

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2263770	(X3) Date Survey Completed 04/16/2025
Name of Provider or Supplier Millard Henry Clinic Of Dardanelle	Street Address, City, State 1714 State Hwy 22 W, Dardanelle, 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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory humidity records for January through March 2025, manufacturer's instructions, and through interviews with laboratory staff, it was determined the laboratory failed to document corrective actions when humidities were outside of the specified performance specifications. Survey findings include: A. A review of the Sysmex XP-300 hematology instrument revealed acceptable humidity ranges of 30 to 85% (Sysmex XP-300 Instructions for Use, rev 2017). B. Through a review of environmental logs for January through March 2025, it was shown that humidity was below 30% for the whole day 24 of 90 days. Corrective actions were not documented for any of the failures. C. During an interview at 1:47pm 4/16/25, the Technical Consultant confirmed that the humidity was documented outside of specified acceptable ranges and that no corrective actions were documented.</p>