Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1012127	04/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bisbee Family Health Center	108 Arizona St, Bisbee, AZ	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration verification documentation for the Sysmex XP 300 hematology analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration verification procedures as required for 2017 and 2018. Findings include: 1. The laboratory performs CBC testing using the Sysmex XP 300 with annual test volume of 108. 2. No documentation was presented for review to indicate the laboratory performed a calibration verification at least once every six

	months for entire year of 2017 and documentation was presented for only one calibration performed in 2016. 4. The laboratory retained the thermal printouts of the calibration that was performed in January 2018, but there was no evidence of a calibration report to indicate that the calibration verification performed was acceptable or what the limits of acceptability were for the calibration. 4. The facility personnel confirmed that the laboratory did not perform a calibration verification every six months as required.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of calibration verification records presented for review by the laboratory and interview with the facility personnel, the laboratory failed to have establish policies and procedures in place that monitors the calibration verification activities for the Sysmex XP 300 used to perform patient testing under the specialty of Hematology (see D5439 for findings).