

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2051284	(X3) Date Survey Completed 11/06/2019
Name of Provider or Supplier Eastman Pediatric Clinic DbA New Life Pediatrics	Street Address, City, State 33 South 2nd Avenue, Mc Rae, 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 November 6, 2019. 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:
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 Medonic M series Hematology Analyzer(Medonic), and staff</p>

interview, the laboratory failed to perform calibrations every 6 months. Findings: 1. A review of the calibration documents for the Medonic, the laboratory had documentation that calibrations were performed on the following days: 08/09/2019, 09/28/2018 (11 months), 03/16/2018 (6 months) , 08/04/2018 (7 months), 02/13/2017 (6 months). 2. Interview with staff #2 (CMS 209 form), on 11/06/2019, at approximately 11:30 am, in the breakroom, confirmed that the calibrations were not performed every six months.