

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2001789	(X3) Date Survey Completed 11/22/2023
Name of Provider or Supplier Pediatric Affiliates, Pa	Street Address, City, State 870 River Ave, Lakewood, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with Testing Personnel (TP), the laboratory failed to ensure that all TP who routinely performed Bacteriology testing participated in the American Proficiency Institute (API) PT events in the calendar year 2023. The findings include: 1. A review of PT attestation records showed that 1 out of 9 TP performed all API PT events for Group A Strep Culture and Urine Colony Count in the calendar year 2023. 2. TP #1 as listed on the CMS-209 form confirmed on 11/22/23 at 11:30 am that the PT events were not rotated between TP.</p>
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 Procedure Manual (PM), the Bacitracin Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to use and follow the correct procedure for "Bacitracin Disc Test" from 3/10/23 to the</p>

date of survey. The findings include: 1. The PM had two different procedures for performing "Bacitracin Disc Test." a. One procedure stated to use "Negative (E.coli) controls" and the other procedure stated to use "Negative (S.agalactiae) controls." 2. The laboratory followed the incorrect procedure and used the incorrect negative control of E.coli for Bacitracin QC on Lot # 2056368 and 3062072. 3. The Bacitracin Disc Test procedure states to use "2 Blood Agar Plates" but the laboratory only has Hardy diagnostics Selective Strep Agar Media. 4. TP #1 as listed on CMS-209 form confirmed on 11/22/23 at 11:45am the laboratory followed the incorrect procedure for Bacitracin Disc Test.