Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0655351	11/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cfvhs-Cfvmc Laboratory - Transfusion Service	1638 Owen Drive, Fayetteville, NC	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's quality assessment policy, review of 2019 and 2020 laboratory records, and interview with GS (general supervisor) #2 on 11/2/20 and the Corporate Director of Laboratory Service on 11/4/20, the laboratory failed to have effective mechanisms in place to identify and correct problems and prevent their recurrence. Findings: The laboratory's "Quality Management Program" (GEN 8) states on page 11 "Monitoring and Assessment ... 1. Internal assessments may include evaluation of quality indicators, targeted audits of a single process, or system audits. A. Quality indicators are specific performance measurements designed to monitor one or more processes during a defined time period. The indicators are useful for evaluating service demands, production, and process stability. B. QA Compliance /Regulatory Coordinator or designees perform system and single process audits on an on-going basis (monthly, quarterly, and annually). C. Safety Improvement Reports (SIR) are completed thru the hospital Quality and Patient Safety software for incidents and events. SIRs are reviewed through the hospital and corporate Quality Councils. 2. Laboratory assessments and regulatory audits provide a review of policies and practices to ensure safe and appropriate processes. Audits are based on measurable, predetermined performance criteria. Audit Corrective Action Reports will be completed for any internal issue that is identified. 3. Peer review and blood administration/ laboratory audit results are periodically reported to the applicable

	oversight committee. A. SIRs are to be completed for patient events, incidents and concerns related to transfusion and laboratory services. ... C. SIRs are completed for laboratory service issues such as ... laboratory errors that require corrected reports ...." On page 12, "Quality Improvement", the policy states "... 7. Laboratory process improvement will review all aspects of care from the pre-analytical to post-analytical processes. This review may include but is not limited to the appropriateness of testing, accuracy of specimen collection and testing, and the timeliness of response to the results. Current indicators are reported on the Laboratory Performance Improvement Dashboard and Blood Utilization Review. Indicators are updated as part of the ongoing evaluation and during annual review of the effectiveness of the Quality Management Program. ..." On page 12-13, the policy states "Management of Non-Conforming Events ... 1. The Laboratory has a process to address the following aspects of deviation management: a. Documentation and classification of occurrences b. Tracking and trending of occurrences c. Determination of the effect on quality of services ... g. Implementation of corrective action h. Implementation of preventive action ... j. Evaluation of effectiveness of corrective and preventive actions 2. Tracking is done through the Laboratory performance Improvement Committee, Laboratory PI Dashboard, ... Corrective Action reports, and online reporting. ..." Review of the laboratory's 2020 quality assessment records revealed that the laboratory performed quality assessment reviews on a routine basis (weekly, monthly, periodically) and utilized a dashboard to monitor performance indicators on a monthly basis. Review of the "General Laboratory Quality Assurance" checklist revealed the items listed for monthly review included Review/ Print Critical Value Report" and "Review/ Print Corrected Results Report". The Performance Improvement dashboard monitored "Total SIRs/Trends", "# Outstanding SIRs", and Corrected Reports (Clinical Lab)". The "Benchmark" (threshold) for corrected reports was listed as 30 or less per month, and review of the Performance Improvement dashboard revealed the laboratory met the benchmark for each month (January through September) of 2020. During interview 11/2/20 at approximately 11:00 a.m. GS #2 stated that she performs reviews of maintenance, quality control, critical values, and corrected reports monthly. She stated she reviews the list of corrected reports to determine which ones should be included in the number listed on the Performance Improvement dashboard. She stated most of them are not included in the number because they are not "true" corrected reports, and she verified the procedure did not state how to determine which ones should be included. She stated that she would investigate if she identified a problem during her review and the laboratory director would be involved if the problem was "significant". It was unclear how the laboratory determined whether a problem was significant. During interview 11/4/20 at approximately 2:45 p.m., the Corporate Director of Laboratory Service stated their "Quality Management Program" policy needs to be updated. The laboratory's quality assessment program failed to identify and correct the following problems identified during the complaint investigation survey: 1. The laboratory failed to ensure policies and procedures were complete and current for the testing performed (see D5403). 2. The laboratory failed to verify performance of the Epic electronic medical records system prior to its integration into routine use (see D5421). 3. The laboratory failed to calibrate the low molecular weight heparin testing performed on the BCS XP analyzers at least once every six months (see D5437). 4. The laboratory failed to follow their established notification policy to ensure accurate and reliable low molecular weight heparin test results were reported when reporting errors were detected (see D5779). 5. The laboratory failed to ensure appropriate corrective action was taken and documented when the laboratory identified that incorrect patient test results were reported (see D5791).

