Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475409	12/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pushmataha Hospital	510 E Main St, Antlers, 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 12/18/2018 - 12/21/2018. The laboratory was found out of compliance with the following CLIA regulations: 493.1250: D5400: Condition: Analytic Systems 493.1403: D6000: Condition: Laboratory Director, Moderate Complexity 493.1409: D6033: Condition: Technical Consultant The findings were reviewed with the technical consultant, the laboratory manager, testing person #1, testing person #2, and the hospital controller during an exit conference performed at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and the laboratory manager, the laboratory director failed to sign proficiency testing attestation statements to attest the proficiency testing samples were analyzed in the same manner as patient specimens. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records and identified attestation statements had been signed by a person who did not qualify as a technical consultant (if delegated in writing for moderate complexity testing) or had

	not been signed; (2) The following was identified for 2 of the 12 events reviewed: (a) Third 2017 Hematology/Coagulation Event: (i) The attestation form was signed by the laboratory manager, who obtained an HEW certification which did not meet the regulatory requirements of a technical consultant or a laboratory director for moderate complexity testing. (b) Third 2018 Hematology/Coagulation Event: (i) The attestation form had not been signed by the laboratory director or signed by another qualified individual. (3) The surveyor explained to the technical consultant and the laboratory manager, proficiency testing attestation statements for moderate complexity testing must be signed by the laboratory director or a technical consultant (if delegated) to attest the proficiency testing samples were tested in the same manner as patient specimens. NOTE: The Interpretive Guidelines under D2015, stated, "For moderate complexity testing, in accordance with 493.1407(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of 493.1409. For high complexity testing, in accordance with 493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of 493.1447." NOTE: D2015 was cited at the previous recertification survey performed 09/19/16-09 /22/16.
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 technical consultant and the laboratory manager, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed the 2017 and 2018 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program): (a) First 2017 Hematology Event (i) WBC (White Blood Count): 5 of 5 results exhibited a Negative bias (aa) XE-01: SDI -1.3 (bb) XE-02: SDI -1.9 (cc) XE-03: SDI -1.6 (dd) XE-04: SDI -2.6 (ee) XE-05: SDI -2.8 (b) Third 2017 Chemistry Event: (i) pH: 4 of 5 results exhibited a Negative bias (aa) BG-12: SDI -2.4 (bb) BG-13: SDI -2.8 (cc) BG-14: SDI -2.3 (dd) BG-15: SDI -2.2 (c) Second 2018 Chemistry Event: (i) Amylase: 4 of 5 results exhibited a Positive bias (aa) CH-06: SDI 3.8 (bb) CH-07: SDI 1.3 (cc) CH-08: SDI 1.5 (dd) CH-10: SDI 2.4 (ii) AST (Aspartate Aminotransferase): 4 of 5 results exhibited a Positive bias (aa) CH-06: SDI 2.0 (bb) CH-07: SDI 2.6 (cc) CH-09: SDI 2.2 (dd) CH-10: SDI 2.5 (iii) BUN: 4 of 5 results exhibited a Positive bias (aa) CH-06: SDI 2.7 (bb) CH-08: SDI 1.0 (cc) CH-09: SDI 1.4 (dd) CH-10: SDI 3.5 (iv) Calcium: 4 of 5 results exhibited a Positive bias (aa) CH-06: SDI 3.9 (bb) CH-07: SDI 4.3 (cc) CH-09: SDI 3.2 (dd) CH-10: SDI 3.1 (v) Uric Acid: 4 of 5 results exhibited a Positive bias (aa) CH-06: SDI 3.9 (bb) CH-07: SDI 2.9 (cc) CH-09: SDI 2.3 (dd) CH-10: SDI 2.8 (d) Third 2018 Chemistry Event (i) Albumin: 3 of 5 results exhibited a Positive bias (aa) CH-13: SDI 2.9 (bb) CH-14: SDI 2.0 (cc) CH-15: SDI 2.6 (ii) Chloride: 4 of 5 results exhibited a Positive bias (aa) CH-11: SDI 2.7 (bb) CH-13: SDI 2.6 (cc) CH-14: SDI 3.1 (dd) CH-15: SDI 3.3 (iii) Potassium: 3 of 5 results exhibited a Positive bias (aa) CH-11: SDI 1.8 (bb) CH-13: SDI 2.0 (cc) CH-15: SDI 2.4 (iv) Sodium: 4 of 5 results exhibited a Positive bias (aa) CH-11: SDI 2.2 (bb) CH-13: SDI 2.1 (cc) CH-14: SDI 2.3 (dd) CH-15: SDI 2.4 (2) There was no

	documentation found in the records the laboratory identified and evaluated the biases to determine if a systematic failure had occurred, and there was no documentation the laboratory took corrective action (e.g., reviewed quality control record, maintenance records, calibration, patient results affected, etc.) for the biases; (3) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor the laboratory had not identified or evaluated the biases, and corrective action had not been taken. NOTE: D5211 was cited at the previous recertification survey performed 09/12/16-09/22/16.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and the laboratory manager, the laboratory failed to evaluate the accuracy of testing when a proficiency testing result had not been graded by the proficiency program. Findings include: (1) On the first day of the survey, the surveyor reviewed the 2017 and 2018 proficiency testing records and identified the laboratory did not address a result not graded by the proficiency testing program for Blood Cell Identification testing: (a) First 2018 Hematology Event (i) Sample BCI-01 had not been evaluated by the proficiency testing program due to "No Consensus" among the participants; (ii) The laboratory reported, "Lymph, reactive (atyp, variant)." Under "Expected Result" it stated, "See Data Summary;" (iii) There was no evidence found in the records that the laboratory reviewed the data summary to evaluate their result. (2) The surveyor reviewed the records with the laboratory manager, who stated to the surveyor the non-graded proficiency testing result had not been evaluated.
