Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D1100733	12/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Women's Clinic	11750 Sw Barnes Rd Ste 300, Portland, 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 records and discussion with staff on 12/12/2019 at 1100, there was only one written documentation of bi-annual verification for the ten (10) providers performing vaginal wet mounts. Findings include: 1. The documennt used to record bi-annual verification for the first part of 2018 could not be produced. 2. Staff verified that there was no writtenn documentation of bi-annual verification for the ten (10) providers for the first half of 2018.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the procedure manual, no Quality Assuance (QA) plan could be produced. Findings include: 1. There was no written procedure for Quality Assurance for the general laboratory system. 2. There was no written documentation of of QA acttivities for 2018 and 2019.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of records and discussion with staff, room temperature outliers were not responded to. Findings include: 1. For the month of May 2019, room temperature was out established range seven (7) out of twenty two (22) days of the month. 2. For the month of September 2019, room temperature was out of established range six (6) out of twenty (20) days of the month.