Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472320	10/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mangum Regional Medical Center	1 Wickersham Drive, Mangum, 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 10/08/18 to 10/12/18. The laboratory was found out of compliance with the following CLIA regulations: 493.1213: D5024: Condition: Hematology 493.1230: D5200: Condition: General Laboratory Systems 493.1250: D5400: Condition: Analytic Systems 493.1403: D6000: Condition: Laboratory Director Moderate Complexity 493.1409: D6033: Condition: Technical Consultant 493.1441: D6076: Condition: Laboratory Director High Complexity The findings were reviewed with the corporate officers and the laboratory manager at the conclusion of the survey.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to examine blood cell identification proficiency testing in the same manner as patient specimens. Findings include: (1) On the first day of the survey, the laboratory manager verified the laboratory routinely performed manual WBC (White Blood Cell) differential testing; (2) The surveyor reviewed proficiency testing records for 5 hematology testing events performed in 2017 and 2018. The records indicated the following for Blood Cell Identification (i.e. WBC differential): (a) Second 2017 Event: (i) Documentation found in the records indicated the 5 blood cell identification

	challenge pictures had been viewed by 4 testing persons (testing persons #1 and #3, and previous testing persons #9 and #11) before the results were submitted to the proficiency testing program. (b) First 2018 Event: (i) Documentation found in the records indicated the 5 blood cell identification challenge pictures had been viewed by 5 testing persons (testing persons #1, #2, #3, and #4 and previous testing person #10) before the results were submitted to the proficiency testing program. (c) Second 2018 Event: (i) Documentation indicated the 5 blood cell identification challenge pictures had been viewed by 5 testing persons (testing persons #1, #2, #3, #5 and #8, and by previous testing person #10) before the results were submitted to the proficiency testing program. (3) On the third day of the survey, the surveyor reviewed the findings with the laboratory manager, who confirmed blood cell identification challenge proficiency testing pictures were routinely reviewed by all available testing persons. The final result was selected from the majority of answers given by the testing persons. In addition, the laboratory manager confirmed it was the laboratory's practice for one testing person to perform patient manual differentials.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory 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); (2) The following was identified for 8 of the 8 events reviewed from 2018: (a) Second 2018 Core Chemistry Event: (i) The attestation form was signed by the laboratory manager who earned an Associate of Applied Science degree in medical laboratory science, which did not meet the educational requirements of a Technical Consultant or a Laboratory Director for moderate complexity testing. (b) Third 2018 Microbiology Event: (i) The attestation form was signed by the laboratory manager who did not qualify as a Technical Consultant or a Laboratory Director for moderate complexity testing. (3) The surveyor explained to 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."
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies and procedures, FDA database, information provided by the manufacturer's distributor, correspondence with the CMS Central Office FDA liaison, observation, and interview with the laboratory manager and testing person #3, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to ensure a written policy included the correct normal patient reference range established by the laboratory for the CA-660 and failed to include a written procedure for twice per year accuracy verification of Bleeding Time testing. Refer to D5403; (2) The laboratory failed to follow the manufacturer's instructions for implementing the Sysmex CA-660 analyzer. Refer to D5411; (3) The laboratory failed to label and store testing materials appropriately. Refer to D5415; (4) The laboratory failed to establish the performance specifications of precision, reportable range, analytical sensitivity, and analytical specificity, and establish the reference interval for an Erythrocyte Sedimentation Rate test system, not cleared or approved by the FDA. Refer to D5423; (5) The laboratory failed to ensure the manufacturer's required maintenance procedures had been performed for the Sysmex XN-550 and the CA-660 analyzers. Refer to D5429; (6) The laboratory failed to have control procedures that detected immediate errors and monitored the accuracy and precision of the analytic process of CBC testing. D5441; (7) The laboratory failed to follow the manufacturer's quality control specifications for ESR testing. Refer to D5479; (8) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791; (9) The laboratory failed to make appropriate reference ranges available for coagulation testing. Refer to D5807.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 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, and interview with the laboratory manager, the laboratory failed to monitor and evaluate the overall quality of general laboratory systems. Findings include: (1) The laboratory failed to have a written competency policy that explained each component required for assessment of the competency of testing persons. Refer to D5209; (2) The laboratory failed to

	review and evaluate proficiency testing results. Refer to D5211; (3) The laboratory failed to have an ongoing mechanism for performing general laboratory systems quality assessment. Refer to D5291.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures and interview with the laboratory manager, the written policy and procedure for assessing employee competency failed to include the six required procedures. Findings include: (1) On the first day of the survey, the surveyor reviewed the laboratory's "Competency and Orientation Plan." The policy did not include the six required procedures to assess testing person competency; (2) The surveyor asked the laboratory manager if the laboratory had a policy in place which explained how the laboratory assessed the competency of testing personnel and included the following components as part of a competency evaluation: (a) Direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing, required at 493.1413(b)(8)(i). Refer to D6047; (b) Monitoring the recording and reporting of test results, required at 493.1413(b)(8)(ii). Refer to D6048; (c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records, required at 493.1413(b)(8)(iii). Refer to D6049; (d) Direct observation of performance of instrument maintenance and function checks, required at 493.1413(b)(8)(iv). Refer to D6050; (e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples, required at 493.1413(b)(8)(v). Refer to D6051; (f) Assessment of problem solving skills, required at 493.1413(b)(8)(vi). Refer to D6052. (3) The laboratory manager stated to the surveyor the laboratory's written policy did not include the six required components listed above to assess testing person competency. NOTE: For non-waived testing, the regulations require initial training, a semiannual evaluation during the first year, and an annual evaluation thereafter for each testing person for ensuring competency.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to 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. The following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) were identified: (a) First 2018 Chemistry Core Event (i) Amylase: 3 of 5 results exhibited a Negative bias (aa) CH-01: SDI -2.5 (bb) CH-02: SDI -2.0 (cc) CH-

