Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0473165	(X3) Date Survey Completed 09/27/2018
Name of Provider or Supplier Cleveland Area Hospital	**Street Address, City, State** 1401 W Pawnee Street, Cleveland, OK	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 09/25,26.27/2018. The laboratory was found out of compliance with the following CLIA regulations: 493.1215; D5024: Hematology 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory manager and testing person #2 at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to sign proficiency testing attestation statements. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records and identified attestation statements had either not been signed by the laboratory director, or 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 19 of 19 events reviewed: (a) First 2017 Hematology /Coagulation Event - The attestation form had been signed by the laboratory manager (this person had earned an Associates Degree in Applied Science, and did not qualify

	as a Technical Consultant or a Laboratory Director for moderate complexity testing); (b) First 2017 Immunology Event - The attestation form had been signed by the laboratory manager; (c) First 2017 Chemistry Core Event - The attestation form had been signed by the laboratory manager; (d) First 2017 Chemistry Miscellaneous Event - The attestation form had been signed by the laboratory manager; (e) Second 2017 Hematology/Coagulation Event - The attestation form had been signed by the laboratory manager; (f) Second 2017 Immunology Event - The attestation form had been signed by the laboratory manager; (g) Second 2017 Chemistry Core Event - The attestation form had been signed by the laboratory manager; (h) Second 2017 Chemistry Miscellaneous Event - The attestation form had not been signed; (i) Third 2017 Hematology/Coagulation Event - The attestation form had been signed by the laboratory manager; (j) Third 2017 Immunology Event - The attestation form had been signed by the laboratory manager; (k) Third 2017 Chemistry Core Event - The attestation form had been signed by the laboratory manager; (l) Third 2017 Chemistry Miscellaneous Event - The attestation form had been signed by the laboratory manager; (m) First 2018 Hematology/Coagulation Event - The attestation form had been signed by the laboratory manager; (n) First 2018 Immunology Event - The attestation form had not been signed; (o) First 2018 Chemistry Core Event - The attestation form had been signed by the laboratory manager; (p) First 2018 Chemistry Miscellaneous Event - The attestation form had been signed by the laboratory manager; (q) Second 2018 Hematology/Coagulation Event - The attestation form had been signed by the laboratory manager; (r) Second 2018 Immunology Event - The attestation form had been signed by the laboratory manager; (s) Second 2018 Chemistry Core Event - The attestation form had been signed by the laboratory manager. (3) The surveyor reviewed the records with the laboratory manager who stated she routinely signed the attestation forms as indicated above; (4) The surveyor explained to the laboratory manager that proficiency testing attestation statements for moderate complexity testing must be signed by the laboratory director or technical consultant (if delegated in writing). NOTE: The Interpretive Guidelines under D2015 state "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, observation, and interview with the laboratory manager, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Refer to D5411; (2) The laboratory failed to have control procedures that monitored the accuracy and precision of the system for hematology and coagulation testing. Refer to

	D5441; (3) The laboratory failed to make appropriate reference ranges available. Refer to D5807. (4) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791.
