

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2079949	(X3) Date Survey Completed 11/19/2024
Name of Provider or Supplier Potomac Pediatrics	Street Address, City, State 15204 Omega Dr Ste 100, Rockville, 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 observation of the written procedure and interview with the laboratory staff member A (LSA), the laboratory did not have a written procedure for performing culture with strep select agar plates and use of TAXO A (taxonomic) disks for these bacterial cultures for specimens from perianal sources. Findings: 1. The laboratory was performing testing on perianal samples for bacterial culture using strep select agar and Taxo A disks. 2. The laboratory written procedure did not have a procedure specific for collection, culture, use of taxonomic disks for Group A strep, interpretation and reporting of results from Perianal sources. This finding was</p>

confirmed with the LSA on August 14, 2024 at 12:30 pm. 3. The written procedure did not state how the laboratory proficiency testing program assesses cultures from perianal sources, when the laboratory is only enrolled in a program to assess throat cultures. The laboratory should be enrolled in a program that assesses rectal samples or perform twice annual verification if a program is unavailable, and this should also be included in the written procedure.