Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475262	09/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Haskell Regional Hospital, Inc	401 Nw H Street, Stigler, 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 09/24/18 through 09/27/18. The findings were reviewed with chief executive officer and laboratory manager/technical consultant #2 during an exit conference performed at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
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/technical consultant #2, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following was identified for 2 of 15 testing events: (a) First 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (b) Second 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (c) Third 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (2) The findings were reviewed with the laboratory manager

	/technical consultant #2 who stated the attestations had not been signed as indicated above.
D3017	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to have a transfusion service agreement between the laboratory and supplier for the procurement, transfer and availability of blood and blood products. Findings include: (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor the laboratory routinely maintained 2 units of O negative packed red blood cells and 2 units of O positive pack red blood cells in the ThermoScientific 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) On the fourth day of the survey, the surveyor reviewed the laboratory's records for a transfusion service agreement between the laboratory and the supplier (Oklahoma Blood Institute) and identified the following: (a) An approved agreement between the laboratory and the blood supplier for the purpose of procurement, transfer and availability of blood and blood products was not available. (4) The surveyor reviewed the findings with laboratory manager/technical consultant #2 who stated a transfusion agreement between the laboratory and supplier was not available as indicated above.
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 laboratory manager/technical consultant #2, the laboratory failed to ensure an adequate alarm system was in place for the blood bank refrigerator. Findings include: REFRIGERATOR ALARM CHECK (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor the laboratory routinely maintained 2 units of O negative packed red blood cells and 2 units of O positive pack red blood cells in the ThermoScientific 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) On the second day of the survey, the surveyor 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) The surveyor then reviewed the alarm check records for 2017 and 2018. It was identified that blood bank alarm checks had not been document as performed since 10 /30/17 through the second day of the survey; (4) The surveyor reviewed the records

	with laboratory manager/technical consultant #2 who stated the blood bank alaram had not been documented as performed as indicated above. TEMPERATURE CHARTS (1) On the second day of the survey, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (2) The surveyor reviewed 28 refrigerator charts dated from 12/26/17 through 09/09/18. The review indicated that 6 of 28 charts had not been changed by the 7th day of usage. The findings include: (a) Chart #5 - The chart was put into use on 01/22/18 and removed on 02/06/18 (15 days); (b) Chart #6 - The chart was put into use on 02/06/18 and removed 02/26/18 (16 days); (c) Chart #7 - The chart was put into use on 02/26/18 and removed 03/07/18 (9 days); (d) Chart #8 - The chart was put into use on 03/07/18 and removed 03/21/18 (14 days); (e) Chart #11 - The chart was put into use on 04/12 /18 and removed 05/01/18 (19 days); (f) Chart #27 - The chart was put into use on 07 /25/18 and removed 08/06/18 (12 days); (3) The surveyor reviewed the charts with the laboratory manager/technical consultant #2, who stated the charts had not been changed by the 7th day of usage as indicated above.
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/technical consultant #2, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2017 Chemistry Core Event (i) LDL (Low Density Lipoprotein) - 3 of 5 results exhibited a negative bias (aa) Sample CH-06 - SDI of -2.0 (bb) Sample CH-07 - SDI of -2.1 (cc) Sample CH-09 - SDI of -2.1 (b) Second 2018 Chemistry Core Event (i) Magnesium - 3 of 5 results exhibited a positive bias (aa) Sample CH-07 - SDI of 2.8 (bb) Sample CH-09 - SDI of 2.1 (cc) Sample CH-10 - SDI of 2.2 (dd) Sample CH-10 - SDI of 3.3 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager/technical consultant #2 who stated the biases had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by:

	Based on a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to evaluate the accuracy of testing when a proficiency result had not been graded by the proficiency program. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2017 second event (aa) Blood Cell Identification - BCI-13 and BCI-14 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the laboratory manager/technical consultant #2 if the results had been documented as evaluated. The laboratory manager /technical consultant #2 both reviewed the records and stated the non-graded results had not been documented as reviewed.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to provide written instructions to clients collecting and referring hematology and chemistry specimens. Findings include: (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated the following to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XS 1000i analyzer; (i) Hematology specimens were transported to the laboratory from outside home health agencies and long term care facilities. (b) The laboratory performed routine chemistry testing using the Beckman Coulter AU480 analyzer; (i) Routine chemistry specimens were transported to the laboratory from outside home health agencies and long term care facilities. (2) The surveyor asked the laboratory manager/technical consultant #2 if instructions (e.g., client service manual) had been written and provided to the home health agencies which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The laboratory manager/technical consultant #2 stated specimen handling instructions had not been written and provided to the clients.
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, procedure manual, and interview with the laboratory manager/technical consultant #2, the laboratory failed to follow the manufacturer's instructions. Findings include: (1) On the third day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor the

