Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0946119	(X3) Date Survey Completed 06/13/2023
Name of Provider or Supplier Pediatric Affiliates, Pa	Street Address, City, State 1001 Rt 9n, Howell, NJ	

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	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Standard Operating Procedures (SOP) and interview with the Testing Personnel (TP), the laboratory failed to provide a procedure for performing negative (no zone) QC with each new lot and/or shipment of BD BBL Taxo Discs for Differentiation of Group A Streptococci from 9/21/21 to the date of the survey. The TP confirmed on 6/13/23 at 12:30pm that they could not provide a procedure for performing QC for each new lot and/or shipment of BD BBL Taxo Discs for Differentiation of Group A Streptococci.

D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records, review of the BD BBL Taxo Discs for Differentiation of Group A Streptococci package insert (PI) and interview with the Testing Personnel (TP), the laboratory failed to perform negative (no zone) QC with each new lot and/or shipment of BD BBL Taxo Discs for Differentiation of Group A Streptococci from 9/21/21 to the date of the survey. The findings include: 1. The PI stated to use a Streptococci Non-A (B, C or D) organism for the negative QC in order for their to be Streptococci growth on the Selective Strep Agar, ensuring that the BD BBL Taxo Discs for Differentiation of Group A Streptococci demonstrates a negative (no zone) reaction. 2. The TP confirmed on 6/13/23 at 1pm that they used E.Coli which would not have growth on the Selective Strep Agar instead of a Streptococci Non-A (B, C or D) as the QC for each new lot and/or shipment of BD BBL Taxo Discs for Differentiation of Group A Streptococci.