Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0225177	11/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of Winchester	1002 Amherst St Bldg C, Winchester, VA	

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	An announced CLIA recertification survey was conducted at Pediatric Associates of Winchester on November 16, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The deficiencies cited are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records and an interview, the laboratory failed to rotate Throat Culture PT among testing personnel (TP) responsible for patient testing for three (3) of five (5) events reviewed (survey timeframe: January 2022 to November 16, 2023). The findings include: 1. Review of the CMS 209 form with the testing personnel on November 16, 2023, at approximately 9:15 AM, confirmed 5 testing personnel (TP) were responsible the reading of throat cultures during the review timeframe of January 2022 to November 16, 2023. 2. Review of the laboratory's scored College of American Pathologists (CAP) D1 Throat Culture PT documentation, a total of 5 events (2022 Events 1-3, 2023 Events 1-2), revealed the following (see personnel code sheet): TP D signed attestation and performed CAP 2022 Events 1,and 3 and 2023 Events 2; TP C signed attestation and performed CAP 2022 Event 2; TP B signed attestation and performed CAP 2023 Event 1. 3. In an exit interview with the laboratory director and testing personnel on November 16, 2023, at approximately 12:15 PM, the above findings were confirmed.

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, proficiency testing (PT) records, lack of documentation and an interview, the laboratory director failed to follow their established policy and document corrective actions for three (3) of five (5) College of American Pathologists (CAP) D1-Throat Culture PT events during the review timeframe of January 2022 until November 16, 2023. The findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, (Quality Assurance-Proficiency Testing", with the following statements, "11. The results will be reviewed carefully when received. The laboratory will undertake appropriate investigative action (s) in the event of proficiency test failure. All corrections or remedial actions will be documented on the proficiency testing log or on the proficiency testing result form." 2. Review of the laboratory's CAP Throat Culture PT documentation from January 2022 until November 16, 2023 (a total of 5 events) revealed a lack of documentation of corrective actions taken for the following: CAP 2022 D1-C Throat Culture scored as 80%; CAP 2023 D1-A Throat Culture scored as 80%; CAP 2023 D1-B Throat Culture scored as 80%. The surveyor requested to review documentation of the corrective actions for above listed PT events. The laboratory provided no documentation for review. 3. In an exit interview with the laboratory director and testing personnel on November 16, 2023, at approximately 12: 15 PM, the above findings were confirmed.