Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0664019	10/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Women's Care Laboratory	590 Country Club Parkway, Eugene, 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
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 personnel records and discussion with the technical supervisor (TS), the laboratory failed to ensure personnel maintain competence through biannual verification. Findings include: 1. During review of testing personnel (TP) competencies, no written documentation of biannual verification could be produced for TP performing semen analysis. 2. The technical supervisor (TS) confirmed during interview 10/10/2019 at approximately 1300 that no written documentation of competency for the aforementioned assay existed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on review of hematology procedures (SOP's) and discussion with the technical supervisor (TS), the laboratory failed to establish the frequency of calibration appropriate for their hematology analyzer by qualified individuals. Findings include: 1. There was no laboratory written and laboratory director (LD) approved SOP for calibration of the new SYSMEX XN-L instrument. 2. The SYSMEX personnel performing the calibration procedure when the instrument was installed are not listed or qualified on the requisite CMS 209 personnel form. 3. The TS confirmed that no laboratory written and LD approved calibration procedure for the SYSMEX XN-L existed during interview 10/10/2019 at approximately 1200.