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, observation, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the ACL Elite analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT ((Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean); (2) On the second day of the survey, the surveyor observed the refrigerator where the testing reagents were maintained and identified the following reagents which appeared to be currently in use: (a) PT - HemosIL Recombiplastin 2G reagent, lot #N0972299 (b) PTT - HemosIL Synthasil APTT reagent, lot #N0588291 (3) The laboratory manager stated to the surveyor the above reagent lot numbers were currently in use, and had initially been put into use as follows: (a) HemosIL Recombiplastin 2G reagent - 12/29/17 (b) HemosIL Synthasil APTT reagent - 08/01/18 (4) The surveyor reviewed the manufacturer's instructions contained in the "Hemostasis Performance Verification Manual" for implementing new reagents, which stated, "When changing to a new lot number of reagent or a new reagent, it is important to establish a new normal reference interval, establish new assay control ranges, and perform a comparison study for all tests". In addition, the manufacturer required the following: (a) Section titled "Establishing a Normal Reference Interval" (i) "Reference Interval should be established whenever there is a change in: * Instrumentation and/or methodology. * Lot number of reagent. * Sample collection procedures. * At least once a year." (ii) "Reference Intervals should be established for each assay the lab performs."; (iii) "Reference Intervals should be established over several days, at different times of the day, including such variables as age of reagent, different vials of reagent, different operators."; (iv) "Donors should be healthy and have no known pathological conditions. Don't use samples from in-patients (due to medical conditions and treatment regiments). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-does aspirin, etc."; (v) "Donors should span the adult age range. Pediatric ranges should be established separately."; (vi) "Donors should be equally divided between male/female."; (vii) "If the INR system is utilized to report PT's, note the geometric mean value of the PT normal reference interval in seconds and use along with the lot-specific ISI value in the INR setup calculation page". (b) Section titled "Comparison Study" (i) "Collect and handle specimens according to accepted laboratory practice for the assay being performed" (ii) "Include diseases/treatments known to affect the assay being performed" (iii) "At least 50% of the samples should be outside of the laboratory normal reference interval, if possible" (iv) "At least 40 specimens should be analyzed. More samples will improve the confidence in the data" (v) "Evaluate the new instrument or reagent

	over clinically meaningful range including data below and above the expected reference range" (vi) "For a given specimen, analysis by the comparative and new methods or reagents should be accomplished within 1 hour of each other to avoid possible degradation of the samples" (vii) "Analyze each patient sample using the new method (or reagents) and the comparative method" (viii) "Examine the results after each run. If an isolated specimen's results for the new and comparative methods differ more than observed for other specimens, retest that specimen in duplicate on both methods. If the difference has been resolved use the repeat data" (ix) "Record data on the data sheets provided" (x) "The analysis of the comparison data can be as simple as a visual comparison, calculation of the difference (delta) between the two methods, or as involved as a regression analysis. The comparison will depend on the types of specimen, instruments and methodologies chosen. The more similarities among those items, the closer will be the comparison results" (5) The surveyor reviewed the implementation records for Recombiplastin 2G reagent lot #N0972299 and APTT reagent lot #N0588291, with the following identified: (a) Recombiplastin 2G lot #N0972299 (i) A geometric mean had not been calculated (the laboratory had calculated the arthrimetic mean instead); (ii) The records showed the mean that had been calculated by the laboratory was 11.45 and when the laboratory manager assisted the surveyor to retrieve the mean that had been programmed into the analyzer, it was identified that the mean that had been programmed into the analyzer was 11.72 (it did not match the 11.45 mean that had been calculated by the laboratory). (b) APTT reagent lot #N0588291 (i) There was no evidence of the age, gender, health, and medication status of the normal donors; (ii) There was no evidence the comparison study had been performed using 20 samples outside of the laboratory normal reference interval (they had only used 20 normal samples). (6) The findings were reviewed with the laboratory manager who agreed the manufacturer's instructions had not been followed for the reagent lot changes as specified above; (7) The following were examples of patient PT/INR