Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473327	01/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pawhuska Hospital Inc	1101 East 15th Street, Pawhuska, 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 survey was performed on 01/29,30,31/2018 The findings were reviewed with the assistant administrator and technical consultant #1 during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1215; D5024: Hematology 493.1403; D6000: Laboratory Director
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with technical consultant #1, the laboratory failed to ensure an adequate alarm system was in place for the blood bank refrigerator. Findings include: (1) On the first day of the survey, technical consultant #1 verified to the surveyors the laboratory routinely maintained 2 units of O negative packed red blood cells in the Allegiance S/P Brand Cryo Frige Series blood bank refrigerator. The units were available for emergency patient transfusions (packed red blood cells must be stored at 1-6 degrees Centigrade-C); (2) Surveyor #1 reviewed the laboratory's written policy for performing alarm checks on the refrigerator. The policy required the alarm checks be performed on a quarterly basis; (3) Surveyor #1 then reviewed the alarm check records for 2016 and 2017. It was identified that 1 of 8 high alarm checks were documented as sounding at a temperature warmer than 6.0 degrees C (the warmest temperature allowed for the storage of packed red blood cells) as follows: (a) 11/01/16 - The temperature sounded

	at 7.7 degrees C. (4) Surveyor #1 reviewed the records with technical consultant #1 who stated the alarm for the warm alarm check, had sounded at a temperature beyond the acceptable storage for the products as indicated above.
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, policies and procedures, manufacturer's instructions, and interview with technical consultant #1, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to demonstrate the performance specification of reportable range for a new analyzer. Refer to D5421; (2) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures on the coagulation analyzer. Refer to D5429; (3) The laboratory failed to follow their written protocol for ensuring the coagulation centrifuge was functioning properly. Refer to D5435; (4) The laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process for PTT testing. Refer to D5441; (5) The laboratory failed to follow the manufacturer's specifications for establishing normal reference intervals for a new coagulation analyzer. Refer to D5479; (6) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791.
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 policies and procedures, and interview with technical consultant #1, the laboratory failed to have written policies and procedures for assessing employee competency. Findings include: (1) On the first day of the survey, surveyor #2 reviewed the laboratory's policies and procedures. A policy that explained how employees were assessed for competency could not be located; (2) Surveyor #2 asked technical consultant #1 if a competency policy was available for review. Technical consultant #1 stated a policy had not been written. 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. The policy/procedure for evaluating competency must include, but is not limited to: *Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing *Monitoring the recording and reporting of test results *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records *Direct observation of performance of instrument maintenance and function

	checks *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples *Assessment of problem solving skills
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to demonstrate the performance specification of reportable range for a new analyzer. Findings include: (1) At the beginning of the survey, technical consultant #1 stated to surveyors the IL ACL Elite analyzer was put into use to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing on 01/21/17; (2) On the third day of the survey, the surveyors reviewed the records of the validation study performed on 12/05/16. There was no evidence the reportable ranges had been demonstrated for PT and PTT; (3) The surveyors asked technical consultant #1 if there was documentation to prove the reportable ranges had been demonstrated. Technical consultant #1 stated there was no documentation which proved the reportable ranges had been demonstrated; (4) Refer to D5479 for examples of patient PT and PTT testing performed when the reportable ranges had not been demonstrated prior to beginning patient testing.
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 and interview with technical consultant #1, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures on the hematology analyzer. Findings include: (1) On the first day of the survey, technical consultant #1 stated to the surveyors CBC (Complete Blood Count) testing was performed using the Sysmex KX-21N analyzer; (2) Surveyor #1 reviewed the maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for maintenance were as follows: (a) Monthly (i) Clean Waste Chamber (ii) Clean Transducer (b) Every 3 Months (i) Clean Sample Rotor Valve (SRV) (3) Surveyor #1 then reviewed maintenance records for 19 months (June 2016 through December 2017) with the following identified: (a) The monthly maintenance had not been documented as performed as follows: (i) The Clean Waste Chamber had not been performed during the following months: (aa) June 2017 (bb) August 2017 (cc) September 2017 (dd) November 2017 (ee) December 2017 (ii) The Clean Transducer

