

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0213175	(X3) Date Survey Completed 12/19/2018
Name of Provider or Supplier Pediatric And Adolescent Care Of Silver Spring Pa	Street Address, City, State 12501 Prosperity Drive Suite 100, Silver Spring, MD	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not have written procedures for isolating and identifying Group A strep on selective strep agar plates from sources other than upper respiratory. Findings: 1. The laboratory performs identification of Group A strep on specimens from rectal and vaginal sources using selective strep agar; 2. The laboratory did not have written procedures for collection and testing of specimens from other sources other than upper respiratory using selective strep agar; and 3. This was confirmed during interview with the lab director on the day of survey.</p>