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 technical consultant, laboratory manager, and testing person #7, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) The laboratory failed to follow its written policy and procedure. Refer to D5401; (2) The laboratory failed to follow the manufacturer's instructions for implementing reagents. Refer to D5411; (3) The laboratory failed to verify the reference intervals used for a new test method were

	appropriate for the patient population serviced by the laboratory. Refer to D5421; (4) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (5) The laboratory failed to ensure function checks were within the manufacturer's acceptable limits before patient testing was conducted. Refer to D5431; (6) The laboratory failed to have control procedures able to detect immediate errors and monitor over time the accuracy and precision of test performance. Refer to D5441; (7) The laboratory failed to perform a negative and a positive control each day of patient testing. Refer to D5449; (8) The laboratory failed to ensure corrective action was taken for unacceptable function checks. Refer to D5781; (9) The laboratory failed to have an ongoing mechanism for performing 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 records, written policy, and interview with the laboratory manager and testing person #7, the laboratory failed to follow its policy for performing manual WBC differentials. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor, the laboratory used the Sysmex XP-300 hematology analyzer to perform CBC (Complete Blood Count) (WBC-White Blood Count), RBC (Red Blood Count), Hemoglobin, etc.) testing. In addition, the laboratory manager stated to the surveyor the laboratory performed a manual WBC differential or smear review on CBC's which met the laboratory's criteria; (2) On the second day of the survey, the surveyor reviewed the laboratory's written CBC policy, which required a manual WBC differential be performed on patient CBC's as follows: (a) WBC of less than 2.0, or greater than 20.0 (b) Automated CBC results with greater than 10% atypical or reactive lymphocytes (3) The surveyor then reviewed patient CBC analyzer printouts from January and April 2018 and identified the following: (a) January 2018 - A manual WBC differential had not been performed on 1 of 10 patient CBC's which met the laboratory's criteria: (i) Patient #140 - Testing performed on 01 /12/18 at 05:26 AM: (aa) The WBC was 24.4 with an automated Lymphocyte count of 35.8%; (bb) There was no documentation found which proved a manual differential had been performed. (b) April 2018 - A manual WBC differential had not been performed on 1 of 10 patient CBC's which met the laboratory's criteria: (i) Patient #141 - Testing performed on 04/25/18 at 04:36 AM: (aa) The WBC was 27.7; (bb) There was no documentation found which proved a manual differential had been performed. (4) The surveyor reviewed the findings with the laboratory manager and testing person #7, who stated to the surveyor the laboratory failed to follow its policy for patient CBC's with a WBC of greater than 20,000, as listed above. NOTE: D5401 was cited at the previous recertification survey performed 09/19/16-09/22/16.
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 and testing person #7, the laboratory failed to follow the manufacturer's instructions for implementing reagents. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the ACL Elite coagulation analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ration) testing. (The INR was calculated using the PT reference interval mean); (2) On the third day of the survey, the surveyor identified HemosIL RecombiPlasTin 2SG reagent, Lot #N0688929 was in use for PT testing. The surveyor then reviewed the lot rollover records from 11/13/18-11/28/18 and identified the reagent was put into use on 11/30/18; (3) The surveyor reviewed the manufacturer's instructions contained in the "ACL Hemostasis System Performance Verification Manual" for implementing new reagents, which stated: (a) Section titled "Changing Reagent or Lot Number of Reagent" (i) "Perform the 'Comparison Study' procedure for all tests that will be reported" (b) Section titled "Comparison Study" (i) "Collect and handle specimens according to accepted laboratory practice for the assay being performed" (ii) "Include diseases/treatments known to affect the assay being performed" (iii) "At least 50% of the samples should be outside of the laboratory normal reference interval, if possible" (iv) "At least 40 specimens should be analyzed. More samples will improve the confidence in the data" (v) "For a given specimen, analysis by the comparative and new methods or reagents should be accomplished within 1 hour of each other to avoid possible degradation of the samples" (vi) "Analyze each patient sample using the new method (or reagents) and the comparative method" (vii) "Examine the results after each run. If an isolated specimen's results for the new and comparative methods differ more than observed for other specimens, retest that specimen in duplicate on both methods. If the difference has been resolved use the repeat data" (vii) "Record data on the data sheets provided" (viii) "Follow the laboratory's routine quality control procedures when collecting comparison data. Keep control charts, and repeat any run that appears to be out of control on either method" (ix) "The analysis of the comparison data can be as simple as a visual comparison, calculation of the difference (delta) between the two methods, or as involved as a regression analysis. The comparison will depend on the types of specimen, instruments and methodologies chosen. The more similarities among those items, the closer will be the comparison results" (4) The surveyor then reviewed the implementation records for the PT reagent, dated 11/13/18-11/28/18 and identified the laboratory failed to follow the manufacturer's instructions for performance of the method comparison study: (a) The laboratory did not utilize a minimum of 40 donor samples, but used 10 patient donor samples; (b) The laboratory did not utilize donor samples from patients with diseases/treatments known to affect the PT assay; (c) The laboratory did not utilize donor samples with results outside the laboratory's normal reference interval. All samples were within the laboratory's normal patient PT reference range (9.8-13.6). (5) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor the laboratory did not use a minimum of 40 patient samples for the comparison study, and failed to include at least 50% from patients with diseases/treatments that affected the PT results with results outside the laboratory's normal patient reference range for PT testing; (6) The following were examples of patient PT/INR testing performed when the reagent lot number was used: (a) Patient #143: Testing performed on 11/28/18 at 11:33 PM (b) Patient #144: Testing performed on 12/16/18 at 07:41 AM (c) Patient #145: Testing performed on 12

