Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0627147	02/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Curry Hlth Dist Dba Curry General Hospital	94220 Fourth Street, Gold Beach, OR	

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 interview with the Laboratory Director (LD) and the General Supervisor (GS) during survey 02/14/2023 and review of hematology records, the laboratory failed to follow the manufacturers direction for hematology and D-dimer instrument calibration. Findings include: 1. Upon review of the calibration records for the Quidel D-Dimer assay, it was noted that the instrument had not been calibrated since 02/01 /2022. The General Supervisor confirmed this finding during interview at

	approximately 12:00 pm on 02/14/2023. 2. Upon review of the documentation for calibration for the Coulter XH 900 analyzer, it was noted that the instrument had not been calibrated since 07/05/2022. The General Supervisor confirmed this finding during interview at approximately 12:00 pm on 02/14/2023. 3. Both instruments require calibration at least every 6 months to insure accuracy of patient test results according the manufacturers instructions for use.