Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0467800	(X3) Date Survey Completed 02/13/2025
Name of Provider or Supplier Helena Regional Medical Center	**Street Address, City, State** 1801 Martin Luther King Jr Drive, Helena, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory test menu, a review of proficiency testing events for 2024, lack of documentation, and interviews with laboratory personnel, it was determined the laboratory failed to enroll in proficiency testing for Ferritin (a CLIA regulated analyte). Survey findings include: A. A review of the laboratory's test menu revealed the laboratory performed Ferritin testing on the Siemens EXL Dimension. B. The surveyor reviewed six chemistry proficiency testing events in 2024 (both Chemistry Core and Chemistry Miscellaneous). There was no documentation that the laboratory performed proficiency testing for Ferritin and no documentation that the laboratory was enrolled in proficiency testing for Ferritin. C. In an interview, at 3:26 pm on 2/11/25 technical consultant #2 (as listed on the CMS-209 form) confirmed the laboratory was not enrolled in proficiency testing for Ferritin.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 observation and interview with laboratory staff, the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 2/13/25 at 12:27 pm, one (of one) container of 10% Neutral Buffered Formalin (lot 130215, REF 28600-1, StatLab, expiration date 9/30/24) was observed in the laboratory, available for use beyond the expiraton date. B) During a tour of the laboratory on 2/13/25 at 12:24 pm, one (of one) container of MiniCollect 0.25mL/0.5 mL K2e K2EDTA tubes (lot A23074BF, REF 450532, Greiner Bio-One, GmbH, expiration date 1/10/25) was observed in the laboratory, available for use beyond the expiraton date. C) In an interview on 2/13/25 at 12:27 pm technical consultant #2 (as listed on the CMS-209 form), confirmed that the items, identified above, had exceeded their expiration dates and were available for use in the laboratory.
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 on review of laboratory policies "General Laboratory Instructions", "Monthly QA Review Chemistry", review of quality control documentation for 2024, lack of documentation, and interviews with laboratory staff, the laboratory failed to document monitoring of chemistry quality control shifts for November of 2024. Survey findings include: A. The surveyor reviewed the "General Laboratory Instructions". The policy states: "iii. Calculated 2SD range will also be compared to peer group ranges and mean. CV's will be evaluated each month per sontituent and compared to peer group CV's. If considerable difference is noted, investigate the cause-..." "iV. ...When an assay is consistently above or below the mean for 10 consecutive runs, monitor if within +/- 1SD-OK, if close to 2SD, the assay will be evaluated as to the mean and range. Recalculate the mean if necessary." B. A review of quality control documentation for November 2024 showed Ethanol level 1 control above the mean for 16 consecutive days with no documentation of whether it was 1SD or 2SD above. A review of quality control documentation for November 2024 showed Urine Total Protein level 1 control above the mean for 11 consecutive days with no documentation of whether it was 1SD or 2SD above. C. "Monthly QA Review Chemistry" stated no shifts were noted. D. Upon request, no documentation showing peer group review, Levy Jennings graphs, or monitoring of shifts showing +/- 1SD and +/-2SD for the month of November 2024 were provided. C. In an interview, at 12:53 a.m. on 2/13/25, technical consultant #2 (as listed on the CMS-209) stated that there were no Levy Jennings graphs or peer review data for the month of November 2024.