	Sysmex CA-530 analyzer was used to perform PT/INR (Prothrombin Time /International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing; (2) The surveyor reviewed the manufacturer's instructions for verifying a normal reference interval which stated: (a) "Donors must be from a healthy population (no known pathological conditions)"; (b) "Donors should not take any medications, including aspirin"; (3) The surveyor reviewed the implementation records for the analyzer. The following was identified for the current PT and PTT reagents put into use on 12/01/17 (PT Reagent - Siemens Dade Innovin lot #549708 and PTT Reagent - Siemens Actin FSL lot #556918A): (a) There was no documentation of the health status and medication history of the donors. (4) The surveyor reviewed the records with the laboratory manager/technical consultant #2 who stated there was no documentation to prove the health status and medication history of the donors.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to monitor temperatures; and failed to ensure the humidity was maintained as required. Findings include: SUMMIT PROFESSIONAL FREEZER (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor chemistry reagents were stored in the Summit Professional Freezer within a range of -20 to -70 degrees C (Centigrade); (2) On the third day of the survey, the surveyor reviewed the temperature records from January 2018 through June 2018 and identified the following: (a) Temperatures not documented between: (i) 01/06/18 and 01/08/18 (3) The surveyor reviewed the findings with the laboratory manager/technical consultant #2 who stated the above temperatures had not been documented. HEMATOLOGY/COAGULATION REFRIGERATOR (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor that a hematology/coagulation refrigerator was monitored daily (acceptable range 2 - 8 degrees C); (2) On the third day of the survey, the surveyor reviewed the temperature records from January 2018 through June 2018 and identified the following: (a) Temperatures not documented between: (i) 01/06/18 and 01/08/18 (ii) 04/14/18 and 04/16/18 (3) The surveyor reviewed the findings with the laboratory manager/technical consultant #2 who stated the above temperatures had not been documented. IMMUNOHEMATOLOGY REFRIGERATOR (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor that the immunohematology refrigerator was monitored daily (acceptable range 2 - 5 degrees C); (2) On the third day of the survey, the surveyor reviewed the temperature records from January 2018 through June 2018 and identified the following: (a) Temperatures not documented between: (i) 04/14/18 and 04/16/18 (3) The surveyor reviewed the findings with the laboratory manager/technical consultant #2 who stated the above temperatures had not been documented. ROOM TEMPERATURE (1) On the first day of the survey, the laboratory manager/technical

	consultant #2 stated to the surveyor that a laboratory room temperature was monitored daily (acceptable range 18-29 degrees C); (2) On the third day of the survey, the surveyor reviewed the temperature records from January 2018 through June 2018 and identified the following: (a) Temperatures not documented between: (i) 01/06/18 and 01/08/18 (ii) 01/20/18 and 01/22/18 (3) The surveyor reviewed the findings with the laboratory manager/technical consultant #2 who stated the above temperatures had not been documented. SYSMEX CA-500 HUMIDITY (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) PT (Prothrombin Time)/INR (International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing was performed using the Sysmex CA-500 analyzer. (2) On the third day of the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzers. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) The surveyor reviewed laboratory records from January 2018 through June 2018 and identified daily monitoring of humidity was less than 30% for the following dates: (a) January 2018 - Days 1,3,4,5,6,12,13,14,15,16,17,18,19,19,22,23,24,25,26,27,29,30,31 (b) February 2018 - Days 2,3,4,5,6,7,8,9,11,12,13,19,21,27 (c) March 2018 - Days 6,8,9,10,14,15,21 (d) April 2018 - Days 7,8,16,17 (4) The surveyor reviewed the storage requirements with the laboratory manager/technical consultant #2, who stated the humidity had not been maintained as required by the manufacturer.
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: The Based on a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to demonstrate the performance specifications for a new test kit. Findings include: (1) At the beginning of the survey, the laboratory manager/technical consultant #2 stated to the surveyor that the laboratory recently obtained the Henry Schein One Step+ Combo test kit to perform patient pregnancy (HCG) testing. The surveyor then asked laboratory manager/technical consultant #2 to verify what specimen type the laboratory used for the testing. The laboratory manager /technical consultant #2 stated that serum samples would be used to perform the testing (classifying the test as non-waived); (2) On the second day of the survey, the surveyor asked the laboratory manager/technical consultant #2 for the date the serum pregnancy test kit had been put into use for patient testing; and for records to substantiate that the performance specifications (e.g., accuracy, precision) had been demonstrated for the test kit before it had been put into use. The laboratory manager /technical consultant #2 stated the following: (a) The test kit had been put into use for patient testing on 04/06/18; (b) The performance specifications had not been demonstrated for the test kit before it was put into use. (3) The surveyor then reviewed laboratory records and identified that eight patient serum pregnancy tests had been performed and reported using the new test kit as follows: (a) Testing performed on 04 /25/18 (b) Testing performed on 04/27/18 (c) Testing performed on 05/03/18 (d)

