

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1001408	(X3) Date Survey Completed 10/22/2024
Name of Provider or Supplier Pediatric Affiliates, Pa	Street Address, City, State 218 Jack Martin Blvd, Brick, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, the Procedure Manual and interview with the Laboratory Manager (LM), the laboratory failed to follow their QC procedure for Throat Culture-Strep Select Agar Plate Quality Control & Sterility from 8/16/23 to 10/22/24. The finding includes: 1. The PM states "designate one of the strep agar plates to be positive (S.pyogenes), the 2nd plate mark negative (E.coli)." 2. The laboratory personnel did not use E.coli as the negative control for SSA. 3. The LM confirmed on 10/22/24 at 11:50 am, the laboratory failed to follow the QC procedure for throat culture.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records, the Procedure Manual and interview with the Laboratory Manager (LM), the laboratory failed to check each new lot number and shipment of Hardy A70 Selective Strep Agar (SSA) media for its ability to inhibit specific organisms from 8/16/23 to 10/22/24. The findings include: 1. The laboratory failed to use at least one organism to confirm the inhibitory characteristic of SSA media for Lot numbers 637237, 625350 and 626998. 2. The LM confirmed on 10/22/24 at 11:45 am, the laboratory failed to perform the above mentioned QC on SSA media.