

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0642313	(X3) Date Survey Completed 04/02/2025
Name of Provider or Supplier Izard Regional Hospital	Street Address, City, State 61 Grasse Street, Calico Rock, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observations made during a tour of the laboratory, laboratory policy, and interviews with staff, the laboratory failed to label staining reagents to indicate expiration date and preparation date. Survey findings include: A. During a tour of the laboratory at 2:57 p.m. on 4/2/2025 the surveyor observed three containers of liquid in the lab. They were labelled "Fixative", "Solution 1", and "Solution 2." No other information was on the containers. B. Laboratory policy stated that all reagents will be labelled with expiration dates and storage requirements. C. In an interview, at 3:01 p. m. on 4/2/2025, the Technical Supervisor confirmed the lack of expiration date and storage requirement labels on the staining reagents.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(iii) Statistical parameters for unassayed control materials</p>

must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on a review of quality control documentation for February 2024, November 2024, and January 2025 chemistry controls, lack of documentation, laboratory policy and interviews with laboratory staff, it was determined the laboratory failed to document criteria for acceptable quality control for Hematology. Survey findings include: A. Laboratory policy "Quality Control Range Establishment" (effective date 9/16/2021) states "When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch or lot number of control materials must be defined and available." B. The surveyor reviewed chemistry quality control documentation for February 2024, November 2024, and January 2025. The surveyor requested data used for calculating the changes in means for quality control evaluation that occurred in January 2025. Initial calculation of the means for all controls of Biorad multiquant controls lots 56761/56763 was available, but the changes in means utilized for Glucose Level 3 (356.63 to 359.63), Albumin Level 1 (2.13 to 2.22), Lactic Acid Level 1 (1.37 to 1.51) and 2 (5.97 to 5.77), Lipase level 2 (139.0 to 139.5), Phosphate Level 1 (2.05 to 1.99), and Aspartate Amino Transferase level 2 (242.46 to 247.24) that occurred mid January had no documented calculations or justification. C. In an interview, at 12:38 p.m. on 4/2/2025, the General Supervisor stated that the documentation of above changes in means for quality control ranges was not available.