Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2269378	01/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sevier County Medical Center	960 Hwy71 N, De Queen, AR	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 upon review of the laboratory's records for establishing the Normal Patient Mean Prothrombin Time (MNPT), the user's manual for the Sysmex 2500 coagulation analyzer, confirmation of the MNPT set in the Sysmex 2500 instrument for calculating the International Normalized Ratio (INR) and interview, the laboratory was using the incorrect MNPT value in the Sysmex 2500 coagulation analyzer for the Innovin reagent Lot # 564671 in use at the date of the survey. Findings follow: A) Review of the user's manual for the Sysmex 2500 coagulation analyzer revealed that the MNPT must be determined specifically for each lot of Innovin Prothrombin Time (PT) and entered into the instrument settings. B) Review of records used to establish the MNPT for Innovin lot # 564671 revealed that the geometric mean of the 20 samples used to establish the MNPT was determined to be 10.9 seconds. C) During a tour of the laboratory on 1/14/26 at 09:53 a.m., the MNPT value on the Sysmex 2500 coagulation analyzer used to calculate the INR result reported on patient results was observed to be 11.3 seconds. D) In an interview on 1/14/26 at 10:15 a.m., the laboratory staff member (#20 on the form CMS 209) confirmed the MNPT set in the Sysmex 2500 coagulation analyzer was 11.3 instead of 10.9, as reported on the records for establishment of the MNPT, which would have caused an error in the calculation of the INR affecting all patient INR tests reported since Innovin reagent lot # 564671 was placed into use.
D5441	CONTROL PROCEDURES

	CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based upon observations made during a tour of the laboratory, review of the user's manual for the EPOC arterial blood gas (ABG) analyzer, the laboratory's Individualized Quality Control Plan (IQCP) for quality control (QC) procedures for the EPOC ABG analyzer, review of ABG QC results for the calendar year 2025, and interview with laboratory personnel, the laboratory did not follow the QC procedures as outlined in the IQCP and did not follow the manufacturer's instructions for use (IFU) for performing external QC on the EPOC ABG analyzer. Findings follow: A) During a tour of the laboratory on 1/14/26 at 09:45 a.m., the EPOC ABG analyzer was observed and cartidge lot # 4520 was available for use. B) Review of the user's manual for the EPOC ABG analyzer revealed "for each lot in each shipment of cartridges analyze at least (2) levels of fluid controls prior to placing cartridges in use". C) Review of the laboratory's IQCP for the EPOC ABG analyzer revealed levels 1,2, and 3 of Eurotrol EPOC Gas-Ise metabolyte must be analyzed and within acceptable limits upon installation of each new cartridge lot prior to patient testing. D) Review of ABG QC results for the calendar year 2025 revealed that only a single set (Level 1,2, and3) of QC results were present for each month and no QC results were recorded for November 2025. E) In an interview on 1/14/26 at 10:00 a.m., the laboratory staff member (# 10 on the form CMS 209) stated that they perform external QC one time per month approximately on the 17th of the month, and they routinely get multiple shipments of reagent cartridges every month and confirmed they they do not follow the procedures outlined in the IQCP or the procedures outlined in the user's manual for the EPOC ABG analyzer.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) 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: Through review of personnel competency records for fourteen testing personnel listed on the CMS 209 form, authorizations to perform tests, and interview, it was determined that the laboratory did not assess the competency of five of fourteen testing personnel semi-annually during the first year of employment. Findings follow: A) Review of personnel records of testing personnel (number 11 on the CMS 209 form) indicated that the employee was hired in June 2022 and authorized by the laboratory director to perform moderately complex Arterial Blood Gas (ABG) testing

	without direct supervision. Competency assessments for ABG testing were dated April of 2024 and January 2025 which did not meet the requirment of twice annual competency assessment during the first year of employment. B) Review of personnel records of testing personnel (number 12 on the CMS 209 form) indicated that the employee was hired in November of 2022 and authorized by the laboratory director to perform moderately complex Arterial Blood Gas (ABG) testing without direct supervision. Competency assessments for ABG testing were dated June of 2024 and March 2025 which did not meet the requirment of twice annual competency assessment during the first year of employment. C) Review of personnel records of testing personnel (number 13 on the CMS 209 form) indicated that the employee was hired in September 2023 and authorized by the laboratory director to perform moderately complex Arterial Blood Gas (ABG) testing without direct supervision. Competency assessments for ABG testing were dated June of 2024 and March 2025 which did not meet the requirment of twice annual competency assessment during the first year of employment. D) Review of personnel records of testing personnel (number 14 on the CMS 209 form) indicated that the employee was hired in September 2023 and authorized by the laboratory director to perform moderately complex Arterial Blood Gas (ABG) testing without direct supervision. Competency assessments for ABG testing were dated June of 2024 and March 2025 which did not meet the requirment of twice annual competency assessment during the first year of employment. E) Review of personnel records of testing personnel (number 15 on the CMS 209 form) indicated that the employee was hired in October of 2023 and authorized by the laboratory director to perform moderately complex Arterial Blood Gas (ABG) testing without direct supervision. Competency assessments for ABG testing were dated September of 2024 and March of 2025 which did not meet the requirment of twice annual competency assessment during the first year of employment. F) In an interview on 1/13/26 at 11:45 a.m. the hospital staff member (number 20 on the form CMS 209) verified that competency evaluations were not performed semi-annually during the first year of employment for the testing personnel identified as number 11, 12, 13, 14 and 15 on the CMS 209 form..
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of the CMS-209 and personnel records presented to the surveyor, as well as interviews with staff, the technical consultant failed to evaluate two of fourteen testing personnel annually after the first year of employment. A) A review of personnel records for Employee #11 (as listed on the form CMS 209) revealed the employee was hired in June 2022 the annual competency assessments in the personnel records presented were dated April of 2024 and January 2025. C) A review of personnel records for Employee #12 (as listed on the form CMS 209) revealed the employee was hired in November 2022 the annual competency assessments in the personnel records were dated June of 2024 and March of 2025. D. An interview, at 11: 45 a.m.on 1/13/26, the laboratory staff member (#20 on the form CMS 209) confirmed that competencies for ABG testing were not performed annually after the first year of employment for the personnel identified above.