	05: SDI -2.4 (ii) Myoglobin: 4 of 5 results exhibited a Negative bias (aa) CM-01: SDI -2.4 (bb) CM-02: SDI -1.9 (cc) CM-03: SDI -2.0 (dd) CM-04: SDI -1.9 (iii) Troponin T: 3 of 5 results exhibited a Negative bias (aa) CM-02: SDI -2.0 (bb) CM-04: SDI -2.5 (cc) CM-05: SDI -2.4 (In addition, the result was unacceptable) (iv) Total Cholesterol: 3 of 5 results exhibited a Negative bias (aa) CH-01: SDI -1.9 (bb) CH-02: SDI -2.1 (cc) CH-05: SDI -2.4 (b) First 2018 Miscellaneous Chemistry Event (i) ALT (Alanine Aminotransferase): 3 of 5 results exhibited a Negative bias (aa) CH-11: SDI -3.1 (bb) CH-12: SDI -2.3 (cc) CH-14: SDI -2.4 (c) Second 2017 Chemistry Core Event (i) Amylase: 5 of 5 results exhibited a Negative bias (aa) CH-06: SDI -2.2 (bb) CH-07: SDI -2.0 (cc) CH-08: SDI -2.0 (dd) CH-09: SDI -2.8 (ee) CH-10: SDI -2.3 (2) There was no documentation found in the records the laboratory identified the biases and took corrective action (e.g., review quality control record, maintenance records, calibration, etc.) to determine the cause or to determine if a systematic failure had occurred; (3) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor the biases had not been thoroughly investigated. NOTE: D5211 was cited at the previous recertification survey performed on 11/29/16 to 12/02/16.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the laboratory manager, the laboratory failed to monitor and evaluate the overall quality of general laboratory systems. Findings include: (1) The laboratory failed to have a written employee competency policy that explained each component required for competency assessment of testing persons. Refer to D5209; (2) The laboratory failed to review and evaluate proficiency testing results. Refer to D5211.
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, FDA database, information provided by the manufacturer's distributor, correspondence with the CMS Central Office FDA liaison, observation, and interview with the laboratory manager and testing person #3, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (2) The laboratory failed to ensure function checks

	were within the manufacturer's acceptable limits before patient testing was conducted. Refer to D5431; (3) The laboratory failed to perform a negative and a positive control each day of patient testing. Refer to D5449; (4) The laboratory failed to comply with 21 CFR 606.160(b)(3)(ii). Refer to D5553; (5) The laboratory failed to ensure units of blood were stored under appropriate conditions. Refer to D5555; (6) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of records, written policies and interview with the laboratory manager and testing person #3, the laboratory failed to ensure the laboratory's written policy included the correct normal patient reference range established by the laboratory for a new test method, and the laboratory failed to have a written procedure for verification of the testing accuracy of a non-regulated analyte. Findings include: NORMAL REFERENCE INTERVAL (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory put the CA 660 coagulation analyzer into use on 11/28/17 to perform PT/INR (Prothrombin Time/International Normalized Ratio) testing; (2) On the third day of the survey, the surveyor reviewed implementation records for the new analyzer. The surveyor identified the laboratory established a normal reference interval (normal reference range) for PT testing of 9.3-11.4 seconds; (3) The surveyor then compared the laboratory's normal reference interval for PT testing in the laboratory's written policy with the range established during the implementation of the analyzer. The written policy included a normal reference interval of 9.3-10.5; (4) The surveyor reviewed the findings with the laboratory manager and testing person #3, who stated the laboratory failed to ensure the procedure manual had been updated with the PT normal reference interval established by the laboratory during the implementation of the new analyzer. ACCURACY VERIFICATION (1) On the first day of the survey, the surveyor reviewed the test menu from the previous recertification survey performed 11/29/16 - 12/02/16 with the laboratory's current test menu and identified the laboratory had not listed Bleeding Time testing as a current test. The surveyor asked the laboratory

	manager if Bleeding Time testing was performed by the laboratory. The laboratory manager stated to the surveyor, Bleeding Time testing would be performed if requested but the test had not been performed since 01/18/18; (2) The surveyor then asked the laboratory manager if the laboratory had a method to verify the accuracy of Bleeding Time testing twice annually. (Because Bleeding Time testing is not a regulated analyte, twice per year accuracy verification is required.) The laboratory manager stated to the surveyor the laboratory did not have a method to verify the accuracy and did not have a written policy and procedure for the twice per year accuracy verification. NOTE: D5403 was cited at the previous recertification survey performed on 11/29/16 to 12/02/16.
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 #3, the laboratory failed to follow the manufacturer's instructions for the testing performed. Findings include: (1) On the third day of the survey, the surveyor reviewed the manufacturer's installation and implementation instructions for establishing reference intervals (normal reference ranges) for PT/INR, PTT (Prothrombin Time), and D-Dimer testing performed on the new CA 660 coagulation analyzer (the manufacturer required the establishment of reference intervals with a new analyzer). The manufacturer referred the reader to CLSI C28-A3c for information about establishing a reference interval, which stated, "As indicated in this document, the working group endorses its previous recommendation that the best means to establish a reference interval is to collect samples from a sufficient number of qualified reference individuals to yield a minimum of 120 samples for analysis, by nonparametric means, for each partition (e. g. sex, age range)." In addition, the manufacturer required the following for establishing normal reference intervals: (a) "Donors must be from a healthy population (no known pathological conditions; no presurgical or hospital patients.);" (b) "Donors should not take any medications, including aspirin;" (c) "Donors within a reasonably even distribution of males and females should be included;" (d) "Donors should span the adult range (NOTE: A separate range should be established for pediatric populations. The FDA defines 'pediatric' up to 21 years of age.);" (e) "Calculate mean and 2 SD range;" (f) "MNPT for INR calculation must be the geometric mean." (2) The surveyor then reviewed the laboratory's reference interval study included in the implementation records for the new analyzer. The surveyor identified the following for PT, PTT, and D-Dimer testing: (a) The reagent lot numbers used at implementation of the new analyzer: (i) PT Reagent: PT Innovin, Lot #569709 (ii) PTT Reagent: Actin FSL, Lot #556917 (iii) D-Dimer Reagent: Innovance D-Dimer, Lot #46092 (b) The reference intervals were established as follows: (i) PT and PTT: (aa) The laboratory utilized 20 donors (10 male and 10 female) (instead of the 120 donors as required for establishment studies for a new analyzer); (bb) There was no evidence found in the records of the health status of the donors (i.e. healthy, with no pathological conditions, patient status-presurgical or hospital inpatient); (cc) There was no evidence found in the records of the medication

