

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0663504	(X3) Date Survey Completed 01/25/2019
Name of Provider or Supplier Concentra - Gaithersburg	Street Address, City, State 803 Russell Ave Suites 1 A, Gaithersburg, MD	
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 calibration record review and interview with the technical consultant (TC), the laboratory failed to ensure that calibrations for the hematology instrument were verified at least once every 6 months. Findings: 1. A review of calibration records from 2017 to 2018 for the CDS Medonic M-Series hematology analyzer showed that calibration verifications were performed 8/30/17 and 8/15/18. No other calibration records were available at the time of the survey. 2. During an interview on 1/25/19 at</p>

1:00 PM, the TC confirmed that documentation that calibration verifications were performed at least once every 6 months were not available at the time of the survey.