	had not been performed during the following months: (aa) May 2017 (bb) July 2017 (cc) August 2017 (dd) October 2017 (ee) December 2017 (4) The surveyors reviewed the records with technical consultant #1 who stated there was no evidence the above maintenance had been performed as required. 39088 Based on a review of records and interview with technical consultant #1, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures on the coagulation analyzer. Findings include: (1) On the first day of the survey, technical consultant #1 stated to the surveyors IL ACL Elite analyzer was put into use on 01/21/17 to perform PT/INR (Prothrombin Time/Inertnational Normalized Ratio) and PTT (Partial Thromboplastin Time) testing; (2) Surveyor #2 reviewed the maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for maintenance were as follows: (a) Daily (i) Check Wash R-Emulsion Level (ii) Perform Needle Cleaning Procedure (iii) Priming - 1st shift (iv) Priming - 2nd shift (v) Priming - 3rd shift (b) Weekly (i) Clean instrument (ii) Clean Rinse Reservoir (iii) Clean Waste Line (c) Biweekly (i) Reboot the analyzer (ii) Clean Rotor Holder and Optic Path (d) Monthly (i) Check and Clean Air Filter (ii) Backup/Archive (3) Surveyor #2 then reviewed maintenance records for 11 months (February 2017 through December 2017) with the following identified: (a) The daily maintenance had not been documented as performed as follows: (i) Priming - 1st shift: (aa) February 2017 - Day 8 (bb) May 2017 - Day 21 (cc) June 2017 - Days 1,4 (ii) Priming - 2nd shift: (aa) February 2017 - Days 7,8 (bb) May 2017 - Day 21 (cc) June 2017 - Days 1,4,7,8,13,29 (iii) Priming - 3rd shift: (aa) June 2017 - Days 1,2,3,4,10,11,19,20,21,22 (bb) July 2017 - Day 6 (iv) Check Wash R-Emulsion Level (aa) May 2017 - Day 21 (bb) June 2017 - Days 1,2 (v) Perform Needle Cleaning Procedure (aa) May 2017 - Day 21 (bb) June 2017 - Days 1,2, (b) The weekly maintenance had not been documented as performed as follows: (i) Between 02/28/17 and 04/08/17 (c) The biweekly maintenance had not been documented as performed as follows: (i) Between 02/25/17 and 04/07/17 (ii) Between 10/27/17 and 12/07/17 (d) Monthly maintenance had not been documented as performed as follows: (i) Between 02/25/17 and 04/08/17 (ii) Between 06/10/17 and 08/08/17 (iii) Between 09/09/17 and 12/23/17 (4) The surveyors reviewed the records with technical consultant #1 who stated there was no evidence the above maintenance had been performed as required.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with technical consultant #1, the laboratory failed to follow their written protocol for ensuring coagulation and urine centrifuges were functioning properly. Findings include: COAGULATION CENTRIFUGE (1) On the first day of the survey, technical consultant #1 stated the following to the surveyors: (a) The laboratory began performing PT/INR (Prothrombin Time/International Normalized Ratio) and PTT

	(Partial Thromboplastin Time) testing on the IL ACL Elite analyzer on 01/21/17; (b) The Horizon Model 642 VES centrifuge processed patient specimens at a speed on 3800 rpm (revolutions per minute) for 10 minutes to obtain plasma for testing. (2) On the second day of the survey, surveyor #1 reviewed a policy titled "Laboratory Equipment Maintenance and Function Checks". It stated "The centrifuge(s) speed and spin time will be checked annually with a tachometer to validate the rpm setting. Time will be checked by a timer"; (3) Surveyor #1 reviewed the centrifuge maintenance records. Although the centrifuge speed checks had been performed on 04/01/16 and 08 /03/17, there was no evidence the centrifuge timer had been checked during the review period; (4) Surveyor #1 reviewed the findings with technical consultant #1, who stated the centrifuge timers had not been checked for accuracy during 2016 and 2017. URINE CENTRIFUGE (1) On the first day of the survey, technical consultant #1 stated to the surveyors urine sediment examinations were performed in the laboratory. The specimens were processed in the LW Scientific centrifuge at a speed of 1500 rpm for 5 minutes; (2) On the second day of the survey, surveyor #1 reviewed a policy titled "Laboratory Equipment Maintenance and Function Checks". It stated "The centrifuge(s) speed and spin time will be checked annually with a tachometer to validate the rpm setting. Time will be checked by a timer"; (3) Surveyor #1 reviewed the centrifuge maintenance records. Although the centrifuge speed checks had been performed on 04/01/16 and 08/03/17, there was no evidence the centrifuge timer had been checked during the review period; (4) Surveyor #1 reviewed the findings with technical consultant #1, who stated the centrifuge timers had not been checked for accuracy during 2016 and 2017.
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 technical consultant #1, the laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process for PTT testing. Findings include: (1) At the beginning of the survey, technical consultant #1 stated the following to surveyors (a) The IL ACL Elite analyzer was put into use to perform PTT (Partial Thromboplastin Time) testing on 01 /21/17; (b) Three levels of control materials were performed each eight hours of patient testing. From 01/21/17 through 12/13/17, the laboratory used Bio-Rad Lyphochek Coagulation control materials. Beginning 12/14/17, the laboratory used HemoSIL control materials; (c) The laboratory established their own means and 2 SD (standard deviation) ranges before new lot numbers of control materials were put into use. (2) On the second day of the survey, the surveyors reviewed quality control (QC) records for testing performed during 01/10/17 through 12/13/17 (during the time the Bio-Rad control materials were in use). The records showed that, although the

