Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0050739	04/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Beaver County Hospital Authority	212 East 8th Street, Beaver, 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 04/28,29,30,2021. The laboratory was found out of compliance with the following CLIA regulations: 493.1210; D5016: Routine Chemistry 493.1215; D5024: Hematology 493.1403; D6000: Laboratory Director, Moderate Complexity Testing The findings were reviewed with the laboratory manager and lead technologist at the conclusion of the survey.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and lead technologist, the laboratory failed to ensure the requirements were met for the subspecialty of Routine Chemistry for Blood Gas and ALT testing. Findings include: (1) The laboratory failed to demonstrate the performance specifications for Blood Gas and ALT-V testing. Refer to D5421; (2) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (3) The laboratory failed to ensure data supported the QC frequency as defined in the QCP portion of the IQCP for Blood Gas testing. Refer to D5445; (4) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791. the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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, written procedure, manufacturer's instructions, and interview with the laboratory manager and lead technologist, the laboratory failed to ensure the requirements were met for the specialty of Hematology for D-dimer and ESR testing. Findings include: (1) The laboratory failed to ensure the demonstrated reportable ranges were utilized for new D-dimer and ESR (Erythrocyte Sedimentation Rate) test methods. Refer to D5421; (2) The laboratory failed to follow the manufacturer's quality control specifications for 4 of 4 ESR control lot numbers. Refer to D5479; (3) The laboratory failed to perform two levels of quality control materials each eight hours of D-dimer testing 26 of 30 days of patient testing. Refer to D5545; (4) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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, observation, and interview with the laboratory manager and lead technologist, the laboratory failed to ensure materials were being stored as required. Findings include: (1) On 04/28/2021 at 04:45 pm, the surveyor observed the outpatient phlebotomy room, located across the hall from the laboratory. The following examples of collection tubes, used by the laboratory to collect patient blood specimens, were observed in the room, with the manufacturer's storage requirements: (a) BD Vacutainer Buff Na Citrate 3.2% tubes - 30 tubes of lot #0227240; storage requirement of 4-25 degrees Centigrade (C); (b) BD Vacutainer Lithium Heparin tubes - 26 tubes of lot #0289731; storage requirement of 4-25 degrees C; (c) BD Vacutainer K2 EDTA tubes - 28 tubes of lot #0316361; storage requirement of 4-25 degrees C. (2) The surveyors asked the laboratory manager and lead technologist if the temperature of the phlebotomy room was being monitored. The laboratory manager and lead technologist stated on 04/28/2021 at 04:55 pm, the laboratory was not monitoring the temperature of the outpatient phlebotomy room.
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, written procedure, and interview with the laboratory manager and lead technologist, the laboratory failed to ensure the demonstrated reportable ranges were utilized for 2 of 4 new test methods; and failed to verify the performance specifications for 2 of 4 new test methods. Findings include: QUIDEL TRIAGE METER PRO (1) On 04/28/2021 at 10:30 am, the laboratory manager stated to the surveyor, the laboratory began using the Quidel Triage Meter Pro analyzer to perform D-dimer testing 02/17/2021; (2) The surveyor reviewed the performance specification records for test system and identified the laboratory had demonstrated a reportable range of 198-4030 ng/ml; (3) The surveyor reviewed the records with the laboratory manager and lead technologist and requested documentation to ensure the laboratory was utilizing the reportable range that had been demonstrated by the laboratory. The laboratory manager and lead technologist provided the written procedure for D-dimer testing, which included the manufacturer's reportable range of 100-5000 ng/ml instead of the reportable range of 198-4030 that had been demonstrated by the laboratory; (4) The surveyor reviewed the findings with the lead technologist who stated on 04/28/2021 at 04:00 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory; (5) Refer to D5545 for examples of patient testing performed. MINII-SED ANALYZER (1) On 04/28 /2021 