	/16/18 at 07:41 AM (d) Patient #146: Testing performed on 12/16/18 at 11:43 AM (e) Patient #147: Testing performed on 12/17/18 at 03:38 AM (f) Patient #148: Testing performed on 12/20/18 at 05:35 PM
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, manufacturer's instructions, and interview with the technical consultant and the laboratory manager, the laboratory failed to verify the reference intervals used for a new test method were appropriate for the patient population serviced by the laboratory. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory replaced the Dimension Xpand analyzer on 10/01/18 with the Dimension ExL 200 analyzer. Examples of the testing performed on the new analyzer included the following: (a) Albumin (b) CK (Creatinine Kinase) (c) Digoxin (d) Serum Quantitative Pregnancy (e) Glucose (f) Potassium (g) Troponin I (h) TSH (Thyroid Stimulating Hormone) (i) Uric Acid (2) On the second day of the survey, the surveyor reviewed the validation records for the new analyzer. There was no documentation found in the records which showed the source of the reference intervals to be used with the new analyzer (i.e. verified the manufacturer's reference intervals (normal ranges) or established its own normal ranges for each analyte). The surveyor asked the laboratory manager how the laboratory obtained the normal ranges. The laboratory manager stated the laboratory use the manufacturer's normal reference intervals for each analyte; (3) The surveyor asked the laboratory manager if the laboratory verified the manufacturer's reference ranges were appropriate for the laboratory's patient population. The laboratory manager stated to the surveyor the manufacturer's reference intervals had not been verified by the laboratory as appropriate for the patient population the laboratory serviced before being put into use for patient testing. NOTE: D5421 was cited at the previous recertification survey performed 09/19/16-09/22/16.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and testing person #7, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: ACL ELITE ANALYZER (1) On the first day of the survey, the laboratory manager stated

	to the surveyor the laboratory used the ACL Elite coagulation analyzer to perform PT /INR (Prothrombin Time/International Normalized Ratio) and APTT (Activated Partial Thromboplastin Time) testing; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The manufacturer required the following maintenance procedures: (a) Weekly: (i) Clean instrument (ii) Clean rinse reservoir (b) Biweekly: (i) Reboot the analyzer (ii) Clean rotor holder and optic path (3) The surveyor reviewed maintenance records from 5 months: December 2017; January, April, July, and November 2018. There was no documentation on the maintenance logs the weekly and biweekly maintenance procedures had been performed as required during 4 of the 5 months reviewed: (a) Weekly - There was no documentation the maintenance procedures had been performed: (i) Between 12/11/17 and 01/07/18 (ii) Between 01/13/18 and 01/24/18 (iii) Between 04/01/18 and 04/28/18 (iv) Between 11/12/18 and 11/27/18 (b) Biweekly - There was no documentation the maintenance procedures had been performed: (i) Between 12/01/17 and 12/31/17 (ii) Between 01/01/18 and 01/31/18 (iii) Between 07/01/18 and 07/31/18 (iv) Between 11 /12/18 and 11/30/18 (4) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor there was no documentation the manufacturer's required maintenance procedures listed above had been performed. DIMENSION XPAND ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed chemistry (e.g., Glucose, Potassium, Total Protein, Uric Acid, etc.) using the Dimension Xpand chemistry analyzer (until 10 /01/18 when it was replaced with the Dimension ExL 200 analyzer); (2) The surveyor reviewed the manufacturer's maintenance requirements for the Dimension Xpand analyzer as stated on the manufacturer's maintenance log. The manufacturer required the following maintenance procedures: (a) Weekly: (i) Clean outside of R2 probe (ii) Clean outside of HM wash probe (b) Monthly: (i) Replace IMT pump tubing (ii) Clean IMT System (iii) Replace/clean air filters (iv) Stylette HM wash probes (v) Replace HM pump head (3) The surveyor reviewed the maintenance logs from 11/20 /17 through 09/30/18 and identified the laboratory failed to perform the maintenance procedures as required by the manufacturer. The findings follow: (a) Weekly: There was no documentation the maintenance had been performed: (i) Between 01/22/18 and 02/05/18 (ii) Between 04/20/18 and 05/01/18 (iii) Between 05/12/18 and 06/19/18 (iv) Between 06/23/18 and 07/17/18 (b) Monthly: There was no documentation the following maintenance procedures had been performed: (i) Replace IMT pump tubing: (aa) Between 01/01/18 and 04/23/18 (bb) Between 05/01/18 and 07/30/18 (ii) Clean IMT System: (aa) Between 11/20/17 and 01/22/18 (bb) Between 01/22/18 and 04/23/18 (cc) Between 04/23/18 and 06/23/18 (iii) Replace/clean air filters: (aa) Between 11/20/17 and 03/31/18 (bb) Between 03/31/18 and 08/30/18 (iv) Stylette HM wash probes: (aa) Between 11/20/17 and 01/01/18 (bb) Between 01/25/18 and 03/31 /18 (cc) Between 04/14/18 and 06/20/18 (v) Replace HM pump head: (aa) Between 11 /20/17 and 01/01/18 (bb) Between 01/01/18 and 03/24/18 (cc) Between 03/24/18 and 06/20/18 (4) The surveyor reviewed the findings with the laboratory manager and testing person #7 who stated to the surveyor, the performance of the maintenance procedures had not been documented as having been performed as listed above. NOTE: D5429 was cited at the previous recertification survey performed 09/19/16-09 /22/16.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with