and PTT testing performed when the manufacturer's instructions had not been followed for the reagent lot changes: (a) Patient #4 - PT/INR testing performed on 12/29/17 (b) Patient #5 - PT/INR testing performed on 12/30/17 (c) Patient #6 - PT/INR testing performed on 01/01/18 (d) Patient #7 - PT/INR testing performed on 01/10/18 (e) Patient #8 - PT/INR testing performed on 01/28/18 (f) Patient #9 - PT/INR testing performed on 02/04/18 (g) Patient #10 - PT/INR testing performed on 02/16/18 (h) Patient #11 - PT/INR testing performed on 03/09/18 (i) Patient #12 - PT/INR testing performed on 03/26/18 (j) Patient #13 - PT/INR testing performed on 04/04/18 (k) Patient #14 - PT/INR testing performed on 04/18/18 (l) Patient #15 - PT/INR testing performed on 04/28/18 (m) Patient #16 - PT/INR testing performed on 05/09/18 (n) Patient #17 - PT/INR testing performed on 05/18/18 (o) Patient #18 - PT/INR testing performed on 05/29/18 (p) Patient #19 - PT/INR testing performed on 06/06/18 (q) Patient #20 - PT/INR testing performed on 06/16/18 (r) Patient #21 - PT/INR testing performed on 06/28/18 (s) Patient #22 - PT/INR testing performed on 07/07/18 (t) Patient #23 - PT/INR testing performed on 07/15/18 (u) Patient #24 - PT/INR testing performed on 07/22/18 (v) Patient #25 - PT/INR and PTT testing performed on 08/01/18 (w) Patient #26 - PT/INR and PTT testing performed on 08/05/18 (x) Patient #27 - PT/INR and PTT testing performed on 08/14 /18 (y) Patient #28 - PT/INR and PTT testing performed on 08/21/18 (z) Patient #29 - PT/INR and PTT testing performed on 08/29/18 (aa) Patient #30 - PT/INR and PTT testing performed on 09/05/18 (bb) Patient #31 - PT/INR and PTT testing performed on 09/11/18 (cc) Patient #32 - PT/INR and PTT testing performed on 09/19/18 (dd) Patient #33 - PT/INR and PTT testing performed on 09/25/18
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, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor *CMP, Amylase, CK, CKMB, Direct Bilirubin, Lactic Acid, Lipase, Magnesium, Pre-albumin, Phosphorus, HCG (Human Chorionic Gonadotropin), Uric Acid, TSH (Thyroid Stimulating Hormone), Acetaminophen, Alcohol, Digoxin, Dilantin, Salicylate, Valproic Acid, Vancomycin, CRP (C-Reactive Protein), and Phenobarbital testing were performed on the Siemens Dimension Xpand Plus analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements were as follows: (a) Weekly (i) Clean Outside of R2 Probe (ii) Clean Outside of HM Wash Probe (b) Monthly (i) Replace IMT Pump Tubing (ii) Clean IMT System (iii) Replace/Clean Air Filters (iv) Stylette HM Wash Probes (v) Replace HM Pump Head (3) The surveyor then reviewed maintenance records for the analyzer from January 2017 through August 2018. The following was identified: (a) Weekly - Not documented as performed between: (i) 11/20/17 and 12/10/17 (ii) 02/03/18 and 02/12/18 (iii) 02/17/18 and 02/25/18 (iv) 07/01/18 and 08/06/18 (b) Monthly - The following had not been documented as performed for 4 of 20 months: (i) June 2017 - Replace/Clean Air Filters, Stylette HM Wash Probes, and Replace HM Pump Head; (ii) July 2017 - Clean IMT System (iii) March 2018 - Clean IMT System (iv) April 2018 - Clean IMT System (3) The surveyor reviewed the records with the laboratory manager who stated the above maintenance procedures had not been documented as being performed as required. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have control procedures that monitored the accuracy and precision

	of the complete analytic process for hematology and coagulation testing. Findings include: HEMATOLOGY (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Cell Dyn 1800 analyzer; (b) Three levels of Cell Dyn quality control (QC) materials were performed each day of patient testing. (2) On the second day of the survey, the surveyor asked the laboratory manager to explain how CBC control results were monitored for variances (i.e., biases, shifts, trends). The laboratory manager stated it was the laboratory's practice to print Levey-Jennings (LJ) graphs and cumulative control records on a monthly basis; (3) The surveyor then reviewed QC records for testing performed from January through August 2018. For 4 of 8 months (April, May, June, and July), LJ graphs and cumulative QC records were not available; (4) The surveyor asked the laboratory manager if the laboratory had printed and reviewed LJ graphs from April through July 2018. The laboratory manager stated the data had been reviewed on the analyzer, however, it had not been printed and maintained; (5) With no data to review, the surveyor determined the laboratory failed to monitor quality control results for variances from April through July 2018. COAGULATION (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the ACL Elite analyzer; (b) Two levels of HemosIL Routine Control materials were performed each eight hours of patient testing; (c) Established ranges were used for determining acceptability of QC results. (2) On the second day of the survey, the surveyor reviewed coagulation records and identified the following: (a) HemosIL Routine Controls (level 