

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2003343	(X3) Date Survey Completed 02/21/2019
Name of Provider or Supplier Southern Pediatric Clinic, Llc	Street Address, City, State 406 Northside Drive, Suite M, Valdosta, 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 21, 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:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the American Academy of Family Physicians (AAFP) Proficiency Testing (PT) documents, and staff interview the laboratory was not enrolled or participating in a HHS approved Proficiency Testing program for the specialty of Microbiology. Findings: 1. Review of the AAFP PT documents, the laboratory was not enrolled in a PT program for the Solana GAS Assay strep test for Microbiology. The Solana GAS assay test is classified as a Moderate Complexity procedure and PT must be performed. 2. Interview with the office manager and Staff #5 (CMS 209 form) on February 21, 2019 at approximately 3:10pm in the doctor's charting room, confirmed that the laboratory was not enrolled in a PT program for the Solana GAS Strep Test Assay. .</p>
D5449	CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the Quality Control (QC) documents for the Solana GAS Assay, the laboratory did not perform QC each day of patient testing. Findings: 1. Review of the QC documents for the Solana GAS Assay showed that the QC was only being performed with each new shipment and each new lot and every 30 days of the same lot number use, and not each day of patient testing. 2. Staff interview with the office manager, and staff #5 (CMS209 form) in the doctor's charting room on February 21, 2019 at approximately 3pm, confirmed that the laboratory was performing QC with each new shipment, each new lot, and after 30 days of using the same lot number.

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 of the American Academy of Family Physicians (AAFP) and staff interview the laboratory was not enrolled in a HHS approved proficiency testing (PT) program for the specialty of Microbiology. Findings: 1. Review of the AAFP PT results that were provided for 2017 and 2018, the laboratory was not enrolled in a HHS approved PT program for the Solana GAS Assay for Group A Strep. 2. Staff interview with the office manager, on February 21, 2019 at approximately 3pm, in the doctor's charting room, confirmed that the laboratory was not enrolled in a HHS approved PT program for the Solana GAS Strep Test for the specialty of Microbiology.