Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0118416	06/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Affiliates, Pa	1616 Route 72 West, Manahawkin, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Report (TR) and interview with the Office Manager (OM), the laboratory failed to report Covid 19 testing accurately. The findings include: 1. The laboratory performed non Food and Drug Administration (FDA) cleared tests and there was no statement "This test has not been FDA cleared or approved; The test has been authorized by the FDA under an Emergency Use Authorization (EUA)" on the Final Report (FR). 2. The OM confirmed on 6/28/23 at 11:00 am that Covid 19 tests were not reported accurately.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain NJCLL for 2023. A Surveyor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 6/28/23 that the laboratory did not have a NJCLL license for 2023.

D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Bacitracin discs in use and interview with the Office Manager (OM) the laboratory failed to check each lot number and shipment of BD Bacitracin Discs for positive and negative reactivity from 5/31/23 to the date of the survey. The finding includes: 1. There was no record of Bacitracin QC for Lot # 2336236 currently in use. 2. Approximately 10 patient run and reported each day. 3. The OM confirmed on 6/28/23 at 10:50 am that the laboratory did not perform QC on Bacitracin disc as stated above.