Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303841	09/25/2024
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) evaluation records, and an interview with the Laboratory Manager (LM), the laboratory had unsuccessful PT scores on 3 unregulated analytes. Failures were noted on three events from 2022-2023. The findings include: 1. A review of the PT evaluation records revealed the laboratory utilized the API PT program to verify the accuracy of laboratory procedures, however, the laboratory failed the following PT events with no other documented method of accuracy verification: A) 2022-Chemistry Second Event: Folate-0%, Vitamin B12-0% B) 2023-Chemistry First Event: Folate-50%, Vitamin B12-50% C) 2022-Immunology Second Event-CRP-50% D) 2023-Immunology First Event-CRP-50% 2. LM confirmed these findings during the exit conference on 09-25-2024 at 12:46 PM.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) evaluation records, corrective action documentation, and an interview with the Laboratory Manager, the laboratory failed to document review and implement additional remedial action for repeat unsuccessful events. No documented review was

	noted for two of the six Hematology and Chemistry events reviewed in 2023; no additional remedial action was noted for three of the five Hematology events reviewed in 2023 through 2024. The findings include: 1. A review of the Hematology API PT records revealed unsuccessful PT scores on the following non-regulated tests: a. 2023- Hematology First Event i. Basophil-0% ii. Eosinophil-0% iii. Monocyte-60% iv. Neutrophils-0% b. 2023- Hematology Third Event i. Basophil-0% ii. Eosinophil-0% iii. Monocyte-0% iv. Neutrophils-0% c. 2024- Hematology First Event i. Basophil-0% ii. Eosinophil-0% iii. Monocyte-0% iv. Neutrophils-0% 2. A review of the Hematology corrective action documentation revealed, "wrong QC setting used." This was noted for all 3 unsuccessful events with no evidence of additional corrective action documented. 3. A further review of the API PT records revealed no evidence of documented review for 2023 Chemistry 3rd Event and Hematology 2nd Event. 4. The LM confirmed the above findings during an interview on 09-24-2024 at 12:25 PM.
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 reviews of Siemens Dimension EXL-200 Chemistry / Immunoassay analyzer, EPOC Arterial Blood Gas (ABG) analyzer records, and an interview with the Laboratory Manager, the laboratory failed to ensure there is monitoring and evaluation of quality of the laboratory's analytical system. The finding include: 1. Calibration verifications were not performed and documented semi-annually on the Siemens Dimension EXL-200 Chemistry / Immunoassay analyzer and the EPOC ABG analyzer. (Refer to D5439). 2. Expired Blood Bank reagents were utilized to perform QC and patient testing. (Refer to D5417). 3. No documented IQCP for the EPOC Arterial Blood Gas analyzer. (Refer to D5445).
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the Blood Bank (BB) Quality Control (QC) records, Blood Bank patient testing worksheets, and an interview with Laboratory Manager (LM), the laboratory utilized expired reagent prior to patient testing. This was noted for 3 out of 12 months reviewed in 2023, during this time five patient tests were affected. The findings include: 1. A review of the BB QC records and BB patient testing worksheets revealed the laboratory utilized expired BB reagents for the following months in 2023: a. QC Kit LotV258150 expired on 4/10/2023; one patient test performed 4/12/2023. b. QC kit LotV259062 expired on 5/8/2023; one patient test performed 5/17/2023. c. QC

	kit LotV247347, expired on 5/25/2023; one patient test performed 05-28-2023. d. A1 cells Lot V259995, B cells Lot V260035, Screening Cells (1,2,3) Lot V260119, and Checkcell V260084 all expired on 6/5/2023; one patient test performed on 6/11/2023 and 6/20/2023. 2. During the exit interview on 9/25/24 at 12:46, the LM confirmed the above findings.
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 Siemens Dimension EXL-200 Chemistry Calibration Verification (C-V) records, EPOC Arterial Blood Gas (ABG) analyzer C-V records, and an interview with the Laboratory Manager (LM), the laboratory failed to perform C-V procedures on analytes that have less than three calibrators, at least every six months as specified by the CLIA requirements. This was noted on two of the three C-Vs reviewed for the Chemistry Dimension EXL-200 from 2022 through 2024; The lack of the EPOC ABG C-V was noted from the date of the last survey (09-21-2022) to the date of the current survey (09-25-2024). The findings include: 1. A review of the Siemens Dimension EXL-200 records revealed C-V was not performed for Chemistry analytes calibrated with less than three calibrators at least every six months according to the CLIA requirement. The following C-Vs were performed with corresponding intervals as follows: a. The first CV was performed 09-29-2022, 9 months later; b. the second CV was performed 06-12-2023, 8 months later; c. the third CV was performed 02-01-2024. 2. There was no evidence of C-V performance and documentation for the EPOC ABG analyzer. (Refer to D5445). 3. The LM confirmed these findings during the exit conference on 09-25-2024 at 12:46 PM.
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 the EPOC Arterial Blood Gas (ABG) IQCP (Individualized Quality Control Plan) records, the EPOC ABG operator's manual, and an interview with the Laboratory Manager, the laboratory failed to establish an IQCP. Surveyor noted the lack of an IQCP for blood gas analysis from the date of the last survey (09-21-2022) to the date of the current survey (09-25-2024). The findings include: 1. A review of the EPOC ABG IQCP revealed an IQCP for the GEM Premier 3000. The current IQCP did not include all the three required parts: Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment as specified by the CLIA regulatory requirement for control procedures. 2. A further review of the CLIA requirements revealed, "The laboratory must establish... frequency of testing control materials using..." 3. The LM confirmed the above findings at the exit conference on 9-25-2024 at 12:46 PM.
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 lack of Quality Assurance (QA) records and an interview with the Laboratory Manager, the laboratory failed to implement and document QA reviews to ensure the quality of the analytical systems. The surveyor noted the non compliant failures occurred from the date of the previous survey on 09-22-2022 until the date of the current survey on 09-25-2024. The findings include: 1. A review of laboratory records revealed a lack of QA reviews to ensure the quality of the analytical systems, as follows: a. Failure to ensure calibration verification was performed and documented semi-annually on the Siemens Dimension EXL-200 Chemistry / Immunoassay analyzer and the EPOC Arterial Blood Gas (ABG) analyzer. (Refer to D5439.) b. Failure to perform and document QC with the frequency specified in the IQCP (Individualized Quality Control Plan) for the EPOC ABG analyzer. (Refer to D5445.) 2. The LM confirmed the above findings at the exit conference on 9-25-2024 at 12:46 PM.
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 the laboratory's test menu, a lack of the IQCP (Individualized Quality Control Plan) for the EPOC Arterial Blood Gas (ABG) analyzer, and an interview with the Laboratory Manager, the Laboratory Director failed to ensure an acceptable and complete IQCP was established and implemented for the patient testing on blood gas analysis performed by the laboratory. The findings include: 1. Refer to D5445.