	at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and the laboratory manager, the laboratory failed to ensure function checks were within the manufacturer's acceptable limits before patient testing was conducted. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory replaced the Dimension Xpand analyzer on 10/01/18 with the Dimension ExL 200 analyzer. Examples of the testing performed on the new analyzer included the following: (a) Albumin (b) Creatinine Kinase (c) Digoxin (d) Serum Quantitative Pregnancy (e) Glucose (f) Potassium (g) Troponin I (h) Thyroid Stimulating Hormone (i) Uric Acid (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions for performing function checks on the Dimension ExL 200 analyzer. The manufacturer required the daily recording of the cuvette temperature. In addition, the manufacturer's acceptable cuvette temperature range was 36.8 to 37.2 degrees Centigrade (C); (3) The surveyor then reviewed the cuvette temperature records from 10/01/18 through 12/19/18 and identified the temperature was beyond the manufacturer's acceptable limit on 40 of the 80 days reviewed. The specific findings follow: (a) 10/01/18 - 10/31/18: The cuvette temperature was unacceptable, or had not been documented on 11 of 31 days: (i) The cuvette temperature was 37.3 C: Days 17,18,19,20 (ii) The cuvette temperature was 37.4 C: Days 21,23 (iii) The cuvette temperature was 37.5 C: Day 22 (iv) The cuvette temperature had not been documented: Days 1,15, 25,31 (b) 11/01/18 - 11/30/18: The cuvette temperature was unacceptable on 21 of 30 days (i) The cuvette temperature was 37.3 C: Days 2,3,4,8,9,10,12,15 (ii) The cuvette temperature was 37.4 C: Days 5,14,16,20,21,22, 23,24,25,26,27 (iii) The cuvette temperature was 37.5 C: Day 28 (iv) The cuvette temperature was 37.6 C: Day 29 (c) 12/01/18 - 12/19/18: The cuvette temperature was unacceptable on 8 of 19 days (i) The cuvette temperature was 36.7 C: Day 15 (ii) The cuvette temperature was 37.3 C: Days 4,5 (iii) The cuvette temperature was 37.4 C: Days 6,8,9 (iv) The cuvette temperature was 37.5 C: Days 7,10 (4) The surveyor reviewed the records with the technical consultant and the laboratory manager, who stated to the surveyor the temperatures had not been maintained as required by the manufacturer. NOTE: D5431 was cited at the previous recertification survey performed 09/19/16-09/22/16.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 and testing person #7, the laboratory failed to have control procedures able to detect immediate errors and monitor over time the accuracy and precision of the complete analytic process. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the Dimension Xpand analyzer was used for chemistry testing until 09/30/18 when it was replaced. The testing performed, included the following: (a) BMP (Basic Metabolic Panel) (b) CMP (Comprehensive Metabolic Panel (c) LP (Lipid Panel) (d) Liver Prof (Liver Profile) (e) Miscellaneous tests: Amylase, CK (Creatinine Kinase), Mg (Magnesium), Uric Acid (2) On the second day of the survey, the surveyor asked testing person #7 what QC (Quality Control) materials the laboratory had been used to monitor the testing listed above. Testing person #7 stated to the surveyor the laboratory analyzed two levels (Level 1 and Level 3) of BioRad Liquichek Multiqual each day of patient testing; (3) The surveyor asked testing person #7 to explain how the laboratory monitored QC results for variances (i.e., biases, shifts, trends). Testing person #7 stated to the surveyor it was the laboratory's practice to print LJ (Levey-Jennings) graphs from the analyzer at the end of the month and also the monthly peer comparison data (i.e. Unity Month Evaluation) received from the QC manufacturer was printed each month. These were reviewed to detect shifts and trends; (4) The surveyor asked for QC records (i.e. LJ graphs, Unity peer data reports) from 01/01/18 through 09/30/18. Testing person #7 stated to the surveyor, the printer on the Dimension Xpand analyzer stopped working about 02/28/18 and the LJ graphs between 03/01/18 and 07/31/18 had not been printed. In addition, testing person #7 stated to the surveyor some the Unity Month Evaluation reports were not available for the QC material because the QC data had not been submitted to the Unity QC program each month during the review period. The surveyor asked testing person #7 if the laboratory used another method to review QC data for variances during those months. Testing person #7 stated to the surveyor, although the QC results were reviewed daily to be sure it was acceptable, the laboratory did not have another method to review the QC results for shifts and trends; (5) The surveyor reviewed the QC records and identified 5 months when the results of the BioRad Multiqual Unassayed, Level 1 and Level 3 QC materials had not been monitored for variances: (a) March 2018 (b) April 2018 (c) May 2018 (d) June 2018 (e) July 2018 (6) The surveyor determined due to the lack of data to review, the laboratory failed to monitor QC results for variances from 03/01/18 through 07/31/18; (7) Examples of patients with chemistry testing performed when the laboratory failed to review QC results for variances, included the following: (a) Patient #1 - CMP testing performed on 03/01/18 (b) Patient #2 - CMP testing performed on 03/02/18 (c) Patient #3 - Uric Acid testing performed on 03/05/18 (d) Patient #4 - CMP testing performed on 03/07/18 (e) Patient #5 - BMP testing performed on 03/08/18 (f) Patient #6 - CK testing performed on 03 /09/18 (g) Patient #7 - CMP testing performed on 03/10/18 (h) Patient #8 - BMP testing performed on 03/11/18 (i) Patient #9 - CMP testing performed on 03/11/18 (j) Patient #10 - CMP testing performed on 03/12/18 (k) Patient #11 - BMP testing performed on 03/13/18 (l) Patient #12 - CMP testing performed on 03/14/18 (m) Patient #13 - CMP testing performed on 03/15/18 (m) Patient #14 - BMP testing performed on 03/17/18 (o) Patient #15 - BMP testing performed on 03/18/18 (p) Patient #16 - CMP testing performed on 03/19/18 (q) Patient #17 - CMP testing performed on 03/20/18 (r) Patient #18 - Amylase testing performed on 03/22/18 (s) Patient #19 - LP testing performed on 03/23/18 (t) Patient #20 - BMP testing performed on 03/24/18 (u) Patient #21 - CMP testing performed on 03/24/18 (v) Patient #22 - BMP testing performed on 03/25/18 (w) Patient #23 - CMP testing performed on 03/26/18 (x) Patient #24 - CMP testing performed on 03/27/18 (y) Patient #25 - BMP testing performed on 03/28/18 (z) Patient #26 - CMP testing performed on 03/29/18 (aa) Patient #27 - CMP testing performed on 03/30/18 (bb)