	laboratory had established a mean and 2 SD limit of acceptability for level 2 PTT, the package insert mean and limits of acceptability had been used as follows: (a) PTT Level 2 Lot# 78442 - The laboratory had established a mean of 57.6 and limits of acceptability of 52.9-62.3. The laboratory had used a mean of 58.3 and limits of acceptability of 46.7-69.9 to evaluate QC results. (3) The surveyors reviewed the records with technical consultant #1, who stated the laboratory had utilized the package insert mean and limits of acceptability, as indicated above, to evaluate PTT QC results for level 2 from January through December 2017.
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 technical consultant #1, the laboratory failed to follow the manufacturer's specifications for establishing normal reference intervals for a new coagulation analyzer. Findings include: (1) At the beginning of the survey, technical consultant #1 stated the following to the surveyors: (a) The IL ACL Elite analyzer was put into use to perform PT/INR (Protime/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing on 01/21/17; (b) The previous analyzer, which had been removed from service on 08/11/15, was the Sysmex CA-500 analyzer; (c) Prior to obtaining the ACL Elite analyzer, PT/INR and PTT testing had been sent to the reference laboratory. (2) On the third day of the survey, the surveyors reviewed the manufacturer's instructions for establishing a normal reference interval which stated: (a) "You must decide before starting which type of study to perform. Will you perform a full reference interval study or will you be verifying a previous reference interval? Either 120 or 20 normal donors following these screening guidelines": (i) "Donors should be healthy and have no known pathological conditions. Don't use patients (they are at the hospital for a medical reason). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high dose aspirin, etc. Donors should span the adult age range. Pediatric ranges should be established separately. Donors should be equally divided between male/female". (b) In addition, the instructions stated, "If you choose to do a full reference interval study, test 120 donors. Ideally specimens will be analyzed over a number of days, resulting in values that represent average run-to-run variation. If you choose to verify a range, you may use a 20-donor study under specific conditions. The main conditions are as follows: The original site must have done a full reference range study The original site must have used the identical type of analytical system (method, instrument and reagents)". (3) Based on the manufacturer's guidelines, the surveyors determined an initial 120 sample study was required, then subsequent studies may be performed using 20 samples due to the following: (a) The laboratory had previously used the Sysmex CA-500 analyzer (which was a different analytic system). (4) The surveyors reviewed the implementation records for the analyzer. The following was identified for PT and PTT: (a) The lot numbers that were in use when the analyzer was implemented (and currently in use) were: (i) PT Reagent - RecombiPlasTin 2G lot #N0462242 (ii) PTT Reagent - SynthASil Lot #N0764155 (b) The normal reference intervals had been established for each test performed on the

