

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0465341	(X3) Date Survey Completed 09/19/2024
Name of Provider or Supplier Family Clinic Of Ashley County Pa	Street Address, City, State 909 Unity Road, Crossett, 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: Based on review of manuals, manufacturer's instruction, temperature logs, and interview with staff, the laboratory failed to follow manufacturer's instructions for operational environment relative humidity for Sysmex XN-330. Findings follow: A) Review of the Sysmex XN-330 instrument manual (XN-L Series XN-530/XN-430 /XN-330, General Information, revision June 2017) revealed the operating environment for relative humidity is "20 to 85% ". B) Upon request, no humidity records were available. C) During an interview on 9/19/24 at 12:02 p.m. the lab director confirmed the humidity was not being monitored to ensure the Sysmex XN-330 was being utilized according to manufacturer's specifications.</p>