Patient #28 - Amylase testing performed on 03/30/18 (cc) Patient #29 - LP testing performed on 03/31/18 (dd) Patient #30 - CMP testing performed on 04/04/18 (ee) Patient #31 - CMP testing performed on 04/05/18 (ff) Patient #32 - CMP, Magnesium testing performed on 04/05/18 (gg) Patient #33 - CMP testing performed on 04/10/18 (hh) Patient #34 - CMP testing performed on 04/10/18 (ii) Patient #35 - Amylase, Uric Acid, LP testing performed on 04/12/18 (jj) Patient #36 - CMP testing performed on 04/19/18 (kk) Patient #37 - CMP, CK testing performed on 04/19/18 (ll) Patient #38 - CMP testing performed on 04/21/18 (mm) Patient #39 - Amylase, Magnesium, Uric Acid testing performed on 04/28/18 (nn) Patient #40 - CMP, LP, Uric Acid testing performed on 04/28/18 (oo) Patient #41 - CMP, CK testing performed on 05/01 /18 (pp) Patient #42 - CMP testing performed on 05/02/18 (qq) Patient #43 - BMP testing performed on 05/03/18 (rr) Patient #44 - Amylase testing performed on 05/04 /18 (ss) Patient #45 - CMP, Magnesium testing performed on 05/04/18 (tt) Patient #46 - LP testing performed on 05/04/18 (uu) Patient #47 - CMP testing performed on 05/05 /18 (vv) Patient #48 - Amylase testing performed on 05/05/18 (ww) Patient #49 - CMP testing performed on 05/06/18 (xx) Patient #50 - Magnesium testing performed on 05/07/18 (yy) Patient #51 - CMP testing performed on 05/07/18 (zz) Patient #52 - CMPtesting performed on 05/08/18 (aaa) Patient #53 - BMP testing performed on 05 /09/18 (bbb) Patient #54 - CMP testing performed on 05/10/18 (ccc) Patient #55 - BMP testing performed on 05/11/18 (ddd) Patient #56 - CMP testing performed on 05 /12/18 (eee) Patient #57 - CMP testing performed on 05/13/18 (fff) Patient #58 - BMP testing performed on 05/14/18 (ggg) Patient #59 - BUN testing performed on 05/14/18 (hhh) Patient #60 - CMP, Magnesium testing performed on 05/14/18 (iii) Patient #61 - BMP testing performed on 05/16/18 (jjj) Patient #62 - LP testing performed on 05/16 /18 (kkk) Patient #63 - Magnesium testing performed on 05/16/18 (lll) Patient #64 - BMP, Uric Acid testing performed on 05/17/18 (mmm) Patient #65 - CMP testing performed on 05/17/18 (nnn) Patient #66 - LP testing performed on 05/18/18 (ooo) Patient #67 - CMP testing performed on 05/19/18 (ppp) Patient #68 - CMP, CK testing performed on 05/20/18 (qqq) Patient #69 - BMP testing performed on 05/21/18 (rrr) Patient #70 - Uric Acid testing performed on 05/21/18 (sss) Patient #71 - Amylse testing performed on 05/22/18 (ttt) Patient #72 - CMP, CK testing performed on 05/23 /18 (uuu) Patient #73 - CMP testing performed on 05/24/18 (vvv) Patient #74 - BMP testing performed on 05/25/18 (www) Patient #75 - CMP, Cholesterol, Magnesium testing performed on 05/26/18 (xxx) Patient #76 - LP testing performed on 05/26/18 (yyy) Patient #77 - CMP testing performed on 05/26/18 (zzz) Patient #78 - CMP testing performed on 05/27/18 (aaaa) Patient #79 - Uric Acid testing performed on 05 /27/18 (bbbb) Patient #80 - Creatinine testing performed on 05/27/18 (cccc) Patient #81 - CMP, Amylase testing performed on 05/28/18 (dddd) Patient #82 - CMP testing performed on 05/28/18 (eeee) Patient #83 - CMP testing performed on 05/29/18 (ffff) Patient #84 - BMP testing performed on 05/30/18 (gggg) Patient #85 - CMP, LP testing performed on 05/30/18 (hhhh) Patient #86 - CMP, LP testing performed on 06 /01/18 (iiii) Patient #87 - CMP, CK testing performed on 06/02/18 (jjjj) Patient #88 - CMP, Uric Acid testing performed on 06/02/18 (kkkk) Patient #89 - CMP testing performed on 06/03/18 (llll) Patient #90 - CK testing performed on 06/03/18 (mmmm) Patient #91 - LP, Magnesium, Uric Acid testing performed on 06/06/18 (nnnn) Patient #92 - CMP, CK testing performed on 06/08/18 (oooo) Patient #93 - CMP testing performed on 06/09/18 (pppp) Patient #94 - CMP, CK testing performed on 06/21/18 (qqqq) Patient #95 - CMP, CK testing performed on 06/25/18 (rrrr) Patient #96 - CK testing performed on 06/30/18 (ssss) Patient #97 - CMP, LP testing performed on 06 /30/18 (tttt) Patient #98 - CMP, LP testing performed on 07/01/18 (uuuu) Patient #99 - CMP testing performed on 07/02/18 (vvvv) Patient #100 - CMP testing performed on 07/03/18 (wwww) Patient #101 - CMP, Amylase testing performed on 07/04/18 (xxxx) Patient #102 - CMP, LP testing performed on 07/05/18 (yyyy) Patient #103 -

	Amylase testing performed on 07/06/18 (zzzz) Patient #104 - Potassium testing performed on 07/07/18 (aaaaa) Patient #105 - CMP testing performed on 07/08/18 (bbbbb) Patient #106 - LP testing performed on 07/09/18 (ccccc) Patient #107 - CMP testing performed on 07/09/18 (ddddd) Patient #108 - BMP testing performed on 07/10 /18 (eeeee) Patient #109 - Liver Prof testing performed on 07/11/18 (fffff) Patient #110 - CMP testing performed on 07/11/18 (ggggg) Patient #111 - CMP testing performed on 07/13/18 (hhhhh) Patient #112 - Creatinine testing performed on 07/14 /18 (iiiii) Patient #113 - CMP testing performed on 07/14/18 (jjjjj) Patient #114 - CMP, Magnesium testing performed on 07/15/18 (kkkkk) Patient #115 - CMP testing performed on 07/16/18 (lllll) Patient #116 - LP testing performed on 07/16/18 (mmmmm) Patient #117 - CMP testing performed on 07/17/18 (nnnnn) Patient #118 - CMP testing performed on 07/18/18 (ooooo) Patient #119 - Amylase testing performed on 07/19/18 (ppppp) Patient #120 - CMP testing performed on 07/19/18 (qqqqq) Patient #121 - CK testing performed on 07/20/18 (rrrrr) Patient #122 - CMP testing performed on 07/20/18 (sssss) Patient #123 - CMP, Amylase testing performed on 07/21/18 (ttttt) Patient #124 - Uric Acid testing performed on 07/22/18 (uuuuu) Patient #125 - CMP testing performed on 07/22/18 (vvvvv) Patient #126 - CMP testing performed on 07/23/18 (wwwww) Patient #127 - CK testing performed on 07 /23/18 (xxxxx) Patient #128 - CMP, Amylase testing performed on 07/24/18 (yyyyy) Patient #129 - BMP testing performed on 07/25/18 (zzzzz) Patient #130 - CMP testing performed on 07/25/18 (aaaaaa) Patient #131 - CK testing performed on 07/26/18 (bbbbbb) Patient #132 - CMP, Amylase testing performed on 07/26/18 (cccccc) Patient #133 - CMP testing performed on 07/27/18 (dddddd) Patient #134 - CMP, LP testing performed on 07/27/18 (eeeeee) Patient #135 - CMP testing performed on 07 /29/18 (ffffff) Patient #136 - Magnesium testing performed on 07/30/18 (gggggg) Patient #137 - CMP, Amylase testing performed on 07/30/18 (hhhhhh) Patient #138 - Uric Acid testing performed on 07/30/18 (iiiiii) Patient #139 - CMP testing performed on 07/31/18 *BMP (Basic Metabolic Panel): BUN, Calcium, Creatinine, Glucose, Chloride, CO2, Potassium, Sodium *CMP (Comprehensive Metabolic Panel) - BUN, Calcium, Creatinine, Glucose, Chloride, CO2, Potassium, Sodium, Albumin, ALT, AST, Alkaline Phosphatase, Total Bilirubin, and Total Protein *LP (Lipid Panel) - Cholesterol, HDL Cholesterol, Triglyceride *Liver Profile - ALT, AST, Alkaline Phosphatase, Total Bilirubin, and Direct Bilirubin NOTE: D2015 was cited at the previous recertification survey performed 09/19/16-09/22/16.
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 and testing person #7, the laboratory failed to perform a negative and a positive control each day of patient testing. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor C. diff (Clostridium difficile) testing was performed on stool samples using the Alere C. diff QuikChek test kit; (2) On the third day of the survey, the laboratory manager stated to the surveyor: (a) The laboratory tested a negative and a positive QC (Quality Control) material every 30 days or when a new

	lot number of test kit was opened; (b) The laboratory did not have an IQCP (Individualized Quality Control Plan) in place for C. diff testing using the test kit. (3) The surveyor reviewed the C. diff QC and patient testing logs from 11/01/17 through 12/20/18. The review indicated a negative and a positive QC material had not been tested on 13 of the 13 days of patient testing; (4) The surveyor reviewed the findings with the laboratory manager and testing person #7 and explained a negative and a positive control material is required to be tested on each day of patient testing, or the laboratory must develop and implement an IQCP to reduce the frequency of QC performance; (5) Patient C. diff testing performed when the laboratory failed to perform a negative and a positive QC material each day of patient testing, follows: (a) Patient #149: Testing performed on 11/07/17 (b) Patient #150: Testing performed on 11/19/17 (c) Patient #151: Testing performed on 11/24/17 (d) Patient #152: Testing performed on 02/10/18 (e) Patient #153: Testing performed on 05/09/18 (f) Patient #154: Testing performed on 06/01/18 (g) Patient #155: Testing performed on 06/18 /18 (h) Patient #156: Testing performed on 07/09/18 (i) Patient #157: Testing performed on 08/26/18 (j) Patient #158: Testing performed on 09/19/18 (k) Patient #159: Testing performed on 11/27/18 (l) Patient #160: Testing performed on 11/27/18 (m) Patient #161: Testing performed on 12/01/18 (n) Patient #162: Testing performed on 12/01/18 (o) Patient #163: Testing performed on 12/18/18 NOTE: D5449 was cited at the previous recertification survey performed 09/19/16-09/22/16.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and the laboratory manager, the laboratory failed to ensure corrective action had been taken when function checks were unacceptable. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory replaced the Dimension Xpand analyzer on 10/01/18 with the Dimension ExL 200 analyzer. Examples of the testing performed on the new analyzer included the following: (a) Albumin (b) Creatinine Kinase (c) Digoxin (d) Serum Quantitative Pregnancy (e) Glucose (f) Potassium (g) Troponin I (h) Thyroid Stimulating Hormone (i) Uric Acid (2) The surveyor then reviewed the manufacturer's instructions (operator's manual) for performing daily function checks on the analyzer. The manufacturer required the cuvette temperatures be read and documented each day. In addition, the manufacturer's acceptable cuvette temperature range was 36.8 to 37.2 degrees C (Centigrade); (3) The surveyor then reviewed the cuvette temperature records from 10/01/18 through 12/19/18 and identified the temperature was beyond the manufacturer's acceptable limit on 39 of the 80 days reviewed. The specific findings follow: (4) From the review, the surveyor identified either unacceptable temperatures were documented or the cuvette temperature had not been documented

	during 3 of the 3 months reviewed, as follows: (a) 10/01/18-10/31/18: (i) The cuvette temperature was unacceptable on 7 of the 27 days documented: Days 17,18, 19,20,21,22,24 (ii) In addition, the cuvette temperature had not been documented on 4 of 31 days: Days 1,15, 25,31 (b) 11/01/18-11/30/18: (i) The cuvette temperature was unacceptable on 21 of 30: Days 2,3,4,5,8,9,10,12,14,15, 16,20,21,22,23,24,25,26,27,28,29 (c) 12/01/18 - 12/19/18: The cuvette temperature was unacceptable on 8 of 19 days: Days 4,5,6,7, 8,9,10,15 (5) The surveyor could not locate documentation that corrective action (e.g. recheck temperature, calibrate cuvettes, etc.) had been taken for the unacceptable temperatures listed above, or for the failure to document the temperature each day; (6) The surveyor reviewed the findings with the technical consultant and the laboratory manager, who stated to the surveyor, the laboratory did not take corrective action for the unacceptable cuvette temperatures listed above and did not take corrective action for the failure to document the cuvette temperature each day. NOTE: D5781 was cited at the previous recertification survey performed 09/19/16-09/22/16.
