Patient #64 - testing performed on 04/27/18 (d) Patient #26 - testing performed on 05/26/18 (e) Patient #32 - testing performed on 07/16/18 (f) Patient #35 - testing performed on 07/26/18 (g) Patient #36 - testing performed on 07/27/18 (h) Patient #38 - testing performed on 09/02/18 (i) Patient #41 - testing performed on 09/19/18 (j) Patient #43 - testing performed on 09/22/18 (k) Patient #44 - testing performed on 09 /24/18
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 technical consultant #2 the laboratory failed to perform a negative and positive control material each day of patient Urine Drug Screen testing. Findings include: (1) On the second day of the survey, technical consultant #2 stated to the surveyor the laboratory began using the Bio-Rad TOX/See Drug Screen Test kit to perform patient Urine Drug Screen testing on 10/05/17; (2) The surveyor asked technical consultant #2 if an IQCP (Individualized Quality Control Plan) had been developed for the test system. Technical consultant #2 stated an IQCP had not been developed. Therefore, the surveyor determined negative and positive QC (quality control) materials must be performed each day of patient testing; (3) The surveyor reviewed QC and patient testing records for October 2017, May 2018, July 2018, and September 2018. The review indicated negative and positive QC materials had not been performed 14 of 15 days of patient testing reviewed; (4) The surveyor reviewed the records with technical consultant #2, who stated negative and positive QC materials had not been performed each day of patient testing; (5) The following patient Urine Drug Screen testing had been performed when negative and positive QC materials had not been tested: (a) Patient #1 - testing performed on 10/05/17 (b) Patient #2 - testing performed on 10/13 /17 (c) Patient #3 - testing performed on 10/25/17 (d) Patient #4 - testing performed on 11/07/17 (e) Patient #5 - testing performed on 11/18/17 (f) Patient #6 - testing performed on 11/28/17 (g) Patient #7 - testing performed on 11/30/17 (h) Patient #8 - testing performed on 05/16/18 (i) Patient #10 - testing performed on 05/25/18 (j) Patient #11 - testing performed on 05/28/18 (k) Patient #12 - testing performed on 07 /02/18 (l) Patient #13 - testing performed on 07/17/18 (m) Patient #14 - testing performed on 09/06/18 (n) Patient #15 - testing performed on 09/18/18
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 blood bank/coagulation department supervisor, the laboratory failed to ensure units of blood were stored under appropriate conditions. Findings include: (1) On the first day of the survey, the blood bank/coagulation department supervisor stated to the surveyor units of packed red blood cells were stored in the Helmer blood bank refrigerator. The units were to be used for patient transfusions; (2) 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; (3) The surveyor reviewed 19 refrigerator charts dated from 05/07/18 through 05/14/18. The review indicated that 6 of 19 charts had not been changed by the 7th day of as follows: (a) Chart #1 - The chart was put into use on 05/14/18 and removed on 05/23/18 (9 days); (b) Chart #2 - The chart was put into use on 05/30/18 and removed on 06/07/18 (8 days); (c) Chart #3 - The chart was put into use on 07/12/18 and removed on 07/20/18 (8 days); (d) Chart #4 - The chart was put into use on 07/28/18 and removed on 08/06/18 (9 days); (e) Chart #5 - The chart was put into use on 08/20/18 and removed on 08/28/18 (8 days); (f) Chart #6 - The chart was put into use on 09/18/18 and removed on 09/26/18 (8 days). (4) The surveyor reviewed the charts with the blood bank/coagulation department supervisor who stated the 6 charts had not been changed by the 7th day, 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, written policies and procedures, manufacturer's instructions, and interview with technical consultant #2, the hematology department supervisor, blood bank/coagulation department supervisor, urinalysis department supervisor, and the chemistry department supervisor, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (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 have written procedures for manual differential and urine microscopic testing. Refer to D5401; (b) The laboratory failed to follow the manufacturer's instructions for establishing normal reference intervals for a new coagulation analyzer; and failed to follow the manufacturer's instructions to ensure flagged results were addressed for hematology. Refer to D5411; (c) The laboratory failed to demonstrate the performance specifications for new test methods; and failed to ensure the verified reportable ranges were used by the laboratory. Refer to D5421; (d) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (e) The laboratory failed to perform calibration verification procedures at least once every 6 months. Refer to D5439; (f) The laboratory failed to perform a negative and positive control material