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of calibration records and interviews with GS (general supervisor) #1 11/2/20 and GS #2 11/3/20, the laboratory's procedures were not complete and current for the testing performed. Findings: 1. Review of laboratory procedure "Result Correction" (GEN 21) revealed the electronic medical records system in the procedure, Cerner Millenium, was not the current system used by the laboratory. The procedure states "Result Correction in Accession Result Entry (ARE): Cerner Millennium computer function used to correct lab results that have been previously performed and verified. Any technologist may correct test results in ARE." The procedure then describes how to correct results in Cerner Millenium. Interview with GS #1 11/2/20 at approximately 11:00 a.m. revealed the laboratory began using Epic electronic medical records system in May of 2019. She confirmed the procedure was not updated to reflect how to enter corrected results using Epic. She stated they had a draft procedure for result correction dated 3 /25/20, but it was still awaiting approval. 2. Review of laboratory procedure "BCS XP Heparin Low Molecular Weight (LMW)" (COAG 26) revealed the procedure failed to include the correct limit at which a dilution should be performed. The procedure states on page 6, "If the LMW Heparin is greater that 1.3, do a manual 1:2 dilution with Standard Human Plasma." Review of current calibration records for LMW heparin on the BCS XP 442027, dated 2/10/20 and analyzer BCS XP 442028, dated 2/11/20 revealed an upper range of 1.28 at which a dilution should be performed. During interview 11/3/20 at approximately 9:30 am, GS #2 confirmed the upper range for LMW heparin was 1.28. She stated they were unaware until they contacted the manufacturer that the upper range would change with each calibration. She also confirmed the procedure was incorrect and a dilution of 1:2 should be performed when the results were greater than 1.28.
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 review of Epic validation records and interview with GS (general supervisor) #1 11/2/20 and the Corporate Director of Laboratory Service 11/3/20, the laboratory failed to verify the performance of the Epic electronic medical records system to ensure the accuracy of LMW (low molecular weight) heparin test results prior to routine use. Findings: Interview with GS #1 11/2/20 at approximately 11:00 a. m. revealed the laboratory began using Epic electronic medical records system in May of 2019. Review of Epic validation records revealed there were no validation records available for LMW heparin. During interview 11/3/21 at approximately 4:30 p.m. the Corporate Director of Laboratory Service stated that not all tests were validated in the production enviroment when Epic was installed. She confirmed that the testing for LMW heparin was not validated in the production enviroment.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of laboratory calibration records and interview with GS (general supervisor) #2 11/2/20, the laboratory failed to perform calibration of the LMW (low molecular weight) heparin testing on the BCS XP analyzer every 6 months as required. Findings: Review of laboratory procedure "BCS XP Calibration" (COAG 23) revealed "The reference curve is valid for the respective lot of the reagent employed. A new curve should be prepared with a new lot of reagent or if indicated by any change in analytical conditions, after major maintenance or service, at least every 6 months and if QC fails to meet established criteria...". Review of laboratory calibration records for the LMWH testing on the BSC XP analyzers revealed BCS XP 1, SN 442028, was calibrated 11/5/18 and 2/11/20. There was a period of approximately 15 months between calibrations. Review of calibration records revealed BCS XP 2, SN 442027, was calibrated 3/14/19 and 2/10/20. There was a period of approximately 11 months between calibrations. Interview with GS #2 11/3/20 at approximately 11:00 am confirmed calibration for the LMW heparin testing on BSC XP 1 and BSC XP 2 was not performed every 6 months as required. She stated they have a low volume of testing for the LMW heparin and they only