at 10:20 am, the laboratory manager stated to the surveyor, the laboratory began using the minii-Sed analyzer to perform ESR (Erthrocyte Sedimentation Rate) testing 01/11/2021; (2) The surveyor reviewed the performance specification records for test system and identified the laboratory had demonstrated a reportable range of 4.0-97.0 mm/hour; (3) The surveyor then reviewed patient testing records and identified that ESR results less than 4.0 (the lowest value demonstrated by the laboratory) had been reported for 4 of 12 records reviewed: (a) Patient Sample #638657974 - Reported as 1 mm/hour on 02/18/2021 (b) Patient Sample #639694524 - Reported as 1 mm/hour on 03/16/2021 (c) Patient Sample #639793184 - Reported as 1 mm/hour on 03/18/2021 (d) Patient Sample #640041570 - Reported as 1 mm/hour on 03/24/2021 (4) The surveyor reviewed the records with the lead technologist who stated on 04/28/2021 at 11:45, the laboratory was not utilizing the reportable range that had been demonstrated by the laboratory. ISTAT 1 AND EG7+ CARTRIDGE (1) On 04/28 /2021 at 10:30 am, the laboratory manager stated to the surveyor the laboratory began using the iSTAT 1 and the EG7+ Cartridge to perform patient Blood Gas (pH, pCO2, and pO2) testing on 02/14/2020; (2) On 04/29/2021, the surveyor requested the performance specification records to ensure the laboratory demonstrated the accuracy, precision, reportable range, and verified the reference ranges for the new test system prior to putting into use for patient testing. The lead technologist stated to the surveyor on 04/28/2021 at 03:30 pm, the laboratory did not verify the performance specifications for the EG7+ cartridge; (3) Refer to D5445 for examples of patient Blood Gas testing performed when the laboratory failed to verify the performance specifications for the new test system. ALT-V REAGENT (1) On 04/28/2021 at 10:30 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed ALT (Alanine Aminotransferase) testing, which was included as part of a CMP (Comprehensive Metabolic Panel) using the Ortho Vitros 350 analyzer; (b) ALT-V (a new ALT reagent), was put into use on 08/22/2019. (2) On 04/30/2021, the surveyor requested the performance specification records for ALT-V to ensure the laboratory demonstrated the accuracy, precision, reportable range, and verified the

	reference range for the new test prior to putting into use for patient testing. The laboratory manager and lead technologist stated to the surveyor on 04/30/2021 at 09: 40 am, the laboratory did not verify the performance specifications for ALT-V; (3) The following were examples of patient CMP testing performed, which included the analyte ALT, when the laboratory failed to verify the performance specifications for the new test: (a) Patient Sample #618784287 - Testing performed on 08/27/2019 (b) Patient Sample #618929575 - Testing performed on 08/31/2019 (c) Patient Sample #622602845 - Testing performed on 12/12/2019 (d) Patient Sample #622988173 - Testing performed on 12/23/2019 (e) Patient Sample #625714440 - Testing performed on 03/06/2020 (f) Patient Sample #62633778 - Testing performed on 03/20/2020 (g) Patient Sample #628834280 - Testing performed on 06/18/2020 (h) Patient Sample #62970429 - Testing performed on 06/30/2020 (i) Patient Sample #63959526 - Testing performed on 03/09/2021 (j) Patient Sample #63945319 - Testing performed on 03/17/2021 (k) Patient Sample #640325287 - Testing performed on 03/31/2021
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 04/28/2021 at 10:30 am, the laboratory manager stated to the surveyor the laboratory performed Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Amylase, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Total Cholesterol, HDL ((High Density Lipoprotein), CO2, CK (Creatine Kinase), Creatinine, Glucose, Lactic Acid, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein Triglycerides, BUN, Uric Acid, Acetaminophen, Alcohol, Salicylates, and Digoxin testing using the Ortho Vitros 350 analyzer; (2) On 04/29 /2021, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log for the analyzer, which required the following weekly maintenance: (a) Clean Tray Platform and Transport Arm (b) Clean Cup Retainer (c) Clean Diluent Bottles (d) Clean Tip Locator Assembly (e) Clean Control Unit Screen (f) Clean Keypad Cover (g) Inspect, Clean, and/or Replace Air Filter (h) Back up QC/Config/Calibration Data (3) The surveyor then reviewed maintenance records for 15 months (January 2020 through March 2021). The weekly maintenance had not been documented as performed between: (a) 04/10/2020 and 04/24/2020 (b) 10/23/2020 and 11/06/2020 (4) The surveyor reviewed the records with the laboratory manager who stated on 04/29/2021 at 04:50 pm, the maintenance had not been performed as stated above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through

