Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0867962	08/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Salem Womens Clinic Lab	1395 Liberty 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 for 2021, 2022 and 2023 and interview with testing personnel (TP #1) and the Laboratory Director (LD), the laboratory failed to ensure that the attestation form was filled in and signed by the LD. Findings include: 1. Fifteen (15) individual PT testing events were reviewed during survey August 1, 2023. Zero out of fifteen (15) testing event attestations had been signed off by the LD. 2. Upon review of the PT records for 2021, event #3 for Immunology, no signed attestation by the LD could be produced. 3. Upon review of the PT records for 2022 for Chemistry, Microbiology, and Immunology (3 events for each specialty), it was revealed that none of the twelve (12) PT testing events for 2022 had been attested to / signed by the LD. 3. Upon review of the PT testing events for 2023 Chemistry (2 events), Microbiology (2 events) and Immunology (1 event) received year to date, it was revealed that none of the five (5) events had been attested to / signed by the LD. 5. Interview with the LD and TP#1 at approximately 1330 confirmed that the attestation for each of the fifteen (15) PT events reviwed during survey had not been signed by the LD.
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 review of laboratory Standard Operating Procedures (SOP's) for this facility and interview with Testing personnel (TP #1) and the Laboratory Director (LD), the LD failed to ensure that an approved Corrective Action (CA) plan was in place and being followed for any missed Proficiency testing (PT) analyte result. Findings include: 1. Upon review of Chemistry PT testing results for event 3, 2021, it was revealed that one (1) of two (2) specimens for Thyroid Antibody (Anti - TPO) were unacceptable. No CA for this missed PT analyte could be produced. 2. Upon review of Immunology PT testing results for event 2, 2022, it was revealed that two (2) of two (2) specimens for Anti-TPO were unacceptable. No CA for this missed PT analyte could be produced. 3. Upon review of Microbiology PT testing results for event 1, 2023, it was revealed that two (2) out of five (5) specimens for Chlamydia trachomatis were unacceptable. No CA for this missed PT analyte could be produced. 4. Upon review of Chemistry PT testing results for event 3, 2023, it was revealed that one (1) out of two (2) specimens for Estradiol were unacceptable. No CA for this missed PT analyte could be produced. 5. The LD and TP #1 confirmed during interview 08/01/2023, at approximately 1400 that no corrective action, written or otherwise, had been performed or documented for the missed PT analytes.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the lack of any written evidence demonstrating a Quality Assessment (QA) plan was in place and interview with Testing personnel (TP #1) and the Laboratory Director (LD), the LD failed to ensure a written QA plan was in place and being followed. Findings include: 1. During survey on 08/01/2023, this surveyor asked to review the lab's QA plan. No written QA plan or policy regarding QA monitors and frequency of review of collected QA data could be produced. 1. Upon request by this surveyor to TP #1 for written records and activities of QA activity, none could be produced for 2022 or 2023. 2. The LD and TP #1 confirmed during interview at approximatey 1330 08/01/2023, that no QA plan or written documentation of QA activity could be produced for 2022 or 2023.