

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0929322	<b>(X3) Date Survey Completed</b>  04/26/2019
<b>Name of Provider or Supplier</b>  Rheumatology Associates Of Balto Llc	<b>Street Address, City, State</b>  1220b East Joppa Rd #310, Baltimore, MD	
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>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 records and interview with the technical consultant, the laboratory did not ensure that calibration verification was performed and documented every six month for the hematology analyzer and the chemistry analyzer. Findings: 1. The manufacturer of the hematology analyzer requires calibration verification to be performed every six months. The laboratory records show that the calibration verification was performed on 05/04/17 and then on 06/12/18 showing an</p>

11 month gape between calibrations. Additional records show that the calibration verification was performed on 07/27/18 and then on 03/21/19 showing an 8.5 month gape between calibrations. 2. The chemistry records show that the last time linearity was performed was in 2017 verifying the reportable range of the analyzer. 3. During the survey on 04/26/19 at 11:00 AM the technical consultant confirmed that the calibration verification for the hematology and chemistry analyzers were not being performed every six months as required.