	493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and lead technologist, the laboratory failed to ensure data supported the QC frequency as defined in the QCP portion of the IQCP. Findings include: (1) On 04/28/2021 at 10:30 am, the laboratory manager stated the following to the surveyor: (a) The laboratory began using the iSTAT 1 and the EG7+ Cartridge to perform patient Blood Gas (pH, pCO2, and pO2) testing on 02/14/2020; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) On 04/29/2021, the surveyor reviewed the IQCP (dated as effective on 02/01/2020) and identified the QCP (Quality Control Plan) required two levels of external QC (Quality Control) materials be performed every 30 days and with new lot numbers or shipments of test cartridges; (3) The surveyor then reviewed the supporting documentation for the QCP and identified the following: (a) The laboratory had not tested external QC materials to support the QC frequency of every 30 days, as defined in the QCP; (b) Two levels of QC had been tested for 9 days (not at least 30 days). (4) The surveyor reviewed the records with the laboratory manager and lead technologist and asked if additional documentation was available to support the reduced external QC frequency of every 30 days. The laboratory manager and lead technologist stated to the surveyor on 04/29 /2021 at 03:45 pm, QC had not been tested for at least 30 days; (5) The following were examples of patient Blood Gas testing performed: (a) Patient Sample #624927802 - Testing performed on 02/14/2020 (b) Patient Sample #625361211 - Testing performed on 02/26/2020 (c) Patient Sample #625714524 - Testing performed on 03/06/2020 (d) Patient Sample #626332334 - Testing performed on 03/24/2020 (e) Patient Sample #626553832 - Testing performed on 04/02/2020 (f) Patient Sample #628479648 - Testing performed on 06/09/2020 (g) Patient Sample #628967114 - Testing performed on 06/23/2020 (h) Patient Sample #629524974 - Testing performed on 07/07/2020 (i) Patient Sample #630455458 - Testing performed on 07/30/2020 (j) Patient Sample #630890794 - Testing performed on 08/11/2020 (k) Patient Sample #631197584 - Testing performed on 08/18/2020 (l) Patient Sample #631945364 - Testing performed on 09/06/2020 (m) Patient Sample #632740412 - Testing performed on 09/25/2020 (n) Patient Sample #633895269 - Testing performed on 10 /23/2020 (o) Patient Sample #634178803 - Testing performed on 10/30/2020 (p) Patient Sample #634421398 - Testing performed on 11/05/2020 (q) Patient Sample #634727254 - Testing performed on 11/12/2020 (r) Patient Sample #635427328 - Testing performed on 11/30/2020 (s) Patient Sample #638330154 - Testing performed on 02/09/2021 (t) Patient Sample #638650379 - Testing performed on 02/18/2021 (u) Patient Sample #639290160 - Testing performed on 03/05/2021 (v) Patient Sample #639671628 - Testing performed on 03/15/2021
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and the lead technologist, the laboratory failed to perform control procedures each day of blood bank testing for 1 of 10 days of patient testing. Findings include: (1) On 04/28/2021 at 10:00 am, the laboratory manager stated to the surveyor the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)) using the tube method; (2) The surveyor reviewed records for blood bank testing performed from 01/02/2020 and 04/12/2021 and identified quality control had not been performed for 1 of 10 days when a patient Type and Screen had been performed. The specific day was 09/25/2020; (3) The surveyor reviewed the records with the lead technologist who stated on 04/28/2021 at 03:10 pm, quality control had not been documented as performed on 09/25/2020.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and lead technologist, the laboratory failed to follow the manufacturer's quality control specifications for 4 of 4 lot numbers. Findings include: (1) On 04/28/2021, the laboratory manager stated the following to the surveyor: (a) The laboratory began using the minii-Sed analyzer to perform ESR (Erthrocyte Sedimentation Rate) testing 01/11/2021; (b) The Seditrol Erythrocyte Sedimentation Rate control materials (level 1 and level 2) were performed each day of patient testing. (2) On 04/29/2021, the surveyor reviewed the manufacturer's instructions for the control materials. They stated "It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as a guide; (3) The surveyor then reviewed QC (Quality Control) records for 4 lot number of