	each day of patient Urine Drug Screen testing. Refer to D5449; (g) The laboratory failed to ensure units of blood were stored under appropriate conditions. Refer to D5555. NOTE: D5791 was cited on the previous recertification survey performed 04 /03/17-04/05/17.
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, written policies and procedures, manufacturer's instructions, and interview with technical consultant #2, the blood bank/coagulation department supervisor, hematology department supervisor, urinalysis department supervisor, and the chemistry department supervisor, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (3) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (4) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (5) The laboratory director failed to ensure policies and procedures were available. Refer to D6031. NOTE: D6000 was cited on the previous recertification survey performed 04/03/17-04/05/17.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records, written procedure, and interview with technical consultant #2, the urinalysis department supervisor, and the hematology department supervisor, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure performance specifications were demonstrated for new test methods; and failed to ensure the verified reportable ranges were used by the laboratory. Refer to D5421.
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 technical consultant #2, the blood bank/coagulation department supervisor, and the hematology department supervisor, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for establishing normal reference intervals for a new coagulation analyzer, and addressing flags for hematology. Refer to D5411; (2) The laboratory director failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429. NOTE: D6014 was cited on the previous recertification survey performed 04/03/17-04/05/17.
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 technical consultant #2 and the chemistry department supervisor, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure calibration verification procedures were performed at least once every 6 months. Refer to D5439; (2) The laboratory director failed to ensure negative and positive control materials were performed each day of patient Urine Drug Screen testing. Refer to D5449. NOTE: D6020 was cited on the previous recertification survey performed 04/03/17-04/05/17.
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, written policies and procedures, manufacturer's instructions, and interview with technical consultant #2, the hematology department supervisor, blood bank/coagulation department supervisor, urinalysis department supervisor, and the chemistry department supervisor, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791. NOTE: D6021 was cited on the previous recertification survey performed 04/03/17-04 /05/17.
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 technical consultant #2, the hematology department supervisor and the urinalysis department supervisor, the laboratory director failed to ensure policies and procedures were available. Findings include: (1) The laboratory director failed to ensure written procedures were available for manual differential and urine microscopic testing. 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, written procedure, manufacturer's instructions, and interview with technical consultant #2, the blood bank/coagulation department supervisor, hematology department supervisor, chemistry department supervisor, and the urinalysis department supervisor, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Refer to D6040; (2) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (3) The technical consultant failed to ensure evaluations included all moderate complexity testing performed. Refer to D6054.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)

	The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on a review of records, written procedure, and interview with technical consultant #2, the urinalysis department supervisor, and the hematology department supervisor, the technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Findings include: (1) The technical consultant failed to ensure the performance specifications were demonstrated for new test methods; and failed to ensure the verified reportable ranges were used by the laboratory. Refer to D5421.
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 technical consultant #2, the blood bank/coagulation department supervisor, hematology department supervisor, and the chemistry department supervisor, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for establishing normal reference intervals for a new coagulation analyzer, and addressing flags for hematology. Refer to D5411; (2) The technical consultant failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429; (3) The technical consultant failed to ensure calibration verification procedures were performed at least once every 6 months. Refer to D5439; (4) The technical consultant failed to ensure negative and positive control materials were tested each day of patient Urine Drug Screen testing. Refer to D5449. NOTE: D6042 was cited on the previous recertification survey performed 04/03/17-04/05/17.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the technical consultant failed to ensure evaluations included all moderate complexity testing performed. Findings include: (1) On the first day of the survey, technical consultant #2 stated to the surveyor the following testing was performed in the laboratory: (a)