	history of the donors. (ii) D-Dimer: (aa) The laboratory utilized 18 donors (9 male and 9 female) (instead of the 120 donors as required for establishment studies for a new analyzer); (bb) There was no evidence found in the records of the health status of the donors (i.e. healthy, with no pathological conditions, patient status-presurgical or hospital inpatient); (cc) There was no evidence found in the records of the medication history of the donors. (3) The surveyor reviewed the findings with the laboratory manager and testing person #3 and asked for additional documentation (i.e. health status, medications, patient status) for the donors utilized in the study. The laboratory manager and testing person #3 stated to the surveyor the health status and the medication histories of the donors had been documented but the documentation could not be located. In addition, a 120 donor sample study for establishment of the normal reference intervals as required by the manufacturer had not been performed. (The surveyor discussed this with the laboratory manager following the survey.); (4) For examples of PT and D-Dimer patient testing performed when the laboratory failed to follow the manufacturer's requirements for establishment of the reference intervals for the new analyzer, see above; (5) Examples of PTT testing performed when the laboratory failed to follow the manufacturer's requirements for establishment of the reference interval for the new analyzer, include the following: (a) Patient #8: Testing performed on 02/21/18 (b) Patient #18: Testing performed on 05/13/18 (c) Patient #57: Testing performed on 07/01/18 (d) Patient #58: Testing performed on 07/20/18 (e) Patient #59: Testing performed on 10/09/18 NOTE: D5411 was cited on the previous recertification survey performed 11/29/16-12/02/16.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager and testing person #3, the laboratory failed to label testing materials appropriately. Findings include: (1) On the first day of the survey, the laboratory manager verified the laboratory put the CA-660 analyzer into use on 11/28/17 to perform PT/INR (Prothrombin Time /International Normalized Ratio) testing; (2) On the fourth day of the survey, the surveyor observed the contents of the H/C True laboratory refrigerator and identified a small, unlabeled glass bottle stored in the refrigerator; (3) The surveyor asked testing person #3 to identify the contents of the small bottle. Testing person #3 explained the small glass bottle was filled with Innovin, the reagent used in PT/INR testing. The small bottle of Innovin was placed on the analyzer during a patient run to keep the larger reagent bottle refrigerated; (4) The surveyor explained to the laboratory manager and testing person #3, reagents, solutions, control materials, or other testing materials must be labeled to indicate the identity, concentration, storage requirements, preparation and expiration dates, and any other information required for proper use; (5) The laboratory manager and testing person #3 agreed the laboratory failed to ensure the bottle had been labeled appropriately with the identity, concentration, storage requirements, preparation and expiration dates, and any other information required for the proper use of the contents.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on a review of records, FDA database, information provided by the manufacturer's distributor, correspondence with the CMS Central Office FDA liaison, and interview with the laboratory manager, the laboratory failed to establish the performance specifications of precision, reportable range, analytical sensitivity, analytical specificity, and reference interval for an Erythrocyte Sedimentation Rate test system, not cleared or approved by the FDA. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor ESR (Erythrocyte Sedimentation Rate) testing was performed using the Diesse Mini-Cube analyzer; (2) On the second day of the survey, the laboratory manager stated the laboratory began patient testing on 07/03/18; (3) The surveyor attempted to verify the classification of the test system. Since classification of test systems are performed by the FDA (Food and Drug Administration), the surveyor reviewed the FDA test classification database. The database did not include a classification for the test system (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test to high complexity); NOTE: Previous to this survey, the state agency contacted the CMS Dallas Regional Office regarding the analyzer encountered at another facility. The CMS Regional Office in turn contacted the CMS Central Office FDA liaison for confirmation of the classification of the test system. On 08/03/18, the state agency received an email from the CMS Central Office FDA liaison confirming that, if the test was not listed on the FDA CLIA database, then it was a high complexity test and the FDA had not automatically classified all automated ESR test systems as moderate complexity; (4) The surveyor explained to the laboratory manager the previous decision of the CMS Central Office FDA liaison concerning the analyzer and explained the test system was not cleared or FDA approved and was therefore, classified as high complexity, which required the laboratory to establish the performance specifications of precision, reportable range, analytical sensitivity, and analytical specificity, and reference interval (normal range). The laboratory manager contacted the manufacturer's distributor. The manufacturer's distributor provided an email that stated the analyzer was considered moderately complex, because the FDA had classified all ESR analyzers as moderately complex testing. The surveyor reviewed the previous findings of the CMS Central Office FDA liaison that the Diesse Mini-Cube analyzer was not classified as moderately complex; (5) The surveyor then reviewed implementation records for the analyzer. Although the laboratory had performed a comparison of patient testing (i.e. accuracy) with the new test system against the previous automated ESR analyzer, there was no evidence the precision, analytical sensitivity, analytical specificity, and reference intervals had been established; (6) The surveyor reviewed the validation records with the laboratory

	manager who stated there was no documentation to prove the precision, analytical sensitivity, analytical specificity, and reference intervals had been established; (7) The following were examples of patient ESR testing performed using the Diesse Mini-cube ESR analyzer: (a) Patient #1: Testing performed on 07/05/18 (b) Patient #2: Testing performed on 07/08/18 (c) Patient #3: Testing performed on 07/26/18 (d) Patient #4: Testing performed on 07/30/18 (e) Patient #5: Testing performed on 08/14 /18 (f) Patient #6: Testing performed on 08/15/18 (g) Patient #7: Testing performed on 08/16/18 (h) Patient #9: Testing performed on 08/20/18 (i) Patient #10: Testing performed on 08/30/18 (j) Patient #11: Testing performed on 09/04/18 NOTE: D5423 was cited on the previous recertification survey performed 11/29/16-12/02/16.
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 #3, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: SYSMEX XN-550 (1) On the first day of the survey, the laboratory manager stated to the surveyor the Sysmex XN-550 hematology analyzer was put into use on 11/15/17 to perform CBC (Complete Blood Count) (i.e., WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) testing; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance instructions for the analyzer, which were: (a) Daily: Perform shutdown of the analyzer (b) Weekly: Perform routine cleaning (3) Maintenance records from 12/01/17 through 09 /30/18 were reviewed by the surveyor. The surveyor identified the following: (a) Daily: The daily maintenance had not been performed on 4 of the 243 days reviewed during the review period: (i) 01/20/18 (ii) 01/21/18 (iii) 09/07/18 (iv) 09/24/18 (b) Weekly: The weekly maintenance had not been performed during 2 of the 10 months reviewed, as follows: (i) Between 03/27/18 and 04/10/18 (ii) Between 04/10/18 and 04 /24/18 (4) The surveyor reviewed the findings with the laboratory manager and testing person #3. Both stated there was no documentation the manufacturer's required maintenance procedures had been performed, as listed above; (5) Examples of CBC patient testing performed when the manufacturer's required maintenance procedures had not been performed, include the following: (a) Patient #12: Testing performed on 01/21/18 (b) Patient #13: Testing performed on 01/21/18 (c) Patient #14: Testing performed on 01/21/18 (d) Patient #15: Testing performed on 01/21/18 (e) Patient #16: Testing performed on 09/07/18 (g) Patient #17: Testing performed on 09/24/18 (h) Patient #19: Testing performed on 09/24/18 (i) Patient #20: Testing performed on 09/24/18 (j) Patient #21: Testing performed on 02/23/18 (k) Patient #22: Testing performed on 02/23/18 (l) Patient #23: Testing performed on 02/26/18 (m) Patient #24: Testing performed on 02/26/18 (n) Patient #25: Testing performed on 02/27/18 (o) Patient #26: Testing performed on 02/28/18 (p) Patient #27: Testing performed on 03/07/18 (q) Patient #28: Testing performed on 03/13/18 (r) Patient #29: Testing performed on 03/14/18 (s) Patient #30: Testing performed on 03/31/18 (t) Patient #31: Testing performed on 04/02/18 (u) Patient #32: Testing performed on 04/09/18 COBAS INTEGRA 400 (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed testing on the Cobas Integra 400

