Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2044019	09/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Southeast Georgia Pediatrics, Llc	1701 D Boulevard Square, Waycross, 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 September 15, 2022. 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 Abbott Cell-Dyn Emerald (Emerald) Hematology Analyzer

	and staff interview, the laboratory failed to calibrate the Emerald every six months from March 2021 to March 2022. Findings: 1. Review of the Emerald calibration documents, the laboratory calibrated the Emerald on March 5, 2021, and the next documented calibration was March 10, 2022. The emerald was not calibrated during the 12 month period. 2. Interview with staff #1, (CMS 209 form), on September 15, 2020 at approximately 1:30pm, in the office, confirmed the aforementioned statement.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on review of the Abbott Cell-Dyn Emerald (Emerald) Hematology analyzer documentation, , the laboratory director failed to provide oversight for the overall operation and administration of the laboratory. The laboratory failed to perform calibrations for a 12 month period from March 2021 thru March 2022. Findings: 1. Review of the Emerald Calibration documentation, the laboratory did not document calibration performance from March 5, 2021 thru March 10, 2022. The laboratory director is responsible for the overall operation of the laboratory. 2. Interview with staff #1 (CMS 209 form), on September 15, at approximately 1:30 pm, in the office, confirmed the aforementioned statement.