control materials used from 01/11/2021 through 04/29/2021. The records showed the laboratory had used the package insert means and limits or established a mean and used the manufacturer's limits for each level of control instead of establishing their own means and limits as stated in the manufacturer's package insert: (a) Controls in use from 01/11/2021 through 03/31/2021: (i) Level 1 lot #C138 - The laboratory had used the manufacturer's range of 6-18 mm/hour; (ii) Level 2 lot #C238 - The laboratory had used the manufacturer's range of 40-94 mm/hour. (b) Controls put into use on 04/01/2021 and were currently in use: (i) Level 1 lot #C139 - The laboratory had established a mean of 8.0 (manufacturer's mean was 10), but used the manufacturer's limits of acceptability, resulting in a range of 1-15 mm/hour (manufacturer's range was 3-17 mm/hour); (ii) Level 2 lot #C239 - The laboratory had used the manufacturer's range of 37-89 mm/hour. (4) The surveyor reviewed the findings with the lead technologist, who stated to the surveyor on 04/29/2021 at 11:30 am, the laboratory had not followed the manufacturer's instructions for establishing means and limits of acceptability for the controls; (5) The following were examples of patient ESR testing performed: (a) Patient Sample #6379652091 - Testing performed

	on 02/01/2021 (b) Patient Sample #638565813 - Testing performed on 02/16/2021 (c) Patient Sample #638876388 - Testing performed on 02/24/2021 (d) Patient Sample #639195481 - Testing performed on 03/03/2021 (e) Patient Sample #639703392 - Testing performed on 03/16/2021 (f) Patient Sample #640826737 - Testing performed on 04/13/2021 (g) Patient Sample #641053114 - Testing performed on 04/19/2021 (h) Patient Sample #641258927 - Testing performed on 04/23/2021
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and lead technologist, the laboratory failed to perform two levels of quality control materials each eight hours of D-dimer testing 26 of 30 days of patient testing. Findings include: (1) On 04/28/2021 at 10:30 am, the laboratory manager stated to the following to the surveyor: (a) The laboratory began using the Quidel Triage Meter Pro analyzer to perform D-dimer testing 02/17/2021; (b) Two levels of QC (Quality Control) materials were performed every 30 days and with new lot numbers of test devices. (2) The surveyor asked the lead technologist if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The lead technologist stated on 04/28 /2021 at 04:30 pm, an IQCP had not been developed. Therefore, the surveyor determined two levels of QC materials must be performed each eight hours of patient testing; (3) The surveyor reviewed QC and patient testing records for testing performed from 02/17/2021 through 04/28/2021. The records showed two levels of QC materials had not been performed each eight hours of patient D-dimer testing for 26 of 30 days of patient testing reviewed. Two levels of QC materials had not been performed for the following days when D-dimer testing had been performed: (a) Patient Sample #638611530 - Testing performed on 02/17/2021 (b) Patient Sample #638642874 - Testing performed on 02/18/2021 (c) Patient Sample #638698297 - Testing performed on 02/19/2021 (d) Patient Sample #638847767 - Testing performed on 02/23/2021 (e) Patient Sample #638962906 - Testing performed on 02/26/2021 (f) Patient Sample #639041606 - Testing performed on 02/28/2021 (g) Patient Sample #63090350 - Testing performed on 03/01/2021 (h) Patient Sample #639120872 - Testing performed on 03/02/2021 (i) Patient Sample #639319173 - Testing performed on 03/06/2021 (j) Patient Sample #639332400 - Testing performed on 03/07/2021 (k) Patient Sample #639458576 - Testing performed on 03/10/2021 (l) Patient Sample #639529520 - Testing performed on 03/11/2021 (m) Patient Sample #639560820 - Testing performed on 03/12/2021 (n) Patient Sample #639630279 - Testing performed on 03/14/2021 (o) Patient Sample #639657331 - Testing performed on 03/15/2021 (p) Patient Sample #639817234 - Testing performed on 03/18/2021 (q) Patient Sample #639884768 - Testing performed on 03/20/2021 (r) Patient Sample #640185825 - Testing performed on 03/28/2021 (s) Patient Sample #640325546 - Testing performed on 03/30/2021 (t) Patient Sample #640437074 - Testing performed on 04/03/2021 (u) Patient Sample #640508292 - Testing performed on 04/05/2021 (v) Patient Sample #640694673 - Testing performed on 04/09/2021 (w) Patient Sample #640918461 - Testing performed on 04/15/2021 (x) Patient Sample #641124257 - Testing performed on 04/20/2021 (y) Patient Sample #641344995 - Testing performed on 04/26/2021 (z)