1 lot #N1173919 and level 3 lot #N0579852) were put into use on 03 /21/18. The following was identified for this lot change: (i) PT - A 2 standard deviation (SD) range of 11.66-12.62 was established for level 1 and a 2 SD range of 46.86-54.94 was established for level 3; (ii) PTT - A 2 SD range of 26.72-28.84 was established for level 1 and a 2 SD range of 49.82-52.5 was established for level 3; (iii) The surveyor reviewed QC records beginning 04/01/18 and identified the established ranges had not been utilized. The ranges utilized were: (aa) PT - A 2 SD range of 10.1-12.9 for level 1 and a 2 SD range of 48.4-56.4 for level 3; (bb) PTT - A 2 SD range of 25.6-28.4 for level 1 and a 2 SD range of 46.9-55.44 for level 3. (b) HemosIL SynthasIL PTT Reagent (lot #N0588291) was put into use on 08/01/18. The following was identified for the QC ranges established for this lot change for level 3: (i) A 2 SD range of 49.98-53.22 was established; (ii) The surveyor reviewed QC records beginning 08/23/18 and identified the established range had not been utilized. The range utilized was: (aa) A 2 SD range of 46.9-55.44. (3) The surveyor reviewed the records with the laboratory manager who stated the established QC ranges had not been utilized as indicated above; (4) Refer to D5411 for examples of patient testing performed.
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, observation, and interview with the laboratory manager, the laboratory failed to have an ongoing mechanism for

	performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Refer to D5411; (b) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (c) The laboratory failed to have control procedures that monitored the accuracy and precision of the system for hematology and coagulation testing. Refer to D5441.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to make appropriate reference ranges available. Findings include: BLOOD GAS TESTING (1) On the first day of the survey, the clinical manager stated to the surveyor Arterial Blood Gas (pH, pCO2, and PO2) testing and Venous pH testing were performed using the iSTAT 1 analyzer and the G3+ test cartridge; (2) On the second day of the survey, the surveyor reviewed records of patient testing performed on the analyzer in 2018 and identified a venous pH test that had been performed on 09/16/18 and asked the laboratory manger to print the report; (3) The surveyor reviewed the report for the venous pH testing performed on patient #1 on 09 /16/18. The report did not include reference intervals for venous pH. The reference intervals on the report were for arterial pH; (4) The surveyor reviewed the report with the laboratory manager who stated the report did not include a reference interval for venous pH. CBC TESTING (1) On the first day of the survey, the laboratory manager stated to the surveyor CBC (Complete Blood Count) testing was performed using the Cell Dyn 1800 analyzer; (2) On the second day of the survey, the surveyor reviewed two patient CBC reports - the first report (Patient #1) was for an adult male patient with the testing performed on 09/16/18 at 08:57 pm; the second report (Patient #2) was for an adult female patient with the testing performed on 05/12/18 at 04:33 pm; (3) The reference intervals, appeared to the surveyor, to be interchanged (the male report contained reference ranges typically for a female and the female report contained reference ranges typically for a male) for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit, which were: (a) Male Report (i) RBC - 3.80-5.20 K/ul (ii) Hemoglobin - 11.4-15.4 g/dl (iii) Hematocrit - 34.0-45.0% (b) Female Report (i) RBC - 4.50-5.90 K/ul (ii) Hemoglobin - 13.5-17.5 g/dl (iii) Hematocrit - 41.0-53.0% (4) The surveyor reviewed the findings with the laboratory manager who stated the reference ranges were not correct, and the female reference ranges should be lower than the male reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals. PT AND PTT TESTING (1) On the first day of the survey, the laboratory manager stated to the surveyor PT (Prothrombin Time) and PTT (Partial Thromboplastin Time) testing were performed using the ACL Elite analyzer; (2) On the second day of the survey, the surveyor reviewed the implementation records for the current lot numbers of reagents. The following was identified for PT and PTT: (a) PT Reagent (i) HemosIL Recombiplastin 2G reagent, lot #N0972299 put

	into use on 12/29/17 (ii) The normal reference range that had been established was 10.0-13.8 seconds (b) PTT Reagent (i) HemosIL Synthasil APTT reagent, lot #N0588291 put into use on 08/01/18 (ii) The normal reference range that had been established was 26.0-39.2 seconds (3) The surveyor then reviewed a patient PT and PTT report: (a) Patient #3 - Testing performed on 09/19/18 with the following reference ranges: (i) PT reference range of 9.0-12.0 seconds (ii) PTT reference range of 24-32 seconds (4) The surveyor reviewed the findings with the laboratory manager who stated the established normal reference ranges for PT and PTT were not included on the patient report.