analyzer until 07/31/18, when it was replaced with the Dimension EXL 200 chemistry analyzer. Examples of the testing performed on the Cobas Integra 400 analyzer, included Acetaminophen, Alcohol, Digoxin, Dilantin, Albumin, Amylase, CK (Creatinine Kinase), Glucose, Lipase, Uric Acid, Total Bilirubin, Total Cholesterol, Hemoglobin A1C, D-Dimer, etc.); (2) On the third day of the survey, the surveyor reviewed the manufacturer's required weekly maintenance procedure, as recorded on the "Cobas Integra 400/400 plus Analyzer" maintenance log, which were: (a) Clean probes and splash guard (b) Clean ISE tower automatically (c) Back up database (3) Maintenance logs from 01/01/17 through 07/31/18 were reviewed. The surveyor identified the weekly maintenance had not been performed during 3 of the 19 months reviewed: (a) Between 07/06/17 and 07/15/17 (b) Between 07/15/17 and 07/27/17 (c) Between 07/27/17 and 08/07/17 (d) Between 01/08/18 and 01/22/18 (4) The surveyor reviewed the findings with the laboratory manager and testing person #3. Both stated there was no documentation on the logs which proved the manufacturer's required maintenance procedures had been performed, as listed above; (5) An example of patient testing performed when the manufacturer's required maintenance procedures had not been performed: Patient #33: Testing performed on 07/08/17. COBAS E411 (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed the following testing on the Cobas e411 analyzer, until it was replace by the Dimension EXL 200 analyzer on 07/31/18. Examples of the testing performed on the Cobas Integra 400 analyzer, included PBNP (B-Type Natriuretic Peptide), CKMB (Creatinine Kinase Myocardial fraction), Quantitative Serum pregnancy, Total PSA (Prostate Specific Antigen), T3, T4, TSH (Thyroid Stimulating Hormone), and Troponin, etc.); (2) On the third day of the survey, the surveyor reviewed the manufacturer's required maintenance procedures, as recorded on the "Cobas e411 analyzer Maintenance Log." The manufacturer required the following maintenance procedures be performed: (a) Daily: (i) Clean S/R (Specimen/Reagent) probe (ii) Check condensation inside reagent rotor and system reagent compartments (iii) Finalization (Daily, if the analyzer does not automatically enter finalization during the course of the day.) (b) Weekly: (i) Clean incubator and aspiration station (ii) Clean sipper probe (3) Maintenance logs from 01/01/17 through 07/31/18 were reviewed. The findings follow: (a) Daily: The manufacturer's daily maintenance procedures had not been performed as required : (i) Clean S/R probe, check condensation inside reagent rotor and system reagent compartments had not been performed during 3 of the 19 months reviewed: (aa) 06/01/17 (bb) 10/29/17 (cc) 12/20 /17 (ii) Check condensation inside reagent rotor and system reagent compartments had not been performed during 1 of the 19 months reviewed: (aa) 06/08/17 (bb) 06/09/17 (cc) 06/26/17 (dd) 06/29/17 (b) Weekly: The manufacturer's required weekly maintenance procedures had not been performed during 9 of the 19 months reviewed: (i) Between 01/27/17 and 02/07/17 (ii) Between 03/24/17 and 04/06/17 (iii) Between 10/23/17 and 11/06/17 (iv) Between 11/06/17 and 11/21/17 (v) Between 11/24/17 and 12/06/17 (vi) Between 01/08/18 and 01/22/18 (vii) Between 07/18/18 and 07/30/18 (4) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor there was no documentation on the logs the manufacturer's required maintenance procedures had been performed, as listed above. SYSMEX CA-660 (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory put the Sysmex CA-600 analyzer into use on 11/28/17 to perform PT/INR (Prothrombin Time/International Normalized Ratio), APTT (Activated Partial Thromboplastin Time), and D-dimer testing; (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The manufacturer required the following weekly maintenance procedure: (a) Clean instrument interior/exterior (3) The surveyor reviewed maintenance records from 12/01/17 through 09/30/18 for 10 months. There was no documentation on the