	performed calibration when the analyzer indicated a calibration was needed to perform the test.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's "Result Correction" policy, review of patient test reports and interview with the Corporate Director of Laboratory Service and GS (general supervisor) #1 on 11/4/20, the laboratory failed to follow their established notification policy to ensure accurate and reliable test results were reported when reporting errors were detected. Findings: Review of the laboratory's "Result Correction" policy (GEN 21) revealed on page 2 "STEP 1. Phone the charge nurse or physician immediately of the discrepancy. ..." On page 3 it states "Inpatient Notification of Result Correction: STEP 1. Phone the nursing unit and inform of the discrepancy. ... STEP 6. ...Nursing will be informed through telephone for the corrected result, and the call will be documented in the Laboratory Information System." Review of random patient test reports revealed no documentation of nursing being informed of the following corrected LMW (low molecular weight) heparin test results: 1. Blood specimen 19A-301G0214 for LMW heparin revealed a corrected result of 2.2 IU/mL, previously reported as 1.1 IU/mL. 2. Blood specimen 20A-090G0153 for LMW heparin revealed a corrected result of 1.72 IU/mL, previously reported as 0.86 IU/mL. 3. Blood specimen 20A-206G0093 for LMW heparin revealed a corrected result of 2.00 IU/mL, previously reported as 1.28 IU/mL. 4. Blood specimen 20A-217G0001 for LMW heparin revealed a corrected result of 1.66 IU/mL, previously reported as 0.83 IU/mL. 5. Blood specimen 20A-301G0166 for LMW heparin revealed a corrected result of 2.30 IU/mL, previously reported as 1.15 IU/mL. GS #1 stated during interview at approximately 2:00 p.m. that it should show up in the "com log" (communication log) in the electronic medical records system if a call was made and documented. Interview with the Corporate Director of Laboratory Service and GS #1 at approximately 2:05 p.m. confirmed the laboratory failed to document the notification of corrected patient test results to nursing as specified in the "Result Correction" policy.
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 review of the laboratory's quality assessment policy, review of patient test reports, review of email communication, and interview with GS (general supervisor) #2 on 11/2/20, the laboratory failed to have a system in place to ensure appropriate corrective action was taken and documented when the laboratory identified that

	incorrect patient test results were reported. Findings: The laboratory's "Quality Management Program" (GEN 8) states on page 11 "Monitoring and Assessment ... 1. ... C. Safety Improvement Reports (SIR) are completed thru the hospital Quality and Patient Safety software for incidents and events. SIRs are reviewed through the hospital and corporate Quality Councils. ... 3. ... A. SIRs are to be completed for patient events, incidents and concerns related to transfusion and laboratory services. ... C. SIRs are completed for laboratory service issues such as ... laboratory errors that require corrected reports ....". Review of LMW (low molecular weight) heparin test reports for MRN #1262411 revealed: 1. LMW heparin result of 1.28 IU/mL (International units per milliliter) reported 7/22/20 at 1917; 2. LMW heparin result of 1.28 IU/mL reported 7/23/20 at 0144; 3. LMW heparin result of 1.28 IU/mL reported 7 /23/20 at 0440; 4. LMW heparin result of 1.28 IU/mL reported 7/23/20 at 1542; 5. LMW heparin result of 1.28 IU/mL reported 7/23/20 at 2236; 6. LMW heparin result of 1.28 IU/mL reported 7/24/20 at 0854. Corrected report of 2.00 IU/mL issued 7/24 /20 at 1604 noted "Corrected report due to sample requiring a dilution. 1:2 dilution performed, corrected result is 2.00. Patient expired." During interview at approximately 11:15 a.m., GS #2 stated that one of the testing personnel brought it to her attention 7/24/20 that this patient (MRN #1262411) had the same LMW heparin result of 1.28 on more than one specimen that was tested by the laboratory. GS #2 stated she pulled the specimen collected that morning and re-ran it. She stated she realized there was a problem, performed a dilution, and issued a corrected report. During interview at approximately 11:20 a.m., GS #2 stated she sent an email to all testing personnel to notify them of the problem. Review of the email revealed it was sent 7/24/20 at 3:35 p.m. The email stated "We have had a few LMW Heparins over the last few days that needed dilutions performed. The BCS will give a >1.28 result, it will cross into epic as 1.28 with a "Out of instrument operating range" error and will not auto-verify. This is your indication a dilution is needed. Perform a 1:2 dilution with standard plasma, program to run on analyzer, and multiply your result by 2, you can result up to 2.56, If your diluted result is >1.28, multiply using your dilution factor (2) and then report >2.56 in EPIC by placing a comment with result." She stated she opened a ticket with IT (Information Technology) 7/27/20 to add a > sign to patient test results as needed to ensure accurate LMW heparin results were reported. The ticket was closed by IT 8/3/20, indicating the issue was resolved. During interview at 11:35 a.m., GS #2 stated she did not document the identified problem in the quality assessment records, did not request review by the laboratory director, did not complete a safety improvement report, and did not provide remedial training for testing personnel. She also stated she did not review any other patients to see if their LMW heparin results could have been affected. Review of LMW heparin test reports revealed there were three patients (MRN #355154, #707154, #3579982) tested prior to identification of the problem whose results were flagged with the "Instrument Errors: Out of Operating Range" warning. There was no documentation that their results were evaluated after the problem was identified to determine whether the results were adversely affected. Review of patient LMW heparin test reports revealed one patient (MRN #1180311) was tested between the time IT was notified and the time the ticket was resolved. A LMW heparin result of 1.28 IU/mL was reported on this patient 8/2/20 at 0149. There was no documentation that the specimen was diluted or re-tested.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the Corporate Director of Laboratory Service 11/3/20, the laboratory director failed to ensure that competency evaluations were performed by personnel who met the qualification requirements to serve as general supervisor in a high complexity laboratory. Findings: The laboratory's "Employee Training, Competency Assessment and CE Requirements" procedure (GEN32) states on page 2 "Competency Assessors (Individuals performing competency assessments must be qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing.) The Section Director, (CFV Manager), is responsible for performing and recording competency assessment for high complexity testing. The duties for performing the competency assessment may be delegated, in writing, to individuals meeting general supervisor qualification for high complexity testing. ... A current list of Assessors may be found on the InfoWeb / Laboratory / Lab Education. ..." Review of personnel records revealed all personnel performing competency assessments did not meet the qualifications to serve as general supervisor in a high complexity laboratory. For example, TP #23 had documented the competency assessment for TP #4 in November 2019. TP #23 has an associate degree in medical laboratory technology. She was hired in March 2019 and trained March/April of 2019. TP #23 evaluated TP #4's competency for both high and moderate complexity testing. TP #4's competency evaluation was reviewed and signed by GS (general supervisor) #1 and the laboratory director. During interview at approximately 4:15 p.m., the Corporate Director of Laboratory Service verified that all "competency assessors" did not meet the qualifications for general supervisor, but they were planning to make some changes. She provided a copy of the draft policy GEN 92 which had not been implemented at the time of the survey. The policy lists duties delegated to other personnel by the laboratory director and the policy states that the Corporate Director of Laboratory Service and the Core Lab Manager (general supervisor #1) are responsible for competency assessment.
D6179	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(5) Each individual performing high complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, clinical consultant, or director. This STANDARD is not met as evidenced by: Based on review of patient LMW (low molecular weight) heparin test reports and interview with GS (general supervisor) #2 on 11/2/20, testing personnel failed to identify and correct problems with LMW heparin test results before the results were

	reported. Review of random patient LMW heparin test reports revealed testing personnel failed to recognize the "Instrument Errors: Out of Operating Range" warning for LMW heparin test results and failed to perform a dilution as required for the following specimens: 1. Specimen #19A-302G0090, resulted 10/29/19 by TP #13; 2. Specimen #20A-090G0031, resulted 3/30/20 by a former TP no longer employed; 3. Specimen #20A-196G0013, resulted 7/14/20 by TP #17; 4. Specimen #20A-198G0139, resulted 7/16/20 by TP #5; 5. Specimen #20A-204G0271, resulted 7/23/20 by TP #17; 6. Specimen #20A-205G0149, resulted 7/23/20 by TP #8. GS #2 stated during interview at approximately 11:30 a.m. that the testing personnel should have recognized the specimens required a dilution before the LMW heparin results could be reported.