

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0264125	(X3) Date Survey Completed 04/17/2018
Name of Provider or Supplier A O P Pa Db a Central Georgia Cancer Care	Street Address, City, State 800 First Street, Suite 410, Macon, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 17, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 review of the calibration documents for the Horiba Pentra 60C+ and staff</p>

interview the laboratory failed to document the calibration for the Horiba Pentra 60C+ hematology analyzer at least every 6 months. Findings: 1. Review of the calibration documents for the Horiba pentra 60C+ hematology analyzer, from 2016, 2017 and 2018, the laboratory failed to document the calibration of the analyzer for a period of 12 months from October 2016 to October 2017. 2. Interview with staff #2 (CMS 209 form), on April 17, 2018 at 4pm in the Conference Room, confirmed that there was no documentation that the Horiba Pentra 60C+ was calibrated between October 2016 and October 2017.