Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303841	02/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Crenshaw Community Hospital	101 Hospital Circle, Luverne, AL	

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
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 the EPOC System Standard Operating Procedure, a lack of calibration verification records, and an interview with the acting Technical Consultant, the laboratory failed to perform calibration verifications at least every six months as per CLIA regulations. The findings include: 1. A review of the EPOC records revealed no calibrations verification records since the initial validation performed on 02/13/2020. Patient testing on the EPOC started on 02/20/2020. 2. A

	review of the EPOC System Standard Operating Procedure page 14 revealed "... Calibration Verification...Performance of this procedure at defined intervals may be required by regulatory or accreditation bodies..." Analytes calibrated with less than three calibrators must have a calibration verification performed every six months as per CLIA regulations. 3. During an interview at 8:50 AM on 02/04/2021, the acting Technical Consultant confirmed the laboratory had not performed calibration verifications since the initial validation in February 2020. .
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records for ACL Elite D-Dimer, the manufacturer's package insert for the D-Dimer control, and an interview with the acting Technical Consultant, the laboratory failed to establish the mean and standard deviation for the D-Dimer controls, as per manufacturer's instructions. One lot number of controls had been in use for D-Dimer since addition to the ACL Elite test menu on 11/03/2020. The findings include: 1. A review of quality control records for the ACL Elite D-Dimer revealed quality control acceptable ranges were not established when D-Dimer controls for lot B33168 were put into use. 2. A review of the package insert for the D-Dimer control revealed "...The Low and High D-Dimer Controls concentration ranges were determined over multiple runs on IL Coagulation Systems using a specific lot of D-Dimer reagents. The mean of the control range determined in each laboratory may vary due to the lot of reagent used. Due to differences in reagents and instrumentation, each laboratory should establish its own Target Value and Acceptance Range (mean and standard deviation)...". 3. During an interview on 02/04 /2021 at 12:40 PM, the Technical Consultant confirmed the mean and standard deviation were not established for D-Dimer Controls. .
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 the initial test validation records for the ACL Elite D-Dimer and an interview with the acting Technical Consultant, the surveyor determined the Laboratory Director failed to document approval of the validation before patient testing began. This affected one of three new instruments/analytes installed, since the previous survey on May 08-09, 2018. The findings include: 1. A review of the 11/03 /2020 validation records for the ACL Elite D-Dimer revealed no documentation of the LD's review and approval (as indicated by a signature and date). 2. During an interview on 02/04/2021 at 12:40 PM, the acting Technical Consultant confirmed patient testing started on 11/06/2020 on the ACL Elite D-Dimer. .
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 personnel listed on Form CMS-209 (Laboratory Personnel Report), a review of the personnel files, and an interview with the Technical Consultant, the surveyor determined the Technical Consultant failed to ensure five of six testing personnel had documentation of annual competency evaluations in 2019 and 2020. The findings include: 1. A review of employee records provided by the Human Resources (HR) representative revealed missing competency evaluations for the testing personnel. The acting Laboratory Manager was able to locate some additional files in the laboratory, however there was no documentation of annual competency evaluations for the following Testing Personnel (TP): A) TP #1: No 2020 evaluation B) TP #2: No 2020 evaluation C) TP #3: No 2020 evaluation D) TP #4: No 2019 evaluation E) TP #6: No 2020 evaluation 2. During an interview on 2/3/2021 at 11:00 AM, the acting Laboratory Manager had telephoned the previous Manager / Technical Consultant, who stated all the employees had participated in the annual hospital Skills Fair Training and competency assessments. She believed this was sufficient. 3. In an interview on 2/3/2021 at 11:15 AM, the Emergency Room Nurse Manager provided the surveyor a list of the competencies covered during the annual hospital Skills Fair Training. These included general reviews (safety, handwashing, HIPAA, COVID prevention, ect.) for all hospital employees. The Nurse Manager further stated, "Specific department competencies should be handled by the manager or supervisor." SURVEYOR ID #32558 Licensure and Certification Surveyor