	analyzer as follows: (i) PT and PTT (aa) 25 donors had been utilized; (bb) For 10 of the donors, there was no evidence of their health status, medication history, age and gender; (cc) For 15 of the donors, 2 were male and 13 were female (not equally divided between male and female). (5) The surveyors reviewed the records with technical consultant #1 who stated the following: (a) The laboratory did not perform the 120 sample study; (b) The laboratory had not documented the health status, medication history, age, and gender for 10 of the donors; (c) The laboratory had not ensured the 15 donors were equally divided between male and female. (6) The following were examples of patient testing performed when the normal reference intervals had not been established for the new analyzer as required: (a) Patient #1 - PT /INR testing performed on 01/27/17 (b) Patient #2 - PT/INR testing performed on 01 /30/17 (c) Patient #3 - PT/INR and PTT testing performed on 02/01/17 (d) Patient #4 - PT/INR testing performed on 02/08/17 (e) Patient #5 - PT/INR testing performed on 02/20/17 (f) Patient #6 - PT/INR testing performed on 02/24/17 (g) Patient #7 - PT /INR testing performed on 03/14/17 (h) Patient #8 - PT/INR testing performed on 03 /20/17 (i) Patient #9 - PT/INR and PTT testing performed on 03/31/17 (j) Patient #10 - PT/INR testing performed on 04/04/17 (k) Patient #11 - PT/INR testing performed on 04/11/17 (l) Patient #12 - PT/INR and PTT testing performed on 04/17/17 (m) Patient #13 - PT/INR testing performed on 04/30/17 (n) Patient #14 - PT/INR testing performed on 05/03/17 (o) Patient #15 - PT/INR testing performed on 05/08/17 (p) Patient #16 - PT/INR and PTT testing performed on 05/24/17 (q) Patient #17 - PT /INR and PTT testing performed on 05/27/17 (r) Patient #18 - PT/INR testing performed on 06/02/17 (s) Patient #19 - PT/INRand PTT testing performed on 06/16 /17 (t) Patient #20 - PT/INR testing performed on 06/29/17 (u) Patient #21 - PT/INR testing performed on 07/11/17 (v) Patient #22 - PT/INR testing performed on 07/18 /17 (w) Patient #23 - PT/INR and PTT testing performed on 07/26/17 (x) Patient #24 - PT/INR testing performed on 08/08/17 (y) Patient #25 - PT/INR and PTT testing performed on 08/16/17 (z) Patient #26 - PT/INR testing performed on 08/23/17 (aa) Patient #27 - PT/INR and PTT testing performed on 08/31/17 (bb) Patient #28 - PT /INR testing performed on 09/10/17 (cc) Patient #29 - PT/INR testing performed on 09 /14/17 (dd) Patient #30 - PT/INR testing performed on 09/20/17 (ee) Patient #31 - PT /INR testing performed on 09/28/17 (ff) Patient #32 - PT/INR testing performed on 10 /09/17 (gg) Patient #33 - PT/INR testing performed on 10/11/17 (hh) Patient #34 - PT /INR testing performed on 10/15/17 (ii) Patient #35 - PT/INR testing performed on 10 /24/17 (jj) Patient #36 - PT/INR testing performed on 10/31/17 (kk) Patient #37 - PT /INR and PTT testing performed on 11/06/17 (ll) Patient #38 - PT/INR testing performed on 11/17/17 (mm) Patient #39 - PT/INR and PTT testing performed on 11 /21/17 (nn) Patient #40 - PT/INR testing performed on 12/04/17 (oo) Patient #41 - PT /INR testing performed on 12/14/17 (pp) Patient #42 - PT/INR and PTT testing performed on 12/17/17 (qq) Patient #43 - PT/INR and PTT testing performed on 12/26 /17 (rr) Patient #44 - PT/INR testing performed on 01/02/18 (ss) Patient #45- PT/INR testing performed on 01/14/18 (tt) Patient #46 - PT/INR testing performed on 01/23 /18 (uu) Patient #47 - PT/INR testing performed on 01/30/18 (vv) Patient #48 - PTT testing performed on 01/30/18
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)