	maintenance log the weekly had been performed between 12/11/17 and 12/28/17; (4) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor there was no documentation on the log the manufacturer's required weekly maintenance procedure listed above had been performed; (5) Examples of patient testing when the laboratory failed to follow the manufacturer's required maintenance procedures, include the following: (a) Patient #34: D-Dimer testing performed on 12 /23/17 at 00:20 AM (b) Patient #35: PT/INR testing performed on 12/26/17 at 08:20 AM NOTE: D5429 was cited on the previous recertification survey performed 11/29 /16-12/02/16.
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 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 put the Dimension EXL 200 chemistry analyzer into use on 07 /31/18. Examples of the testing performed, include Acetaminophen, Alcohol, Digoxin, Dilantin, Albumin, Amylase, CK (Creatinine Kinase), Glucose, Lipase, Uric Acid, Total Bilirubin, Total Cholesterol, Hemoglobin A1C, D-Dimer, etc.; (2) On the third day of the survey, the surveyor reviewed the manufacturer's instructions for performing function checks on the 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 07/31/18 through 10/11/18 and identified the cuvette temperature was beyond the manufacturer's acceptable limit on 10 of the 73 days reviewed. The specific findings follow: (a) September: 6 of 30 cuvette temperature were unacceptable: (i) 36.4 degrees C - 1 of 30 temperatures: Day 30 (ii) 36.7 degrees C - 2 of 31 temperatures: Days 6,10 (iii) 37.3 degrees C - 3 of 30 temperatures: Days 12,16,17 (b) October: 4 of 31 cuvette temperatures were unacceptable: (i) 36.6 degrees C - 2 of 31 temperatures: Days 8,9 (ii) 36.7 degrees C - 2 of 31 temperatures: Days 6,10 (4) The surveyor reviewed the findings with the laboratory manager, who stated the temperatures had not been maintained as defined by the manufacturer. NOTE: D5431 was cited on the previous recertification survey performed 11/29/16-12/02/16.
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, manufacturer's instructions, and interview with the laboratory manager and testing person #3, the laboratory failed to have control procedures that detected immediate errors and monitored the accuracy and precision of the analytic process of CBC testing. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor, the laboratory performed CBC (Complete Blood Count) (WBC-White Blood Count), RBC-Red Blood Count, Hgb (Hemoglobin), Hct (Hematocrit), Platelet Count, etc.) testing using the Sysmex XN-550 hematology analyzer (put into use on 11/15/17). In addition, it was verified with the surveyor, the laboratory tested 3 levels (Level 1, Level 2, and Level 3) of Sysmex XN-L Check QC (Quality Control) materials each day of patient testing; (2) The surveyor reviewed the Sysmex XN-550 QC records from 9 QC lot numbers used from 11/15/17 through 5/19/18 for each level of QC material for the analytes WBC, RBC, Hgb, Hct, and Platelet count. The lot numbers reviewed were: (a) 11/15/17 to 01/31 /18: (i) Level 1: Lot #73001401 (ii) Level 2: Lot #73001402 (iii) Level 3: Lot #73001403 (b) 02/06/18 to 02/28/18 and 03/01/18 to 04/02/18: (i) Level 1: Lot #80191401 (ii) Level 2: Lot #80191402 (iii) Level 3: Lot #80191403 (c) 04/18/18 to 05/19/18: (i) Level 1: Lot #81031401 (ii) Level 2: Lot #81031402 (iii) Level 3: Lot #81031403 (3) For 6 of the 9 lot numbers listed above used, no control outliers were identified (approximately 1 out of every 20 control results should be defined as unacceptable and there were no results that were beyond the laboratory's established range) for the analytes listed above. In addition, the LJ (Levey Jennings) graphs indicated the following for the analytes: (a) 02/06/18 to 02/28/18 and 03/01/18 to 04 /02/18: (i) Level 1: Lot #80191401 (aa) WBC: The mean used was 2.47. The upper limit or +2SD (Standard Deviation) was 4.94 and the lower limit or -2SD was 0.00 (bb) RBC: The mean was 2.34. The upper limit was 4.68 and the lower limit was 0.00; (cc) Hgb: The mean was 6.3. The upper limit was 12.6 and the lower limit was 0.0; (dd) Hct: The mean was 17.7. The upper limit was 35.4 and the lower limit was 0.0; (ee) Platelet: The mean was 53. The upper limit was 106 and the lower limit was 0. (ii) Level 2, Lot #80191402 (aa) WBC: The mean was 6.98. The upper limit was 13.6 and the lower limit was 0.00; (bb) RBC: The mean was 4.22. The upper limit was 8.44 and the lower limit was 0.00; (cc) Hgb: The mean was 12.6. The upper limit was 25.2 and the lower limit was 0.0; (dd) Hct: The mean was 34.5. The upper limit was 69.0 and the lower limit was 0.0; (ee) Platelet: The mean was 221. The upper limit was 442 and the lower limit was 0. (iii) Level 3, Lot #80191403 (aa) WBC: The mean was 16.51. The upper limit was 33.02 and the lower limit was 0.00; (bb) RBC: The mean was 5.22. The upper limit was 10.44 and the lower limit was 0.00; (cc) Hgb: The mean was 17.0. The upper limit was 34.0 and the lower limit was 0.0; (dd) Hct: The mean was 45.6. The upper limit was 91.2 and the lower limit was 0.0; (ee) Platelet: The mean was 519. The upper limit was 1038 and the lower limit was 0. (b) 04/01/18 to 04/18/18: (i) Level 1: Lot #81031401 (aa) WBC: The mean used was 2.47. The upper limit was 4.94 and the lower limit was 0.00 (bb) RBC: The mean was 2.29. The upper limit was 4.58 and the lower limit was 0.00; (cc) Hgb: The mean was 5.9. The upper limit was 11.8 and the lower limit was 0.0; (dd) Hct: The mean was 17.1. The upper limit was 34.2 and the lower limit was 0.0; (ee) Platelet: The mean was 59. The upper limit was 118 and the lower limit was 0. (ii) Level 2, Lot #81031402 (aa) WBC: The mean was 7.07. The upper limit was 14.14 and the lower limit was 0.00; (bb)

	RBC: The mean was 4.39. The upper limit was 8.78 and the lower limit was 0.00; (cc) Hgb: The mean was 12.5. The upper limit was 25.0 and the lower limit was 0.0; (dd) Hct: The mean was 35.2. The upper limit was 70.4 and the lower limit was 0.0; (ee) Platelet: The mean was 242. The upper limit was 484 and the lower limit was 0. (iii) Level 3, Lot #81031403 (aa) WBC: The mean was 16.01. The upper limit was 32.02 and the lower limit was 0.00; (bb) RBC: The mean was 5.27. The upper limit was 10.54 and the lower limit was 0.00; (cc) Hgb: The mean was 16.5. The upper limit was 33.0 and the lower limit was 0.0; (dd) Hct: The mean was 45.1. The upper limit was 90.2 and the lower limit was 0.0; (ee) Platelet: The mean was 564. The upper limit was 1128 and the lower limit was 0. (4) The surveyor asked testing person #3 how the laboratory obtained the mean and limits listed above for each QC level and analyte. Testing person #3 explained prior to putting the new QC lot number into use, each level was tested to obtain 20 data points. The mean was calculated from the 20 data points and the ranges were set using the manufacturer's "Evidence Based Quality Control Limits," specific for each level and analyte. In addition, testing person #3 explained the values listed on the LJ graphs were the values used to monitor the acceptability of the QC results. Testing person #3 stated it was discovered after the lots listed above had been utilized, the manufacturer's Evidence Based Quality Control Limits had not been saved after being entered into the analyzer. (On 04/09/18, the limits were re-entered.) The manufacturer's evidence based quality control limits % which were to be used, follow; (a) Level 1: (i) WBC: 9.6 (ii) RBC: 5.1 (iii) Hgb: 4.9 (iv) Hct: 6.0 (v) Platelet: 30.5 (b) Level 2: (i) WBC: 7.3 (ii) RBC: 4.4 (iii) Hgb: 3.5 (iv) Hct: 5.7 (v) Platelet: 11.5 (c) Level 3: (i) WBC: 6.0 (ii) RBC: 4.4 (iii) Hgb: 3.5 (iv) Hct: 5.3 (v) Platelet: 9.1 (5) The surveyor determined from the LJ graphs, instead of utilizing the manufacturer's Evidence Based QC Limits %, the laboratory used a limit of 100% for each level and analyte listed above. Therefore, the surveyor determined the laboratory did not have a method to detect immediate errors of the analytic process, and failed to monitor the accuracy and precision of CBC testing for the time periods and QC lot numbers listed above; (6) The surveyor reviewed the findings with the laboratory manager and testing person #3. Both stated the laboratory failed to use the manufacturer's Evidence Based QC Limits % for each analyte and level for the 6 QC lot numbers listed above, and agreed the limits used by the laboratory to monitor acceptability of QC results would not detect immediate errors and would not monitor the accuracy and precision of CBC testing; (7) Examples of patient CBC testing performed during the time periods the laboratory failed to use the manufacturer's Evidence Based QC Limits %, include the following: (a) Patient #21: Testing performed on 02/23/18 (b) Patient #22: Testing performed on 02/23/18 (c) Patient #23: Testing performed on 02/26/18 (d) Patient #24: Testing performed on 02 /26/18 (e) Patient #25: Testing performed on 02/27/18 (f) Patient #26: Testing performed on 02/28/18 (g) Patient #27: Testing performed on 03/07/18 (h) Patient #28: Testing performed on 03/13/18 (i) Patient #29: Testing performed on 03/14/18 (j) Patient #30: Testing performed on 03/31/18 (k) Patient #31: Testing performed on 04 /02/18 NOTE: D5441 was cited on the previous recertification survey performed 11/29 /16-12/02/16.
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, 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 Clostridium difficile (C. diff) testing was performed on stool samples using the Alere TechLab C. diff QuikChek Complete test kit; (2) On the third day of the survey, the laboratory manager stated the following to the surveyor: (a) The test kit was in use when the laboratory manager began employment on 01/19/18; (b) The laboratory tested a negative and a positive QC (Quality Control) material when a new test kit was opened or when a new lot number of test kit was opened; (c) 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 "TechLab Tox A/B QuikChek" QC and patient testing logs from 08/15/17 through 10/01/18. The review indicated a negative and a positive QC material had not been tested on 19 of 27 days of patient testing reviewed; (4) The surveyor reviewed the records with the laboratory manager and explained, the test kit was listed on the FDA testing complexity database as "moderate complexity," which required a negative and a positive control material be performed on each day of patient testing, or the development and implementation of 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 #36: Testing performed on 08 /15/17 (b) Patient #37: Testing performed on 09/13/17 (c) Patient #38: Testing performed on 09/25/17 (d) Patient #39: Testing performed on 10/21/17 (e) Patient #40: Testing performed on 11/16/17 (f) Patient #41: Testing performed on 11/19/17 (g) Patient #42: Testing performed on 11/28/17 (h) Patient #43: Testing performed on 01/15/18 (i) Patient #44: Testing performed on 03/06/18 (j) Patient #45: Testing performed on 04/30/18 (k) Patient #46: Testing performed on 04/30/18 (l) Patient #47: Testing performed on 05/01/18 (m) Patient #48: Testing performed on 05/25/18 (n) Patient #49: Testing performed on 06/05/18 (o) Patient #50: Testing performed on 06 /15/18 (p) Patient #51: Testing performed on 06/22/18 (q) Patient #52: Testing performed on 08/15/18 (r) Patient #53: Testing performed on 09/14/18 (s) Patient #54: Testing performed on 09/28/18 (t) Patient #55: Testing performed on 10/01/18 NOTE: D5449 was cited on the previous recertification survey performed 11/29/16-12/02/16.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. 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 #3, the laboratory failed to follow the manufacturer's quality control specifications. Findings include: (1) On the second day of the survey, the laboratory manager stated the following to the surveyor: (a) The laboratory began using the Diesse Mini-Cube analyzer to perform automated ESR (Erythrocyte Sedimentation Rate) testing on 07/03/18; (b) Streck ESR-Chex Plus control materials (Level 1 and Level 2) were analyzed each day of patient testing. (2)

