Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0867962	08/05/2025
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
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Laboratory's procedure manual, personnel records, and other laboratory documents for Quality Control (QC), temperature and Quality Assurance (QA), the Laboratory Director (LD) failed to fulfill the duties of the LD. Findings include: See D6020, D6030, D6032, D6046
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and 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 the two (2) Individual Quality Control Plans (IQCP's) in place at this facility during survey, and interview with the Laboratory Director (LD), it was noted that both IQCP's were lacking a developed Quality Control Plan (QCP) and Quality Assessment Plan (QAP) review. Findings include: 1. Upon review of the two IQCP's used by this facility, it was noted that both lacked a complete IQCP, as they did not have evidence of review of two (2) of the requisite parts of an IQCP. 2. Upon review of the IQCP for the Beckton Dickson (BD) Affirm test system, it was noted that the date of the risk assessment was 11/21/2017. Upon request for past written

	review of the BD Affirm IQCP Risk assessment dated 11/21/2017, none could be produced. 3. Upon review of the IQCP for the Cepheid GenX for Chlamydia trachomatis and Neiserria gonorrhea test system, it was noted that the date of the risk assessment was 11/21/2017. Upon request for past written review of the Cepheid Gen X for Chlamydia trachomatis and Neiserria gonorrhea Risk Assessment dated 11/21 /2017, none could be produced. 4. The LD confirmed during interview at 12:00 pm that there was no written detail for quarterly or annual review of QCP or QAP for the two IQCP's currently in use 5. The laboratory reports performing 1682 assays that involve these instruments and organisms annually.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual presented during survey and interview with the Laboratory Director (LD) and testing personnel #1 (TP #1), the LD failed to have a written procedure for competency assessment of TP performing moderate complexity testing which includes infectious agents listed by the State of Oregon as "Reportable Conditions". Findings include: 1. Upon review of the laboratory's procedure manual presented during survey, no procedure for competency assessment for all TP performing moderate complexity could be produced. 2. Upon review of the laboratory's procedure manual presented during survey, no procedure for reporting "reportable conditions" to the State of Oregon Public Health Lab or the County Public Health Lab could be produced. 3. Oregon state law says: "The laboratory must report to the local health department or state, the "reportable conditions"as indicated in OAR Chapter 333, Division 018". 4. Upon request for written documentation of competency assessment for TP #1 for 2024 and 2025 to date, none could be produced. 5. Upon request for written documentation of reportable conditions that had been reported to the Public Health Authorities in 2024 and 2025 to date, no written log or other documentation of reporting could be produced. 5. The LD and TP#1 confirmed during onsite interview @ 12:00 pm. that there is currently no procedure for competency assessment nor for "Reportable conditions". 6. The lab reports performing 14,752 moderate complexity assays annually.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the Laboratory Director (LD), the LD failed to create and maintain a current list with designation of duties for all persons authorized to perform any phase of laboratory testing. Findings include: 1. Upon request for a current list of all Medical Assistants (MA's) who are responsible for laboratory post analytical communication with Public Health officials for Reportable Conditions diagnosed at this lab, none could be produced. 2. Upon request for the procedure the MA's are taught to follow for reporting Reportable Conditions to Public Health Officials, none could be produced. 3. The sole testing personnel (TP #1), who performs all the moderate complexity testing in this lab, did not have a current written designation of duties. 4. On site interview with the LD at 12:00 pm, confirmed there was no current and inclusive designation of duties for all persons involved involved in any phase of laboratory testing. 5. The laboratory reports performing 14,752 laboratory assays annually.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on request for written competency assessments for the one (1) testing personnel (TP #1), the Techical Consultant (TC), (also the Laboratory Director or LD), failed to ensure TP #1 had annual competency assessments for moderate complexity testing. Findings include: 1. Upon request for written competency assessments for TP #1 who performs moderate complexity testing in this lab, none could be produced for 2024 or 2025 to date. 2. The laboratory currently uses three (3) instruments to perform moderately complex testing. 1. The Cepheid Genex for Chlamydia trachomatis and Neisseria gonorrhea 2. The Becton Dickson (BD) Affirm for Candida species, Gardnerella vaginalis and Trichomonas vaginalis. 3. The Roche Cobas e 411, currently performing nine (9) different endocrinology assays. 3. Interview with the LD (also the TC) and TP #1 at 12:00 pm confirmed that there was no written competency documentation for any of the moderate complexity tests run by TP #1 for 2024 and 2025 to date. 4. The laboratory reports performing 14,752 moderate complexity assays annually.