Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0467303	03/18/2021
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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (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. (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. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of quality control documentation, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to establish statistical parameters over time for Bio-Rad Control Lot #26461 and Lot #26462. Survey findings include: A. During a review of July 2020, November 2020, and February 2021 quality control documentation for chemistry tests performed on the Dimension EXL 200, the surveyor observed the following 2 standard deviation (SD) ranges in use as acceptable ranges that didn't correlate with the Dimension EXL calculated 2 SD ranges from February 2021: Creatinine (Lot #26461) 2 SD in use 0.8 (calculated 2 SD 0.18); CPK (Lot #26461) 2 SD in use 15.1 (calculated 2 SD 3.82); Glucose (Lot #26461) 2 SD in use 8.6 (calculated 2 SD 2.2); Iron (Lot 26461) 2 SD in use 17.2 (calculated 2 SD 3.01); Creatinine (Lot #26462) 2 SD in use 1.0 (calculated 2 SD .23); Alkaline Phosphatase (Lot # 26462) 2 SD in use 78.0 (calculated 2 SD 15.8); CPK (Lot # 26462) 2 SD in use (calculated 2 SD 8.573); and Iron (Lot #26462) 2 SD

	in use 6.24 (calculated 2 SD 1.79). B. During an interview with employee #4 (as listed on the form CMS-209), at 1:24 p.m. on 3/18/2021, the surveyor requested documentation of the establishment of the 2 SD ranges in use as acceptable ranges for chemistry quality control. Employee #4 was unable to provide the documentation and confirmed the documentation was not available.