

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2263770	(X3) Date Survey Completed 05/15/2023
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory, review of manufacturer's instruction manual, review of the laboratory's temperature and humidity records and interviews with staff, it was determined the laboratory humidity was below the manufacturer's requirement for the laboratory's Sysmex XP-300. Survey findings include: A) During a tour of the laboratory on 5/15/23 at 11:10 a.m., Sysmex XP-300 was observed in the main laboratory. B) Review of the manufacturer's instruction manual for Sysmex XP-300 and Dardanelle Lab Temperature Ranges revealed conditions of operating requirement listed as "15C-30C (humidity 30%-85%)". C) Review of the laboratory's room temperature and humidity log for October, November, and December of 2022 revealed ten days humidity below 30%. D) Review of the laboratory's room temperature and humidity log for January, February, and March of 2023 revealed six days humidity below 30%. E) In an interview on 5/15/23 at 11:49 a.m. the laboratory staff member (# 2 on the CMS 209 form) confirmed that the Sysmex XP-300 was in use sixteen days below 30% humidity.</p>