	Manual Differential testing (b) Blood Gas (pH, pCO2, pO2) and Lactate testing using the Gem Premier 3500 analyzer (2) The surveyor then reviewed personnel records for 8 persons performing Manual Differential and Blood Gas/Lactate testing in the laboratory (hematology department supervisor/testing person #1, urinalysis department supervisor/testing person #2, chemistry department supervisor/testing person #3, testing person #4, blood bank/coagulation department supervisor/testing person #5, testing person #6, testing person #7, and testing person #8). The records verified that evaluations had been performed as follows: (a) Hematology Department Supervisor/Testing Person #1 - Performed on 04/25/17 and 04/18/18; (b) Urinalysis Department Supervisor/Testing Person #2- Performed on 05/08/17 and 06/07/18; (c) Chemistry Department Supervisor/Testing Person #3 - Performed on 02/20/17 and 01 /20/18; (d) Testing Person #4 - Performed on 02/24/17 and 01/29/18; (e) Blood Bank /Coagulation Department Supervisor/Testing Person #5 - Performed on 08/31/17 and 08/23/18; (f) Testing Person #6 - Performed on 10/15/18; (g) Testing Person #7 - Performed on 02/19/18; (h) Testing Person #8 - Performed on 03/19/18. (3) There was no evidence the evaluations, performed for the above persons, included an assessment of Manual Differential testing and Blood Gas/Lactate testing performed on the Gem Premier 3500 analyzer; (4) The surveyor reviewed the findings with technical consultant #2, who stated the above evaluations did not include Manual Differential testing and Blood Gas/Lactate testing performed on the Gem Premier 3500 analyzer.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the technical supervisor failed to provide technical supervision in accordance with 493.1447 of this subpart. Findings include: (1) The technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor met the educational qualifications. Refer to D6111.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is 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)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(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 (c)(1)(ii) Be certified in

clinical pathology 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 (c)(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 (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(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 (d)(1)(ii) Be certified in clinical pathology 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 (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(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 (e)(1)(ii) Be certified in clinical pathology 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 (e)(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 (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology 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 (f)(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 (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(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 (g)(1)(ii) Be certified in clinical pathology 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 (g)(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 (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology 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 (h)(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 (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(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 (i)(1)(ii) Be certified in clinical pathology 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 (i)(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 (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology 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 (j)(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 (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology 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 (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology 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; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a

training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) 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-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology 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 (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) 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-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology 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 (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology 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 (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology 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 (n)(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 (n)(2)(ii) Have at least 1 year of laboratory training or

experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(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 (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(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 (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology 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 (q)(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 (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor 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. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high

	complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor, met the qualifications. Findings include: (1) On the first day of the survey, the surveyor reviewed records for two testing persons who had been hired to perform high complexity testing (ABO/Rh, Antibody Screen and Compatibility testing) since the previous recertification survey performed 04/03/17 through 04/05/17. The records indicated the semi-annual evaluations for the testing persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical supervisor: (a) Testing Person #7 - The 02 /19/18 semi-annual evaluation had been performed by technical consultant #2 (this person had earned a bachelor of science degree); (b) Testing Person #8 - The 03/19/18 semi-annual evaluation had been performed by technical consultant #2. (2) The surveyor explained to technical consultant #2 that all components of the semi-annual competency evaluations must be performed by a person who qualifies as a technical supervisor (493.1449 (q) an individual with an MD or DO with a current medical license in state of laboratory's location and certified in anatomic pathology by ABP or AOBP or equivalent qualifications or resident in a program leading to ABP or AOBP certification in anatomic and clinical pathology who performs duties delegated by the technical supervisor for histopathology). NOTE: The regulations only allow for an individual qualifying as a general supervisor to perform initial training and annual competency evaluations as stated at 493.1463 "Standard; General supervisor responsibilities: (b)(3) Providing orientation to all testing personnel; and (b)(4) Annually evaluating and documenting the performance of all testing personnel"