	The surveyor reviewed the manufacturer's instructions for the control materials, which stated "Upon receipt of a new control lot, it is recommended that an individual laboratory establish its own mean and limits;" (3) The surveyor then reviewed quality control records for 2 lot numbers of control materials used from 07/03/18 through 09 /30/18. The records verified the laboratory used the package insert means and limits for each level of control instead of establishing its own means and limits, as stated in the manufacturer's package insert: (a) Lot #403: Used from 07/03/18 through 07/20/18 (b) Lot #427: Used from 07/20/18 through 9/30/18 (4) The surveyor reviewed the findings with the laboratory manager and testing person #3, who stated although the laboratory verified results of the QC testing were within the manufacturer's acceptable limits, the laboratory did not establish its own means and limits of acceptability as required by the manufacturer, but instead used the manufacturer's package insert limits to verify acceptability of the results; (5) Refer to D5423 for examples of patient ESR testing when the laboratory failed to follow the manufacturer's specifications for the QC materials. NOTE: D5479 was cited at the previous recertification survey performed on 11/29/16 to 12/02/16.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to comply with 21 CFR 606.160(b)(3)(ii). The laboratory failed to visually inspect units of packed red blood cells immediately before distribution for transfusion. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory stored units of PRBC's (Packed Red blood Cells) in the blood bank refrigerator, to be used for patient transfusions; (2) On the third day of the survey, the surveyor reviewed the blood bank records and chose 10 days when units of PRBC's were released from the blood bank for patient transfusion. A total of 12 units of PRBC's had been released. For 4 of those 12 units, there was no documentation at distribution (i.e., at release to the nurse for patient transfusion) a visual inspection of the units had been performed: (a) 09/10/18: 2 of 2 crossmatched units had not been visually inspected (b) 03/01/18: 2 of 2 crossmatched units had not been visually inspected (3) The surveyor reviewed the findings with the laboratory manager, who stated the visual inspection of the units listed above, had not been documented at the time of release for transfusion.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to ensure units of blood were stored under appropriate conditions. Findings include: (1) On the third day of the survey, the surveyor observed the blood bank refrigerator. A thermograph temperature recorder was connected to the refrigerator which continuously recorder the refrigerator temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (2) The surveyor reviewed a random selection of 40 refrigerator charts, dated from January 2017 through September 2018. From the review, the surveyor identified 3 thermograph charts of the 40 charts reviewed had not been changed by the 7th day of usage, as follows: (a) Chart #1: The chart was put into use on 04/21/17 and removed on 04/31/17 (10 days); (b) Chart #2: The chart was put into use on 05/26/17 and removed on 06/04/17 (9 days); (c) Chart #3 - The chart was put into use on 09/01/17 and removed on 09/10/17 (9 days). (3) The surveyor reviewed the findings with the laboratory manager who stated the thermograph charts were to be removed each 7 days and the laboratory failed to follow its procedure for removing and replacing the thermographs as required. NOTE: D5555 was cited at the previous recertification survey performed 11/29/16 - 12/02/16.
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, FDA database, information provided by the manufacturer's distributor, correspondence with the CMS Central Office FDA liaison, observation, and interview with the laboratory manager and testing person #3, 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 due to the following issues identified during the survey: (a) The laboratory failed to ensure written policies included correct normal reference ranges and failed to ensure policies and procedures were available for all testing performed by the laboratory. Refer to D5403; (b) The laboratory failed to ensure the manufacturer's instructions were followed. Refer to D5411; (c) The laboratory failed to ensure testing materials were labeled appropriately. Refer to D5415; (d) The laboratory failed to establish the performance specifications of Precision, Reportable Range, Analytical Sensitivity, Analytical Specificity, and Reference Interval for an Erythrocyte Sedimentation Rate test system, not cleared or approved by the FDA. Refer to D5423; (e) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (f) The laboratory failed to ensure function checks were within the manufacturer's acceptable limits before patient testing was conducted. Refer to D5431; (g) The laboratory failed to have control procedures that detected immediate errors and monitored the accuracy and precision of the testing process. Refer to D5441; (h) The laboratory failed to

