Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0867962	03/04/2019
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) records and discussions with the staff the laboratory failed to enroll in PT for the regulated analytes performed using the Roche Cobas e 411 Chemistry Analyzer. Findings include: 1. The surveyor requested and the laboratory failed to provide PT testing results for the following regulated analytes. These analytes were TSH, Free Thyroxine, Triiodothronine and PSA. 2. The laboratory started in house testing of patients samples for these analytes April 2018. 3. The testing personnel was not aware that the laboratory needed to enroll in PT for these analytes. 4. The Laboratory Director and the testing personnel concurred with these findings 03/04/2019 at 12:00PM.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on review of Proficiency Testing records and discussion with the staff the laboratory failed to verify the accuracy of the test or procedure twice annually for the unregulated analytes performed using the Roche Cobas e411 Chemistry Analyzer. Findings include: 1. The surveyor requested and the laboratory failed to provide biannual verification of the test system for the following non regulated analytes. Vitamin B12, Vitamin D, Estradiol, Testosterone,TPO, FSH and SHBG. for 2018 and 2019. 2. The Laboratory Director and the testing personnel concurred with these findings 03/04/2019 at 12:00PM.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration records and discussion with the staff the laboratory failed to perform calibration verification every six months for the analytes performed using the Roche Cobas E411 Chemistry Analyzer. Findings include: 1. The surveyor requested and the laboratory failed to provide documentations of calibration verifications for the following analytes. Vitamin B 12, Vitamin D, TPO (Thyroid Peroxidase Antibody), Estradiol, FSH (Follicle Stimulating Hormone), PSA (Prostate Specific Antigen), Testosterone, TSH (Thyroid Stimulating Hormone), SHBG (Sex Hormone Binding Globulin), Free T3 and Free T4. 2. The last documented calibration verifications were performed 12/13/2017. 3. The Laboratory Director and the full time testing personnel concurred with these findings on 03/04/2019 at 12:00 PM.