	Patient Sample #641438860 - Testing performed on 04/28/2021 (4) The surveyor reviewed the records with the laboratory manager and lead technologist. Both stated on 04/28/2021 at 04:45 pm, two levels of QC materials had not been performed each eight hours of patient testing.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure units of blood were stored under appropriate conditions for 3 of 26 temperature charts. Findings include: (1) On 04/28/2021 at 11:00 am, the laboratory manager stated to the surveyor units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 04/28/2021 at 11:30 am, 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; (3) The surveyor reviewed 26 refrigerator charts dated from 10/16/2020 through 04/23/2021. The review showed that 3 of 26 charts had not been changed by the 7th day of as follows: (a) Chart #1 - The chart was put into use on 10/23/2020 and removed on 11/02/2020 (10 days); (b) Chart #2 - The chart was put into use on 12/18/2020 and removed on 12/28/2020 (10 days); (c) Chart #3 - The chart was put into use on 04/09/2021 and removed on 04/23/2021 (14 days). (4) The surveyor reviewed the charts with the laboratory manager who stated on 04/28/2021 at 01:30 pm, the charts had not been changed by the 7th day, as stated above.
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, written procedure, manufacturer's instructions, observation, and interview with the laboratory manager and lead technologist, 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 ensure materials were being stored as required. Refer to D5413; (b) The laboratory failed to ensure the demonstrated reportable ranges were utilized for 2 of 4 new test methods;

	and failed to verify the performance specifications for 2 of 4 new test methods. Refer to D5421; (c) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (d) The laboratory failed to ensure data supported the QC frequency as defined in the QCP portion of the IQCP. Refer to D5445; (e) The laboratory failed to perform control procedures each day of blood bank testing for 1 of 10 days of patient testing. Refer to D5449; (f) The laboratory failed to follow the manufacturer's quality control specifications for 4 of 4 lot numbers. Refer to D5479; (g) The laboratory failed to perform two levels of quality control materials each eight hours of D-dimer testing 26 of 30 days of patient testing. Refer to D5545; (h) The laboratory failed to ensure units of blood were stored under appropriate conditions for 3 of 26 temperature charts. Refer to D5555.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, written procedure, and interview with the laboratory manager and lead technologist, 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 a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.
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, written procedure, and interview with the laboratory manager and lead technologist, 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 demonstrated reportable ranges were utilized for 2 of 4 new test methods; and failed to verify the performance specifications for 2 of 4 new test methods. Refer to D5421.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and lead technologist, 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 data supported the QC frequency as defined in the QCP portion of the IQCP. Refer to D5445; (2) The laboratory director failed to ensure the manufacturer's quality control specifications had been followed for 4 of 4 lot numbers. Refer to D5479; (3) The laboratory director failed to ensure two levels of quality control materials had been performed each eight hours of D-dimer testing 26 of 30 days of patient testing. Refer to D5545.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written procedure, and interview with the laboratory manager and lead technologist, 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.
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 the laboratory manager, the technical consultant failed to evaluate personnel performing moderate complexity testing at least annually for 2 of 6 persons. Findings include: (1) On 04/28/2021, the surveyor reviewed personnel records for 6 persons who performed moderate complexity testing during 2019, 2020, and to date in 2021. For 2 of the 6 persons (testing person #3 and

	testing person #5), there was no evidence annual evaluations had been performed as follows: (a) Testing Person #3 - Between 10/25/2019 and 03/26/2021 (b) Testing Person #5 - Between 09/05/2018 and 10/21/2020 (2) The surveyor reviewed the findings with the laboratory manager who stated on 04/28/2021 at 12:15 pm, the annual evaluations had not been performed as indicated above.