	Testing performed on 05/06/18 (e) Testing performed on 05/20/18 (f) Testing performed on 07/11/18 (g) Testing performed on 08/01/18 (h) Testing performed on 08/12/18 NOTE: The deficiency was cited on the previous recertification survey performed on 02/28/17 through 03/02/17
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/technical consultant #2, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: HEMATOLOGY (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i 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 requirement for weekly maintenance was as follows: (a) Power Down IPU (3) The surveyor then reviewed maintenance records for 13 months (August 2017 through August 2018). There was no evidence the weekly maintenance had been performed: (a) Between 08/26/17and 09/10/17 (b) Between 10/20/17 and 11/11/17 (c) Between 02/14/18 and 03/01/18 (d) Between 03/14 /18 and 04/04/18 (e) Between 06/22/18 and 07/09/18 (f) Between 07/26/18 and 08/10 /18 (4) The surveyor reviewed the records with the laboratory manager/technical consultant #2, who stated the maintenance had not been performed as required. COAGULATION (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor that PT/INR (Protime/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing was performed on the Sysmex CA-500 analyzer; (2) One the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for maintenance were as follows: (a) Daily (i) Turn instrument off, then on (ii) Empty Waste bottle (iii) Replensish diH2O in Rinse Bottle (iv) Replenish Reaction Tubes (v) Empty Reaction Tube Trash drawer (vi) Wipe Probe with Alcohol Swab (vii) Check and drain Penumatic Trap Chamber (viii) Replace CA Clean 1 (ix) Rinse Probe with CA CLEAN (x) Check Temperatures (Sysmex-Temp) (b) Weekly (i) Clean diH2O Rinse Bottle with Alcohol (c) Monthly (i) Replace Reagent Bottles (3) The surveyor then reviewed maintenance records for 8 months (January 2018 through August 2018). There was no evidence the following maintenance had been documented as performed: (a) Daily (i) Between 06/14/18 and 06/17/18 (b) Weekly (i) Between 06/17/18 and 07/11/18 (c) Monthly (i) Between 01 /03/18 and 03/01/18 (ii) Between 03/01/18 and 05/03/18 (4) The surveyor reviewed the records with the laboratory manager/technical consultant #2, who stated the maintenance had not been performed as required. CHEMISTRY - BECKMAN COULTER AU480 (1) On the first day of the survey, the laboratory manager /technical consultant #2 stated to the surveyor that *CMP, Lipid profile (Total Cholesterol, High Density Lipoprotein Cholesterol, Triglyceride), A1C, GGT (Gamma-Glutamyl Transpeptidase), Gentamicin, Vancomycin, Acetaminophen, Ethanol, Ammonia, Salicylate, Iron, Digoxin, Dilantin, Amylase, Lipase, Total Bilirubin, Magnesium testing were performed on the Beckman Counter AU480