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, observation, and interview with the laboratory manager, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to provide overall supervision and effective direction over the operation and administration of the laboratory. Refer to D6004; (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 that proficiency testing samples were tested 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.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. 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 provide overall supervision and effective direction over the operation and administration of the laboratory. Findings include: (1) During the survey performed from 09/25/18 through 09/27/18, the surveyor reviewed records for

	moderate complexity testing performed in the laboratory from January 2017 through the third day of the survey. Examples of the records reviewed include: (a) Personnel records (b) Proficiency testing records (c) Quality control records (d) Calibration and calibration verification records (e) Maintenance and function check records (f) Temperature and humidity records (2) There was no evidence in the records to demonstrate the involvement of the laboratory director. For example, there were no signatures, dates, notes, etc. documented in the records by the laboratory director; (3) The surveyor reviewed the records with the laboratory manager and asked if documentation of the laboratory director involvement was available. The laboratory manager stated documentation was not available.
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, observation, and interview with the laboratory manager, 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 failed to follow the manufacturer's instructions for implementing coagulation reagents. Refer to D5411; (2) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429.
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 or designee failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) 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 and interview with the laboratory manager, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for hematology and coagulation testing. Refer to D5441.
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, observation, and interview with the laboratory manager, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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 and interview with the laboratory manager, the laboratory director failed to ensure test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure appropriate reference ranges were available. Refer to D5807.
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, observation, and interview with the laboratory manager, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035. (2) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042.
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 qualifications. Findings include:

	(1) On the first day of the survey, the surveyor reviewed records for 6 persons performing moderate complexity testing for more than one year, and identified the annual competency evaluations for 6 of 6 persons had been performed by individuals who did not meet the regulatory qualification requirements of the technical consultant: (a) Laboratory Manager/Testing Person #1 - The 12/04/17 evaluation had been performed by testing person #3 (this person had earned an associates degree in applied science); (b) Testing Person #2 - The 12/14/15, 12/01/16, and 12/01/17 evaluations had been performed by the laboratory manager (this person had earned an associates degree in applied science); (c) Testing Person #3 - The 12/01/16 and 12/01/17 evaluations had been performed by the laboratory manager; (d) Testing Person #4 - The 10/16/16 and 10/20/17 evaluations had been performed by the laboratory manager; (e) Testing Person #5 - The 08/01/17 and 08/01/18 evaluations had been performed by the laboratory manager; (f) Testing Person #7 - The 07/02/15, 07/04/16, 07/12/17, and 07/12/18 evaluations had been performed by the laboratory manager. (2) The findings were discussed with the laboratory manager, who confirmed that she had performed the competency evaluations for the above persons; (3) The surveyor explained to the laboratory manager that 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).
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, observation, and interview with the laboratory manager, 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 for implementing coagulation reagents.. Refer to D5411; (2) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (3) The technical consultant failed to ensure control procedures monitored the accuracy and precision of the complete analytic process for hematology and coagulation testing. Refer to D5441.