	(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to perform corrective action for a quality control failure. Findings include: (1) At the beginning of the survey, technical consultant #1 stated the following to the surveyors: (a) The laboratory performed pH, pCO2, pO2 testing using the iSTAT 1 analyzer and the G3+ cartridge; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system requiring 3 levels of control materials be tested monthly. (2) On the second day of the survey, surveyor #2 asked technical consultant #1 to explain the laboratory procedure when unacceptable quality control (QC) results were obtained. Technical consultant #1 stated unacceptable QC results were routinely repeated with corrective action taken and documented; (3) Surveyor #2 reviewed monthly QC records between January 2016 through December 2017 and identified a QC failure for level 1 pO2 (lot# D15307A) tested on 05/09/16, with no documented corrective action. The value obtained was 107 with an acceptable range of 60-90; (4) Surveyor #2 reviewed the records with technical consultant #1 who stated corrective action had not been taken and documented.
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, policies and procedures, manufacturer's instructions, and interview with technical consultant #1, the 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 demonstrate the performance specification of reportable range for a new analyzer. Refer to D5421; (b) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (c) The laboratory failed to follow their written protocol for ensuring centrifuges were functioning properly. Refer to D5435; (d) The laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process for PTT testing. Refer to D5441; (e) The laboratory failed to follow the manufacturer's specifications for establishing normal reference intervals for a new coagulation analyzer. Refer to D5479; (f) The laboratory failed to perform corrective action for a quality control failure. Refer to D5781.
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 a patient report and interview with technical consultant #1, the laboratory failed to provide therapeutic reference intervals for INR test results. Findings include: (1) At the beginning of the survey, technical consultant #1 stated to the surveyors INR-International Normalized Ratio testing was performed using the ACL Elite analyzer; (2) On the second day of the survey, the surveyors reviewed one INR report for a patient tested on 01/30/18. The report did not include a therapeutic range (range for treatment of venous thrombosis, treatment of pulmonary embolism, prevention of systemic embolism, etc); (3) The report was reviewed with technical consultant #1, who stated that INR reports did not include a therapeutic range.
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, policies and procedures, manufacturer's instructions, and interview with technical consultant #1, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure test methods were performed as required to ensure accurate and reliable results were reported. Refer to D6014; (3) The laboratory director failed to attest that 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 that test reports included pertinent information required for interpretation. Refer to D6026.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the

	laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the performance specification of reportable range was demonstrated for a new analyzer. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #1, 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 maintenance procedures were performed as required by the manufacturers. Refer to D5429; (2) The laboratory director failed to ensure the written protocol was followed for ensuring centrifuges were functioning properly. Refer to D5435; (3) The laboratory director failed to ensure the manufacturer's specifications were followed for establishing normal reference intervals for a new coagulation analyzer. Refer to D5479.
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 technical consultant #1, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) On the first day of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. It was identified for 10 of 25 events, the attestation statements had been signed approximately 2-6 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 2016 Chemistry Group 1 Event - The samples had been tested on 09/30/16 and the attestation statement had not been signed by the laboratory director until 01/31/17; (b) Second 2016 Hematology/Coagulation Event - The samples had been tested on 07/26 /16 and the attestation statement had not been signed by the laboratory director until 01 /31/17; (c) Third 2016 Hematology/Coagulation Event - The samples had been tested on 11/15/16 and the attestation statement had not been signed by the laboratory

	director until 01/31/17; (d) Third 2016 Microbiology Event - The samples had been tested on 10/22/16 and the attestation statement had not been signed by the laboratory director until 01/31/17; (e) Second 2016 Immunology Event - The samples had been tested on 08/11/16 and the attestation statement had not been signed by the laboratory director until 01/31/17; (f) First 2017 Chemistry Miscellaneous Event - The samples had been tested on 04/29/17 and the attestation statement had not been signed by the laboratory director until 08/03/17; (g) First 2017 Hematology/Coagulation Event - The samples had been tested on 03/17/17 and the attestation statement had not been signed by the laboratory director until 05/01/17; (h) First 2017 Microbiology Event - The samples had been tested on 02/23/17 and the attestation statement had not been signed by the laboratory director until 05/01/17; (i) Second 2017 Microbiology Event - The samples had been tested on 06/27/17and the attestation statement had not been signed by the laboratory director until 08/03/17; (j) Second 2017 Immunology Event - The samples had been tested on 08/17/17 and the attestation statement had not been signed by the laboratory director until 10/26/17. (2) The surveyors reviewed the findings with the technical consultant #1 and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, 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 control procedures monitored the accuracy and precision of test performance. Refer to D5441. (2) The laboratory director failed to ensure corrective action had been taken for a quality control failure. Refer to D5781.
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 a patient report and interview with technical consultant #1, the

	laboratory director failed to ensure that test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure therapeutic reference intervals were provided for test results. Refer to D5807.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) On the first day of the survey, surveyor #2 reviewed personnel records for 3 persons who performed testing in 2016 and 2017. For 1 of 3 persons there was no evidence an annual evaluation had been documented as performed by the technical consultant. (a) 2016 (i) Testing Person #4 (2) The surveyors reviewed the findings with technical consultant #1, who stated the annual evaluation had not been documented as performed by the technical consultant in 2016 for the above testing person.