Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0667311	01/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Salem Pediatric Clinic	2478 13th St Se, Salem, 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 the Technical Consultant (TC) and General Supervisor (GS), the laboratory failed to ensure the attestation was signed by the Laboratory Director (LD). Findings include: 1. Upon review of the PT events #1, #2 and #3 for 2020, the attestation form for all three (3) lacked the LD's signature for Hematology, Microbiology and Chemistry. 2. Upon review of the PT events for 2019, there was no signature by the LD on the attestation form or the Director Review for PT event #3 for Hematology and Chemistry. 3. In an interview with the TC during survey on 01/04/2021 at approximately 1:00 pm, she confirmed the LD had not signed the attestation documents mentioned in this deficiency.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	This STANDARD is not met as evidenced by: Based on review of Proficiency testing (PT) records and discussion with the Technical Consultant (TC), the laboratory failed to perform corrective action (CA) for the missed resullt for blood cell identification. Findings include: 1. For PT event #1 in 2020, one of five blood cells for sample BCI-01 was mis-identified by the testing personnel. No written CA for this unacceptable result could be produced during inspection on 01/04/2021. 2. The TC confirmed that there had been no CA taken for this PT failure by the Laboratory Director.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of competency records of testing personnel (TP) and discussion with the Techincal Consultant (TC), the Laboratory Director (LD) failed to ensure training and competency assessment of TC was performed and documented by a qualified person. Findings include: 1. Upon review of competency assessments for the TC, it was determined that these assessments were performed by a Lab Assistant unqualified to perform such assessments in Hematology and Chemistry. 2. The TC confirmed that the person who had signed off on these two (2) assessments on July 15, 2020 was a Lab Assistant during survey interview on 01/04/2021 at 1:00 pm. 3. The written training record for the TC on the Reichert Bilirubinometer showed that she had performed this initial training on herself without oversite by the Laboratory Director /Technical Supervisor.