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, manufacturer's instructions, written policies and procedures, and interview with the technical consultant, laboratory manager, and testing person #7, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) The laboratory failed to follow its written policy and procedure. Refer to D5401; (2) The laboratory failed to follow the manufacturer's instructions for implementing reagents. Refer to D5411; (3) The laboratory failed to verify the reference intervals used for a new test method were appropriate for the patient population serviced by the laboratory. Refer to D5421; (4) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (5) The laboratory failed to ensure function checks were within the manufacturer's acceptable limits before patient testing was conducted. Refer to D5431; (6) The laboratory failed to have control procedures able to detect immediate errors and monitor over time the accuracy and precision of test performance. Refer to D5441; (7) The laboratory failed to perform a negative and a positive control each day of patient testing. Refer to D5449; (8) The laboratory failed to ensure corrective action was taken for unacceptable function checks. Refer to D5781. NOTE: D5791 was cited at the previous recertification survey performed 09 /19/16-09/22/16.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on a review of records, written policy and procedure, and interview with the laboratory manager and testing person #7, the laboratory failed to make appropriate reference ranges available. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the ACL Elite coagulation analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ration) testing. (The INR was calculated using the PT reference interval mean); (2) On the third day of the survey, the surveyor identified HemosIL RecombiPlasTin 2SG reagent, Lot #N0688929 was in use for PT testing. The surveyor then reviewed the lot rollover records from 11/13/18-11/28/18. The following was identified: (a) The reagent was put into use on 11/30/18; (b) The laboratory established a normal reference interval (normal reference range) of 9.6-13.8 seconds for PT testing during the lot rollover study. (3) The surveyor then reviewed 1 patient PT/INR test report (Patient #142-testing performed 12/20/18 at 16:29 PM). The test report included the normal reference interval for PT results of 9.1-12.3, which did not match the reference interval established by the laboratory during the lot rollover study of the new PT reagent; (4) The surveyor reviewed the findings with the laboratory manager and testing person #7. Both stated to the surveyor the established normal reference interval for PT included on the patient report did not match the normal reference interval established by the laboratory for PT testing during the lot rollover study of the new PT reagent. NOTE: D5807 was cited at the previous recertification survey performed 09 /19/16-09/22/16.
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 technical consultant, laboratory manager, and testing person #7, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure patient reference ranges had been verified for a new test system. Refer to D6013; (2) The laboratory director failed to ensure testing persons performed test methods as required for accurate and reliable results. Refer to D6014; (3) The laboratory director failed to ensure proficiency samples were tested as required under Subpart H. Refer to D6016; (4) The laboratory director failed to ensure proficiency results were reviewed and evaluated. Refer to D6018; (5) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (6) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (7) The laboratory director failed to ensure appropriate reference ranges were available. Refer to D6026; (8) The laboratory director failed to ensure testing persons followed the laboratory's written policy and procedure as required for accurate and reliable results. Refer to D6031. NOTE: D6000 was cited on the previous recertification survey performed 09/19/16-09 /22/16.
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, manufacturer's instructions, and interview with the technical consultant and the laboratory manager, the laboratory director failed to ensure verification procedures for a new test system were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure patient reference ranges had been verified for a new test system. Refer to D5421. NOTE: D6013 was cited at the previous recertification survey performed 09 /19/16-09/22/16.
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 and testing person #7, the laboratory director failed to ensure testing persons performed test methods as required for accurate and reliable results. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for implementing reagents. Refer to D5411. NOTE: D6014 was cited at the previous recertification survey performed 09/16/16-09/22/16.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant and the laboratory manager, the laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H. Findings include: ATTESTATION

	STATEMENTS SIGNED AFTER SAMPLES TESTED (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. It was identified for 10 of the 12 events reviewed, the attestation statements had been signed approximately 1-4 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 2018 Core Chemistry Event: The samples were tested on 02/07/18 and the attestation statement had not been signed by the laboratory director until 06/06/18; (b) First 2018 Hematology/Coagulation Event: The samples were tested on 03/26/18 and the attestation statement had not been signed by the laboratory director until 06/06/18; (c) First 2018 Microbiology Event: The samples were tested on 03/05/18 and the attestation statement had not been signed by the laboratory director until 06/06/18; (d) First 2018 Miscellaneous Chemistry Event: The samples were tested on 05/03/18 and the attestation statement had not been signed by the laboratory director until 06/06/18; (e) Second 2018 Hematology/Coagulation Event: The samples were tested on 07/23/18 and the attestation statement had not been signed by the laboratory director until 08/01/18; (f) Second 2018 Microbiology Event: The samples were tested on 07/02/18 and the attestation statement had not been signed by the laboratory director until 08/01/18. (2) The surveyor reviewed the findings with the technical consultant and the laboratory manager, and explained the attestation statement must be signed to definitively attest to the fact proficiency samples were tested in the same manner as patient specimens. ATTESTATION STATEMENTS NOT SIGNED BY LABORATORY DIRECTOR OR QUALIFIED DESIGNEE (1) The laboratory director or a qualified designee failed to sign proficiency testing attestation statements. Refer to D2015.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant and the laboratory manager, the laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify problems that require corrective action. Findings include: (1) The laboratory director failed to ensure proficiency testing results were reviewed and evaluated. Refer to D5211; (2) The laboratory director failed to ensure the accuracy of testing when the proficiency testing program did not evaluate submitted results. Refer to D5215.
