Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0622078	08/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of The Northwest	7150 Sw Dartmouth Street, Tigard, OR	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records and discussion with staff, the Laboratory Director (LD) failed to sign the attestation form as required by CFR 493.801(b). Findings include: 1. Attestation forms #1 through #3 for 2017 were signed by a Medical Assistant. 2. Attestation forms #1 and #2 for 2018 were signed by a Medical Assistant.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of this laboratory's procedure for Quality Assurance (QA) and discussion with the Technical Consultant (TC), the laboratory failed to document monthly QA activities as outlined in their procedure. Findings include: 1. The laboratory's procedure for QA provides a checklist that is to be completed monthly.

	There was no written documentation on the checklist for the year (12 months) 2017 and 2018 to date (7 months). 2. The TC confirmed that no written documentation (the checklist) had been done since the last survey during interview on 8/7/2018 at ~1200.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the Laboratory's procedure manual and discussion with the Technical Consultant (TC), the laboratory failed to provide a written procedure for testing personnel to follow when performing urine microscopy. Findings include: 1. There was no written procedure detailing the procedure for performing urine microscopy. 2. The TC confirmed there was no procedure written during interview 8/7 /2018 at 1305.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observataion of laboratory specimen refrigerators and discussion with the Technical Consultant (TC), food products were found being stored with biological hazards. Findings include: 1. Two (2) large bottles of Hersheys Chocolate Syrup were being stored in a refrigerator that also contained biologically hazardous material. 2. The TC confirmed the syrup had been stored in the specimen refrigerator during interviw on 8/7/20118 at ~1230.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of records and discussion with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure Quality Assurance (QA) protocol was followed per laboratory written policy. Findings include: 1. The Laborattory Director (LD) failed to ensure the monthly QA procedure/checklist was completed and signed off monthly for year 2017 (12 months) and 2018 to date (7 months). 2. This was confirmed by the TC during interview 8/7/2018 at ~ 1300.