	perform a negative and a positive control material each day of patient testing. Refer to D5449; (i) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479; (j) The laboratory failed to visually inspect units of packed red blood cells immediately before distribution for transfusion. Refer to D5553; (k) 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 11/29/16-12/02/16.
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 #3, the laboratory failed to make appropriate reference ranges available. Findings include: (1) On the first day of the survey, the laboratory manager stated the CA-660 analyzer was put into use to perform PTT (Partial Thromboplastin Time) testing on 11/28/17; (2) On the third day of the survey, the surveyor reviewed the implementation records for the analyzer and identified the following information for PTT testing: (a) The PTT reagent used at implementation of the new analyzer was PTT Reagent: Actin-FSL, Lot #56917; (b) The laboratory established a normal reference interval (normal reference range) of 23.0-27.8 seconds for PTT during the implementation study. (3) The surveyor then reviewed a patient PTT test report (Patient #56-testing performed 10/09/18 at 10:22 AM). The test report included the normal reference interval of 23.0-37.0 seconds, which did not match the normal reference interval established by the laboratory during the implementation of the analyzer; (4) The surveyor reviewed the findings with the laboratory manager and testing person #3. Both stated to the surveyor the established normal reference interval for PTT included on the patient report did not match the normal reference interval established by the laboratory for PTT testing during the implementation of the new analyzer. NOTE: D5807 was cited at the previous recertification survey performed on 11/29/16 to 12/02/16.
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, observation, FDA database, information provided by the manufacturer's distributor, correspondence with the CMS Central Office FDA liaison, observation, and interview with the laboratory manager and testing person #3, the laboratory laboratory director failed to provide overal management and direction in accordance with 493.1407 of this subpart. Findings include: (1) The laboratory director failed to ensure the individual who performed the duties and responsibilities of the laboratory

	director, met the qualifications. Refer to D6003; (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 attest at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Refer to D6016; (4) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (5) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (6) The laboratory director failed to ensure test reports included pertinent information required for interpretation. Refer to D6026; (7) The laboratory director failed to ensure policies and procedures had been written for all testing in the laboratory. Refer to D6031. NOTE: D6000 was cited at the previous recertification survey performed on 11/29/16 to 12/02/16.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28,

1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical 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; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager, the laboratory director failed to ensure the individual who performed the duties and

	responsibilities of the laboratory director, met the qualifications. Findings include: (1) The laboratory director failed to ensure proficiency testing attestation statements for moderate complexity testing had been signed by the laboratory director, or an individual meeting the educational qualifications. Refer to D2015.
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 #3, 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 laboratory followed the manufacturer's instructions. Refer to D5411; (2) The laboratory director failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429; (3) The laboratory director failed to ensure the laboratory followed the manufacturer's specifications for function checks before patient testing was conducted. Refer to D5431. NOTE: D6014 was cited at the previous recertification survey performed on 11/29/16 - 12/02/16.
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 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 6 of the 8 events from 2018, 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 02/06/18 and the attestation statement had not been signed by the laboratory director until 05/04 /18; (b) First 2018 Hematology/Coagulation Event: The samples were tested on 03/27 /18 and the attestation statement had not been signed by the laboratory director until 05 /04/18; (c) First 2018 Microbiology Event: The samples were tested on 06/29/18 and

	the attestation statement had not been signed by the laboratory director until 08/27/18; (d) First 2018 Immunology/Immunohematology Event: The samples were tested on 04 /10/18 and the attestation statement had not been signed by the laboratory director until 08/27/18; (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 08/27/18. (2) The surveyor reviewed the findings with the laboratory manager, and explained the attestation statement must be signed 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.
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 laboratory manager and testing person #3, 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 the laboratory labeled testing materials appropriately. Refer to D5415; (2) The laboratory failed to have control procedures that detected immediate errors and monitored the accuracy and precision of the analytic process. Refer to D5441; (3) The laboratory director failed to ensure a negative and a positive control material had been performed each day of patient testing. Refer to D5449. NOTE: D6020 was cited at the previous recertification survey performed on 11/29/16 - 12/02/16.
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, FDA database, information provided from the manufacturer's distributor, correspondence with the CMS Central Office FDA liaison, observation, and interview with the laboratory manager and testing person #3, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. 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 at the previous recertification survey performed on 11/29/16 - 12/02/16.
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, policy and procedure, and interview with the laboratory manager and testing person #3, 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 on 11/29/16 to 12/02/16.
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 written policies and procedures, and interview with the laboratory manager, the laboratory director failed to ensure policies and procedures had been written for all testing in the laboratory. Findings include: (1) The laboratory director failed to ensure policies and procedures had been written. Refer to D5403. NOTE: D6031 was cited at the previous recertification survey performed on 12/29/16 - 12/02/16.
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, manufacturer's instructions, and interview with the laboratory manager, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical

	consultant failed to ensure individuals who performed the duties and responsibilities of a technical consultant met the required educational qualifications. Refer to D6035; (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 competency evaluations included direct observation of routine patient test performance, including preparation, if applicable; specimen handling, processing, and testing. Refer to D6047; (4) The technical consultant failed to ensure competency evaluations included monitoring the recording and reporting of test results. Refer to D6048; (5) The technical consultant failed to ensure competency evaluations included the review of test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. Refer to D6049; (6) The technical consultant failed to ensure competency evaluations included direct observation of the performance of instrument maintenance and function checks. Refer to D6050; (7) The technical consultant failed to ensure competency evaluations included an assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. Refer to D6051; (8) The technical consultant failed to ensure competency evaluations included an assessment of problem solving skills. Refer to D6052. NOTE: D6033 was cited at the previous recertification survey performed on 11/29/16 - 12/02/16.
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 laboratory manager, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the educational qualifications. Findings include: EVALUATIONS (1) On the first day of the survey, the surveyor reviewed personnel records for 8 individuals who currently performed the moderate complexity laboratory testing, which included the following: (a) CBC (Complete Blood Count) testing (b) Manual WBC (White Blood Cell) differential tsting (c) Chemistry testing (e.g., Glucose, Potassium, etc.), Endocrinology testing (e.g., TSH (Thyroid Stimulating Hormone, etc.), Quantitative Serum pregnancy, etc.), Toxicology testing (e.g., Alcohol, Digoxin, etc.) (d) Wet prep examinations (e) Coagulation testing (i.e. PT/INR (Prothrombin Time/International Normalized Ratio), PTT (Partial Thromboplasting Time), D-Dimer) (2) The surveyor identified from the review, 1 of the 8 competency evaluations performed in 2018, had been performed by an individual who did not meet the regulatory educational qualification requirements of the technical consultant: (a) Testing Person #3: The 02/20/18 evaluation had been performed by the laboratory manager (this person had earned an Associate of Applied Science degree in medical laboratory technology. (3) The surveyor explained to the laboratory manager that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a Bachelor's Degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). PROFICIENCY TESTING ATTESTATION FORMS (1) Proficiency testing attestation forms had been signed by an individual who did not meet the minimal educational qualifications of a technical consultant. Refer to D2015.
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, procedure manual, and interview with the clinical laboratory laboratory manager and testing person #3, 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 the laboratory followed the manufacturer's instructions. Refer to D5411; (2) The technical consultant failed to ensure the laboratory labeled testing materials appropriately. Refer to D5415; (3) The technical consultant failed to ensure maintenance procedures had been performed as required by the manufacturer. Refer to D5429; (4) The technical consultant failed to ensure function checks were within the manufacturer's acceptable limits before patient testing was conducted. Refer to D5431; (5) The technical consultant failed to ensure the laboratory had control procedures that detected immediate errors and monitored the accuracy and precision