	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 for maintenance were as follows: (a) Daily (i) Inspect the Syringes for Leaks (ii) Inspect he Wash Solution Roller Pump for Leaks (iii) Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars (iv) Inspect the Wash Solution and Replenish As Needed (v) Inspect the Printer (Option) and Paper (vi) Replace the DI water or diluent in the Pre-dilution Bottle (vii) Inspect the Stability of the Upper Cover (viii) Prepare the Sample Probe Wash Solutions (ix) ISE Cleaning (x) ISE Calibration (b) Weekly (i) Clean the Sample Probe and Mix Bars (ii) Perform a W2 (iii) Perform a Photocal (iv) Clean the Pre-dilution Bottle (v) Check Selectivity of the Na/K Electrodes (vi) Enhanced Cleaning of ISE Electrode Line (3) The surveyor then reviewed maintenance records for 8 months (January 2018 through August 2018). The following was identified: (a) There was no evidence the daily maintenance had been performed: (a) Between 01/23/18 and 01/25/18 (b) Between 01 /27/18 and 01/31/18 (c) Between 02/16/18 and 02/18/18 (d) Between 03/21/18 and 03 /23/18 (e) Between 06/08/18 and 06/10/18 (f) Between 06/22/18 and 06/24/18 (g) Between 07/05/18 and 07/07/18 (h) Between 07/20/18 and 07/23/18 (i) Between 07/23 /18 and 07/27/18 (b) There was no evidence the weekly maintenance had been performed: (i) Between 01/18/18 and 02/01/18 (4) The surveyor reviewed the records with the laboratory manager/technical consultant #2, who stated the maintenance had not been performed as required. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein CHEMISTRY - BECKMAN COULTER ACCESS II (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor that CKMB, Troponin I, TSH (Thyroid Stimulating Hormone), FT4 (Thyroxine), PSA (Prostate Specific Antigen), Ferritin, Folate, Vitamin B12 and Vitamin D testing were performed on the Beckman Coulter Access II 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 for daily and weekly maintenance were as follows: (a) Daily (i) Check Zone Temperatures (ii) Check System Supplies (iii) Empty Liquid Waste Bottles (iv) System Backup Successful? (v) Inspect Fluidic Module (vi) Clean Probe Exteriors (vii) Prime Substrate (viii) Run Daily Clean System (b) Weekly (i) Clean Instrument Exterior (ii) Inspect Liquid Waste Bottle (iii) Check Waste Filter Bottle (iv) Inspect/Clean Primary Probe (v) Replace/Clean Primary Probe (vi) Replace/Clean Aspirate Probe (vii) Run System Check (3) The surveyor then reviewed maintenance records for 8 months (January 2018 through August 2018). The following was identified: (a) There was no evidence the daily maintenance had been performed: (a) Between 01/28/18 and 01/31/18 (b) Between 02 /18/18 and 02/20/18 (c) Between 07/20/18 and 07/22/18 (d) Between 08/01/18 and 08 /03/18 (e) Between 08/17/18 and 08/20/18 (b) There was no evidence the weekly maintenance had been performed: (i) Between 02/02/18 and 03/03/18 (ii) Between 03 /17/18 and 03/31/18 (iii) Between 03/31/18 and 04/12/18 (iv) Between 04/12/18 and 05/09/18 (v) Between 07/23/18 and 08/07/18 (vi) Between 08/11/18 and 08/24/18 (4) The surveyor reviewed the records with the laboratory manager/technical consultant #2, who stated the maintenance had not been performed as required.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor Ethanol and Ammonia testing were performed using the Beckman Coulter 480 analyzer; (2) On the third day of the survey, the surveyor requested 2017 and 2018 calibration verification records for the analyzer (since calibration procedures were not routinely performed, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). The laboratory manager /technical consultant #2 provided documentation that verified calibration verification procedures had not been document as performed between 01/14/18 through the third day of the survey, 09/26/18 (due in June 2018). (3) The surveyor reviewed the records with the laboratory manager/technical consultant #2 who stated calibration verification procedures had not been performed every six months as indicated above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to ensure corrective actions were taken when quality control was not performed; and failed to evaluate patient test results obtained when quality control was not performed to determine if the results had been adversely affected. Findings include: D-DIMER TESTING (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated the following to the surveyor:

