

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0371168	(X3) Date Survey Completed 07/12/2021
Name of Provider or Supplier Karmanos Cancer Institute Bloomfield	Street Address, City, State 43097 Woodward Avenue Ste 100, Bloomfield Hills, MI	
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	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to perform calibration for hematology testing on the Horiba ABX Micros 60 analyzer at least every 6 months for 2 (July 2019 to July 2021) of two years. Findings include: 1. A review of the laboratory's calibration documentation for the Horiba ABX Micros 60 hematology analyzer revealed calibration was performed</p>

on the following dates between July 2019 and July 2021: a. 3/4/21 (9 months after 6/3/20) b. 6/3/20 (8 months after 9/19/20) c. 9/19/19 2. A review of the laboratory's "ABX Micros 60" policy and procedure revealed a section titled "Calibration" stating, "Routine calibration must be performed every 6 months and may also need to be performed after: Initial instrument installation. Major maintenance is performed on the instrument. Any major instrument (parts) are repaired or changed. And if controls are consistently out of assay range after all other attempts have been made to clean the instrument and eliminate the controls as the problem." 3. An interview on 7/12/21 at 9:54 am with TC1 confirmed the laboratory did not perform calibrations at least every 6 months and patient testing had not seized during these timeframes.