	of test performance. Refer to D5441;(6) The technical consultant failed to ensure a negative and a positive control material had been performed each day of patient testing. Refer to D5449. NOTE: D6042 was cited at the previous recertification survey performed on 11/29/16 - 12/02/16.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure evaluations for testing personnel competency included direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing for moderate complexity testing. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records and identified 7 testing persons performed patient testing. The surveyor identified the laboratory utilized a form on which competency was indicated by a check mark under "General Criteria." For 4 of the 7 competency evaluations performed in 2018, the form did not include documentation that direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing had been used to assess testing person competency. The findings follow: (a) Laboratory Manager: Semi-annual competency performed on 08/08/18 (b) Testing person #2: Annual competency performed on 08/09/18 (c) Testing person #3: Annual competency performed on 02/20/18 (d) Testing person #4: Annual competency performed on 09/04/18 (2) The surveyor reviewed the findings with the laboratory manager, who stated there was no documentation to prove this component had been included.
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure evaluations for testing personnel competency included monitoring the recording and reporting of test results. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records and identified 7 testing persons performed patient testing. The surveyor identified the laboratory utilized a form on which competency was indicated by a check mark under "General Criteria." For 4 of the 7 competency evaluations performed in 2018, the form did not include documentation that monitoring the recording and reporting of test results had been used to assess testing person competency. The findings follow: (a) Laboratory Manager: Semi-annual competency performed on 08/08/18 (b) Testing person #2: Annual competency performed on 08/09/18 (c) Testing person #3: Annual competency performed on 02/20/18 (d) Testing person #4: Annual competency performed on 09/04/18 (2) The surveyor reviewed the findings with the laboratory

	manager, who stated there was no documentation to prove this component had been included.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure evaluations for testing personnel competency assessment included a review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records and identified 7 testing persons performed patient testing. The surveyor identified the laboratory utilized a form on which competency was indicated by a check mark under "General Criteria." For 4 of the 7 competency evaluations performed in 2018, the form did not include documentation that a review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records had been included to assess testing person competency. The findings follow: (a) Laboratory Manager: Semi-annual competency performed on 08/08/18 (b) Testing person #2: Annual competency performed on 08/09/18 (c) Testing person #3: Annual competency performed on 02/20/18 (d) Testing person #4: Annual competency performed on 09/04/18 (2) The surveyor reviewed the findings with the laboratory manager, who stated there was no documentation to prove this component had been included.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure evaluations for testing personnel competency assessment included direct observation of performance of instrument maintenance and function checks. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records and identified 7 testing persons performed patient testing. The surveyor identified the laboratory utilized a form on which competency was indicated by a check mark under "General Criteria." For 4 of the 7 competency evaluations performed in 2018, the form did not include documentation that direct observation of performance of instrument maintenance and function checks had been included to assess testing person competency. The findings follow: (a) Laboratory Manager: Semi-annual competency performed on 08/08/18 (b) Testing person #2: Annual competency performed on 08/09/18 (c) Testing person #3: Annual competency performed on 02/20

	/18 (d) Testing person #4: Annual competency performed on 09/04/18 (2) The surveyor reviewed the findings with the laboratory manager, who stated there was no documentation to prove this component had been included.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure evaluations for testing personnel competency assessment included testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records and identified 7 testing persons performed patient testing. The surveyor identified the laboratory utilized a form on which competency was indicated by a check mark under "General Criteria." For 4 of the 7 competency evaluations performed in 2018, the form did not include documentation that testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples had been included to assess testing person competency. The findings follow: (a) Laboratory Manager: Semi-annual competency performed on 08/08/18 (b) Testing person #2: Annual competency performed on 08/09/18 (c) Testing person #3: Annual competency performed on 02/20 /18 (d) Testing person #4: Annual competency performed on 09/04/18 (2) The surveyor reviewed the findings with the laboratory manager, who stated there was no documentation to prove this component had been included.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure evaluations for testing personnel competency assessment included an assessment of problem solving skills. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records and identified 7 testing persons performed patient testing. The surveyor identified the laboratory utilized a form on which competency was indicated by a check mark under "General Criteria." For 4 of the 7 competency evaluations performed in 2018, the form did not include documentation that an evaluation of problem solving skills had been included to assess testing person competency. The findings follow: (a) Laboratory Manager: Semi-annual competency performed on 08/08/18 (b) Testing person #2: Annual competency performed on 08/09/18 (c) Testing person #3: Annual competency performed on 02/20 /18 (d) Testing person #4: Annual competency performed on 09/04/18 (2) The surveyor reviewed the findings with the laboratory manager, who stated there was no documentation to prove this component had been included.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, FDA database, information provided by the manufacturer's distributor, correspondence with the CMS Central Office FDA liaison, and interview with the laboratory manager and testing person #3, the laboratory failed to establish the performance specifications of Precision, Reportable Range, Analytical Sensitivity, Analytical Specificity, and failed to establish Reference Intervals for an Erythrocyte Sedimentation Rate test system not cleared or approved by the FDA. Findings include: (1) The laboratory director failed to ensure verification procedures were adequate to establish the performance characteristics. Refer to D6086; (2) The laboratory director failed to ensure the laboratory followed the manufacturer's quality control specifications. Refer to D6087; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6094. NOTE: D6076 was cited at the previous recertification survey performed 11/29/16 - 12/02/16.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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, FDA database, information provided by the manufacturer's distributor, correspondence with the CMS Central Office FDA liaison, and interview with the laboratory manager, the laboratory failed to establish the performance specifications of Precision, Reportable Range, Analytical Sensitivity, Analytical Specificity, and Reference Intervals for an Erythrocyte Sedimentation Rate test system not cleared or approved by the FDA. Findings include: (1) The laboratory failed to ensure the performance specifications of Precision, Reportable Range, Analytical Sensitivity, Analytical Specificity, and Reference Intervals had been established for the Diesse Mini-Cube Erythrocyte Sedimentation Rate test system. Refer to D5423. NOTE: D6086 was cited at the previous recertification survey performed on 11/29/16 to 12/02/16.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that 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 #3, 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 laboratory followed the manufacturer's quality control specifications. Refer to D5479.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, FDA database, information provided by the manufacturer's distributor, correspondence with the CMS Central Office FDA liaison, and interview with the laboratory manager and testing person #3, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) The laboratory director failed to ensure the laboratory established and maintained an effective mechanism for performing quality assessment of high complexity testing due to issues identified during the survey. Refer to D5791. NOTE: D6094 was cited at the previous recertification survey performed on 11/29/16 - 12/02/16