Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0073889	09/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Specialists Of Foxboro & Wrentham	132 Central Street Suite 113-115, Foxboro, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on record review of the laboratory's 'Weekly Eyewash Maintenance' logs and interview with testing personnel #1, (TP1) and the Technical Consultant, (TC), the laboratory failed to follow the procedure for the weekly eyewash function check in the subspecialty of Bacteriology. Findings include: 1. Record review on 9/25/2023 of the laboratory's 'Weekly Eyewash Maintenance' logs from 1/1/2022 through 9/25/2023 revealed: a. The laboratory failed to document weekly eyewash function checks for 11 of 52 weeks in 2022 and 5 of 38 weeks in 2023. b. All logs were signed as reviewed by the TC. 2. Staff interview with TP1 and the TC on 9/25/2023 at 10:00 AM confirmed the above findings. The TC stated, "I need to do better when reviewing the maintenance records for completion." 3. The laboratory performs 700 tests annually in the subspecialty of Bacteriology.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by:

	Based on record review of the laboratory's testing personnel (TP) competency records and interview with TP1 and the Technical Consultant (TC), the TC failed to ensure TP had yearly competency to ensure their ability to perform test procedures accurately in the subspecialty of Bacteriology. Findings include: 1. Record review on 9/25/2023 of the laboratory's 2022 and 2023 to date TP Competency records as compared to the CMS form 209 revealed: a. TP2 had competency for 1/31/2023 and 9/13/2023, but was not listed on the CMS form 209. b. The TC then added TP2 to the CMS form 209. c. Four of Nine TP listed on the updated CMS form 209 did not have documented competency in 2022. d. The laboratory uses the same binder for both office locations. 2. Staff interview on 9/25/2023 at 9:23 AM with TP1 and the TC: a. Confirmed the above findings. b. TP1 stated, "TP2 works at the lab on weekends and should be on the 209." c. The TC stated, "When I checked to see who needed competency in December of 2022, it was hard to fit everyone in for competency before the end of the year. Some TP were off of work or out sick. TP2 works on site here on weekends but primarily works at the other location. Most TP work at both locations. There is only one competency book for both labs and TP only have competency done at one location. TC is not sure which lab the competency sheets are from unless they did a proficiency testing sample." 3. The laboratory performs 700 tests annually in the subspecialty of Bacteriology.