	(a) The laboratory performed D-Dimer testing using the Biosite Triage Meter Plus analyzer; (b) Two levels of quality control materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan); (c) The results for two levels of control materials must be acceptable in order to report patient results. (2) On the third day of the survey, the surveyor then reviewed D-Dimer quality control records for testing performed from June 2017 through July 2018. For the review period, the following was identified for 3 of 14 months: (a) Quality control results could not be located for July 2017; (b) Quality control results could not be located for February 2018; (c) Quality control results could not be located for March 2018. (3) The surveyor asked the laboratory manager/technical consultant #2 if two levels of quality control for D-Dimer testing had been performed. The laboratory manager /technical consultant #2 stated D-Dimer monthly quality controls were not performed in July 2017, February 2018 and March 2018; (4) The surveyor obtained examples of patient D-Dimer testing performed from 02/16/18 through 03/29/18, with D-Dimer results reported when there was no evidence that two levels of controls were performed. They were: (a) Patient testing performed on 02/15/18 (b) Patient testing performed on 02/17/18 (c) Patient testing performed on 03/02/18 (d) Patient testing performed on 03/04/18 (e) Patient testing performed on 03/10/18 (f) Patient testing performed on 03/12/18 (g) Patient testing performed on 03/13/18 (h) Patient testing performed on 03/17/18 (i) Patient testing performed on 03/24/18 (j) Patient testing performed on 03/26/18 (k) Patient testing performed on 03/29/18 (5) The surveyor asked the laboratory manager/technical consultant #2 if results had been evaluated to determine if they had been adversely affected. The laboratory manager/technical consultant #2 stated there was no evidence which would support that the results had been evaluated. ARTERIAL BLOOD GAS TESTING (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated the following to the surveyor: (a) The laboratory performed Arterial Blood Gas testing using the OPTI-CCA-TS analyzer; (b) Two levels of quality control materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan); (c) The results for two levels of control materials must be acceptable in order to report patient results. (2) On the third day of the survey, the surveyor then reviewed Arterial blood Gas quality control records for testing performed from June 2017 through July 2018. For the review period, the following was identified for 3 of 14 months: (a) Quality control results could not be located for February 2018 ; (b) Quality control results could not be located for March 2018; (c) Quality control results could not be located for May 2018. (3) The surveyor asked the laboratory manager/technical consultant #2 is two levels of quality control for Arterial Blood Gas testing had been performed. The laboratory manager/technical consultant #2 stated Arterial Blood Gas monthly quality controls were not performed in February 2018, March 2018 and May 2018; (4) The surveyor obtained examples of patient Arterial Blood Gas testing performed from 05/16/18 through 06/03/18, with Arterial Blood Gas results reported when there was no evidence that two levels of controls were performed. They were: (a) Patient testing performed on 05/16/18 (b) Patient testing performed on 05/18/18 (c) Patient testing performed on 05/26/18 (d) Patient testing performed on 06/03/18 (5) The surveyor asked the laboratory manager/technical consultant #2 if results had been evaluated to determine if they had been adversely affected. The laboratory manager/technical consultant #2 stated there was no evidence which would support that the results had been evaluated.
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 and interview with the laboratory manager/technical consultant #2, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: D-DIMER TESTING (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated the following to the surveyor: (a) The laboratory performed D-Dimer testing using the Biosite Triage Meter Plus analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) On the third day of the survey, the surveyor reviewed the IQCP (dated as effective 05/01/16). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continued to provide accurate and reliable test results. There was no evidence of QA reviews for the IQCP since the effective date; (3) The surveyor reviewed the records with the laboratory manager/technical consultant #2 and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if a QA review had been performed since 05/01/16. The laboratory manager/technical consultant #2 stated a policy had not been written and a QA review had not been performed. ARTERIAL BLOOD GAS TESTING (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated the following to the surveyor: (a) The laboratory performed Arterial Blood Gas testing using the OPTI-CCA- TS analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) On the third day of the survey, the surveyor reviewed the IQCP (dated as effective 05/01/16). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continued to provide accurate and reliable test results. There was no evidence of QA reviews for the IQCP since the effective date; (3) The surveyor reviewed the records with the laboratory manager/technical consultant #2 and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if a QA review had been performed since 05/01/16. The laboratory manager/technical consultant #2 stated a policy had not been written and a QA review had not been performed.
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/technical consultant #2, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) On the first day of the survey, the laboratory manager/technical consultant #2 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex 1000i analyzer; (2) On the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 04/12/18 at 09:45 am; the second report was for an adult male patient with the testing

	performed on 07/12/18 at 11:27 am. Both reports included the same reference intervals for the CBC parameter of RBC (Red Blood Cell which was: (a) RBC (Red Blood Cell) - 4.17 - 5.37 M/UL (b) Hct (Hematocrit) - 39.2 - 48.9 % (3) The surveyor reviewed the findings with the laboratory manager/technical consultant #2 who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
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 laboratory manager/technical consultant #2, 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, the surveyor reviewed 2017 and 2018 proficiency testing records. It was identified for 2 of 15 events, the attestation statements had been signed approximately 1-2 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 2017 Hematology/Coagulation Event - The samples had been tested on 07/25 /17 and the attestation statement had not been signed by the laboratory director until 09 /18/17; (b) First 2018 Chemistry Core Event - The samples had been tested on 02/12 /18 and the attestation statement had not been signed by the laboratory director until 03 /20/18. (2) The surveyor reviewed the findings with laboratory manager/technical consultant #2 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.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview the laboratory manager/technical consultant #2, the technical consultant failed to ensure that persons performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #7 - The initial training for this person was completed on 08/14/17. There was no evidence that a semiannual evaluation had been performed (due 02/2018); (2) The surveyor reviewed

	the records with the laboratory manager/technical consultant #2, who stated there were no records to prove the above persons had been evaluated semiannually.