Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0467303	09/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Autumn Road Family Practice, Pa	904 Autumn Road, Suite 200, Little 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of policy and procedure 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 XS-1000i. Findings follow: A) Review of the Sysmex XS-1000i instrument manual (XS-1000i / XZ-800i Instructions for Use, revision June 2013, Code No. 461-2629-2) revealed the operating environment for relative humidity is "30 to 85% ". B) Review of the laboratory humidity log revealed a target range of "20-80%." C) Review of the laboratory humidity log revealed humidity below 30% on 39 of 41 days of operation in January through March 2024. D) During an interview on 9/17/24 at 1:18 p.m. the lab director confirmed the operation of the Sysmex XS-1000i below 30% humidity and the incorrect range stated on the humidity log.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: Through observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 9/17/24 at 2:42 pm, one (of one) opened container of EKZ II CAL Reagent (lot 3HD136, expiration date 8/1/24) was observed in the laboratory, available for use beyond the expiraton date. B) During a tour of the laboratory on 9/17/24 at 2:42 pm, one (of one) opened container of ADHDL Calibrator (lot 4BD312, expiration date 9/1/2024) was observed in the laboratory, available for use beyond the expiraton date. C) Laboratory policy stated reagents are to be discarded upon their expiration. D) In an interview on 9/17/24 at 2:43 pm the technical consultant, confirmed that the items, identified above, had exceeded the expiration date and were available for use.