

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D1067271	<b>(X3) Date Survey Completed</b>  10/28/2021
<b>Name of Provider or Supplier</b>  Ocmulgee Physicians Laboratory	<b>Street Address, City, State</b>  446 Poplar Street, Macon, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on October 28, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 CellDyn Ruby (Ruby)</p>

hematology analyzer, and staff interview the laboratory failed to calibrate the Ruby at least every 6 months. Findings: 1. Document review for the Ruby hematology analyzer, showed that the calibration was performed on the following days: 04/12/2021 08/14/2020 - eight months 09/19/2019 - 11 months 05/30/2019 2. Interview with the lab manager and Technical Consultant, in the office on October 28, at approximately 4:30 pm confirmed the aforementioned statement.

**D6036**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on review of the calibration documents for the CellDyn Ruby (Ruby) hematology analyzer, and staff interview the Technical Consultant (TC) failed to verify that the calibration of the Ruby was performed at least every 6 months. Findings: 1. Document review for the Ruby hematology analyzer, showed that the calibration was performed on the following days: 04/12/2021 08/14/2020 - eight months 09/19/2019 - 11 months 05/30/2019 2. Interview with the lab manager and Technical Consultant, in the office on October 28, at approximately 4:30 pm confirmed the aforementioned statement.