Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2051284	11/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Eastman Pediatric Clinic Dba New Life Pediatrics	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 30, 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:
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: Based on review of the Installation documents for the Sysmex XP-300 Hematology

	Analyzer (Sysmex) and staff interview, the laboratory failed to perform calibration at least every 6 months. Findings: 1. Review of the Installation documents for the Sysmex was calibrated on 9/8/2020 during the install. There were no other documented calibrations for the Sysmex for March 2021, and September 2021. 2. Interview with staff #2 (CMS 209 Personnel Form), on 11/30/2021 at approximately 11 am in the breakroom, confirmed the above aformentioned statement.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: The Laboratory Director (LD) must ensure that the quality assessment(QA) programs are established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. Review of the Installation documents for the Sysmex Hematology Analyzer, the Sysmex was calibrated on 9/8 /2020 during the install. There were no other documented calibrations for the Sysmex for March 2021, and September 2021. 2. Interview with staff #2 (CMS 209 Personnel Form), on 11/30/2021 at approximately 11 am in the breakroom, confirmed the above aformentioned statement.