Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0081613	02/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of Fall River	851 Middle Street, Fall River, MA	

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
D0000	A CLIA recertification survey was conducted for the Pediatric Associates of Fall River laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview with the Laboratory Director (LD) on 2/23/21, the laboratory failed to document and maintain a copy of all PT records as evidenced by the following: The surveyor reviewed College of American Pathologists (CAP) PT records for calendar years 2019 and 2020. The review revealed that attestation statements provided by the PT program were not signed by the LD and analyst for the following events: 1. FH2- A & C 2019 Hematology Auto Differentials Events 1 and 3 2. HC7-C 2019 Chlamydia/GC with DNA Survey Event 3 3. D1-A 2019 Throat Culture Event 1 4. CM-A 2020 Clinical Microscopy Event 1 5. D1-A 2020 Throat Culture Event 1 6. FH2- A & B 2020 Hematology Auto Differentials

	Events 1 and 2 7. HC7-A & C 2020 Chlamydia/GC with DNA Survey Events 1 and 3 The LD confirmed in an interview on 2/23/21 at 2:15 PM that not all attestation statements were signed by the analyst and laboratory director.
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 record review and interview with the Laboratory Director (LD) on 2/23/21, the laboratory failed to check each lot number and shipment of disks when opened for positive and negative reactivity as evidenced by the following: The laboratory performs throat culture screens for presumptive identification of Group A Streptococci (GAS) using Selective Strep Agar and Bacitracin disks. Quality control (QC) record review on 2/23/21 revealed that the laboratory did not check each lot and each shipment of Bacitracin disks with positive and negative organisms. There were no Bacitracin disk QC records available for the following lot numbers of Bacitracin disks: Lot Number: Expiration Date: 1. 8116687 11/30/19 2. 8150727 12/21/19 3. 429135 6/30/22 4. 429744 6/30/22 5. 431993 7/31/22 Interview with the LD on 2/23 /21 at 2:00 PM confirmed that the laboratory failed to check each lot and shipment of Bacitracin disks using GAS positive and negative organisms.