Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468513	01/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Regional Family Medicine	630 Burnett Drive, Mountain Home, 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 Eightcheck-3WP X-TRA hematology control instructions for use, the Eightcheck-3WP X-TRA assay sheets, Levey-Jennings graphs for Hematology Quality Control for June, September, and December 2020, and through interviews with laboratory staff, it was determined the laboratory failed to verify the criteria of acceptablity of the Eightcheck-3WP X-TRA hematology controls. Survey findings include: A. A review of the Eightcheck-3WP X-TRA hematology control instructions for use revealed the following instructions for setting quality control acceptable ranges: Sysmex recommends that each laboratory use the targets and limits provided on the assay sheet included with each lot of Eightcheck-3WP X-TRA or establish laboratory specific targets and limits. B. Through a review of the Eightcheck-3WP X-TRA assay sheets and Levey-Jennings graphs for Hematology Quality Control for June 2020, it was determined the laboratory failed to enter the correct values from the assay sheets into the quality control program used for determining

	acceptability of controls. Eightcheck-3WP X-TRA assay sheets include the target value and acceptable limits for each parameter of the complete blood count performed on the Sysmex hematology analyzer. The Levey-Jennings graphs show the ranges actually in use by the laboratory to determine the acceptability of the controls. Acceptable limits in use for lot #008507, which were used in June of 2020, include the following: Low Control WBC +/- 1.0 instead of +/- 0.5 which was listed on the assay sheet; Low Control Hemoglobin +/- 0.8 instead of +/- 0.4 which was listed on the assay sheet; Low Control Platelet +/- 34 instead of +/- 17 which was listed on the assay sheet; Normal Control WBC +/- 1.4 instead of +/- 0.7 which was listed on the assay sheet; Normal Control Hemoglobin +/- 1.6 instead of +/- 0.8 which was listed on the assay sheet; Normal Control Platelet +/- 74 instead of +/- 37 which was listed on the assay sheet; High Control WBC +/- 3.6 instead of +/- 1.8 which was listed on the assay sheet; High Control Hemoglobin +/- 1.8 instead of +/- 0.9 which was listed on the assay sheet; and High Control Platelet +/- 126 instead of +/- 63 which was listed on the assay sheet. C. A review of Eightcheck-3WP X-TRA assay sheets and Levey-Jennings graphs for Hematology Quality Control for September and December of 2020 showed similar findings as the June 2020 data. All acceptable limits for the lots of controls used in September and December were double the values listed on the assay sheets. D. In an interview, at 10:15 on 1/27/2021, laboratory employee #2 (as listed on the form CMS-209) confirmed the laboratory had entered the acceptable limits from the assay sheet into the the LIS as the standard deviation and that the laboratory uses two standard deviations as their acceptable range. This practice causes the laboratory to use an acceptable range that is twice the range stated by the manufacturer.