Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0958145	02/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Southern Crescent Pediatrics Pc	191 Fairview Road, Ellenwood, 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 February 26, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and staff interviews, the lab failed to document corrective actions when PT failures occurred. Findings include: 1. Review of PT records (2017-2018) revealed 2018 testing event #3 sample #1 Leukocytes was scored 0 and Platelets sample #1 was scored 60 without corrective actions documented. 2. Interviews with staff #2 (CMS 209 form) and the lab manager on 2/26 /19 at 11:30 AM in the breakroom, confirmed the corrective actions were not documented.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interviews, the laboratory failed to

	follow the written Quality Assessment (QA) policies and procedures found in the manual. Findings include: 1. Review of daily and monthly QA records revealed the forms were not completed or followed 12 of 12 months in 2018. 2. Interview with staff #2 (CMS 209 form) and the lab manager on 2/26/19 at 11:00 am in the breakroom, confirmed the laboratory did not follow the written Quality Assessment (QA) policies and procedures.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on maintenance document review and staff interview, the lab failed to perform maintenance on the CellDyn Emerald analyzer per the manufacturer . Findings include: 1. Review of 2018 CellDyn Emerald maintenance records revealed the lab failed to perform or document the semi-annual maintenance required by the manufacturer. 2. Interview with staff #2 (CMS 209 form) on 02/26/19 in the breakroom at approximately 1155 AM, confirmed the semi-annual maintenance was not performed or documented in 2018.
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 calibration document review and staff interview, the lab failed to calibrate the Cell-Dyn Emerald analyzer every six (6) months as required by the manufacturer. Findings include: 1. Review of calibration data revealed the Emerald was calibrated 12 /19/16, 10/09/17 (10 month span), 05/09/18 (7 month span), and 01/21/19 (8 month

	span). 2. Interview with testing personnel #2 (CMS 209 form) on 2/26/19 at approximately 12 PM in the breakroom, confirmed the time spans.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on document review and staff interviews, the lab failed to enroll and participate in proficiency testing (PT) during the first (1st) testing event of 2018. Findings include: 1. Review of PT documents revealed the lab did not enroll or participate in proficiency testing (PT) during the first (1st) testing event of 2018. 2. Interviews with staff #2 (CMS 209 form) and the lab manager on 2/26/19 at 1130 AM in the breakroom, confirmed the aforementiond lack of enrollment and participation.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory records and staff interview, the laboratory director (LD) failed to ensure that the quality control (QC) program is maintained to identify failures in quality. Findings include: 1. Review of the laboratory's records revealed no documentation of QC review by the LD for the year 2018. 2. Interview with staff #2 (CMS 209 form) in the breakroom at approximately 12 Noon, confirmed the missing aforementioned review of QC.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on review of the laboratory records and staff interview, the laboratory director (LD) failed to ensure the quality assessment (QA) program is maintained and followed. Findings include: 1. Review of the laboratory's records revealed no documentation of QA review by the LD for the year 2018. 2. Review of the laboratory's records revealed no documentation of the LD ensuring staff followed the QA program in the year 2018. 2. Interview with staff #2 (CMS 209 form) and the lab manager on 2/26/19 in the breakroom at approximately 11 AM, confirmed the missing aforementioned review of QA and the adherence to the QA program.