

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2102180	(X3) Date Survey Completed 05/08/2018
Name of Provider or Supplier Kota Cancer Clinic ,Pllc	Street Address, City, State 180 Medical Park Place, Hot Springs, 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
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: Through a review of the Operator's Manual for the Sysmex XS-1000i, a review of Certificates of Calibration Verification, and through interviews with laboratory staff, it was determined the laboratory failed to perform calibration verification following manufacturer's instructions. Survey findings include: A. The Operator's Manual for the Sysmex XS-1000i states, "The laboratory must verify calibration every six months or on an as needed basis to ensure accuracy of the system." B. A review of</p>

Certificates of Calibration Verification for 2016, 2017, and 2018 revealed the following dates of calibration: June 14, 2016; July 14, 2017 (11 months after the previous documented calibration); and March 9, 2018 (8 months after the previous documented calibration). There is no documentation that calibration verification has been performed every six months. C. In an interview at 10:54 on 5/8/2018, the technical consultant (as listed on the form CMS-209) confirmed the laboratory had not performed calibration every 6 months as required by the manufacturer.