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, manufacturer's instructions, and interview with the technical consultant, laboratory manager, and testing person #7, the laboratory director failed to ensure a quality control program was established and maintained to assure the quality of laboratory services provided by the laboratory. Findings include: (1) The laboratory director failed to ensure maintenance procedures were performed and documented. Refer to D5429; (2) The laboratory director failed to ensure function checks were acceptable before patient testing was performed. Refer to D5431; (3) The laboratory director failed to ensure control procedures had been put into place that would detect immediate errors and monitor over time the accuracy and precision of test performance. Refer to D5441; (4) The laboratory director failed to ensure a negative and a positive quality control material was tested each day of patient testing. Refer to D5449; (5) The laboratory director failed to ensure corrective action was taken when the manufacturer's specifications had not been met. Refer to D5781. NOTE: D6020 was cited at the previous recertification survey performed 09/19/16-09 /22/16.
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, manufacturer's instructions, written policies and procedures, and interview with the technical consultant, laboratory manager, and testing person #7, the laboratory failed to ensure an effective quality assessment program had been established and maintained to assure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure the laboratory had an effective quality assessment program due to the issues identified during the survey. Refer to D5791. NOTE: D6021 was cited at the previous recertification survey performed 09/19/16-09/22/16.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation.

	This STANDARD is not met as evidenced by: Based on a review of records, written policy and procedure, and interview with the laboratory manager and testing person #7, the laboratory failed to ensure appropriate reference ranges were available. Findings include: (1) The laboratory director failed to ensure appropriate reference ranges were available. Refer to D5807. NOTE: D6026 was cited at the previous recertification survey performed 09/19/16-09/22/16.
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 records, written policy and procedure, and interview with the laboratory manager and testing person #7, the laboratory director failed to ensure testing persons followed the laboratory's written policy and procedure as required for accurate and reliable results. Findings include: (1) The laboratory failed to follow its policy and procedure for performing manual WBC differentials. Refer to D5401. NOTE: D6031 was cited at the previous recertification survey performed 09/16/16-09 /22/16.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant and laboratory manager, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure that individuals who performed the duties and responsibilities of a technical consultant met the required qualifications. Refer to D6035; (2) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042. NOTE: D6033 was cited at the previous recertification survey performed on 09/19/16-09/22 /16.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant and laboratory manager, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) On the first day of the survey, the surveyor reviewed records for 13 individuals who performed moderate complexity testing and identified competency assessments had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Annual competency: (i) Testing person #2 - The 12/13/18 evaluation had been performed by the laboratory manager (this person obtained an HEW certification); (ii) Testing person #4 - The 11/27/17 and the 12/15/18 evaluations had been performed by the laboratory manager; (iii) Testing person #5 - The 06/22/18 evaluation had been performed by the laboratory manager; (iv) Testing person #6 - The 11/16/17 and the 12/06/18 evaluations had been performed by the laboratory manager; (v) Testing person #8 -The 12/11/18 evaluation had been performed by the laboratory manager; (vi) Testing person #11 - The 11/30/18 evaluation had been performed by the laboratory manager; (vii) Testing person #13 - The 01/25/18 evaluation had been performed by the laboratory manager. (b) Semi-annual competency: (i) Testing person #8 - The 03/30/18 evaluation had been performed by the laboratory manager; (ii) Testing person #9 - The 06/25/18 evaluation had been performed by the laboratory manager; (iii) Testing person #13 - The 06/15/18 evaluation had been performed by the laboratory manager. (2) The findings were reviewed with the technical consultant and the laboratory manager, who stated to the surveyor the competency evaluations listed above had been performed by the laboratory manager who did not meet the

	qualifications of the technical consultant. NOTE: D6033 was cited at the previous recertification survey performed on 09/19/16-09/22/16.
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, written policies and procedures, and interview with the technical consultant, laboratory manager, and testing person #7, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure testing persons followed the laboratory's written policy and procedure as required for accurate and reliable results. Refer to D5401; (2) The technical consultant failed to ensure the laboratory followed the manufacturer's instructions for implementing reagents. Refer to D5411; (3) The technical consultant failed to ensure the laboratory verified the reference intervals used for a new test method as appropriate for the patient population serviced by the laboratory. Refer to D5421; (4) The technical consultant failed to ensure the laboratory performed maintenance procedures as required by the manufacturer. Refer to D5429; (5) The technical consultant failed to ensure the laboratory verified function checks were acceptable before patient testing was conducted. Refer to D5431; (6) The technical consultant failed to ensure the laboratory had control procedures able to detect immediate errors and monitor over time the accuracy and precision of test performance. Refer to D5441; (7) The technical consultant failed to ensure the laboratory performed a negative and a positive control each day of patient testing. Refer to D5449; (8) The technical consultant failed to ensure the laboratory took corrective action for unacceptable function checks. Refer to D5781. NOTE: D6042 was cited at the previous recertification survey performed 09/19/16-09/22/16.