Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0919172	10/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Women's Care Of Alaska	2741 Debarr Road Suite C205, Anchorage, AK	

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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) (c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of procedures and policies and interview with testing personnel one (TP1), the laboratory failed to provide instructions for laboratory specific specimen handling, processing, and reporting for BD Affirm VPIII, Fern testing, and Wet Mounts. The findings include: 1. Review of testing procedures revealed the laboratory is using the manufacturer instructions or other microscopy procedures approved by the laboratory director. a. Review of the BD Affirm VPIII procedure revealed a lack of instructions for specimen labeling and handling, performing controls, corrective actions for failed controls, and entering and reporting results in the patient record. b. Review of the "Fern Test - Amniotic Fluid Crystallization Test" procedure revealed a lack of instructions for specimen labeling, criteria for acceptance or rejection, and entering and reporting results in the patient record. c. Review of the Wet Mount Examinations procedure revealed a lack of patient preparation, specimen labeling and storage, criteria for acceptance or rejection, and entering and reporting results in the patient record. 2. A request for procedures and policies regarding specimen labeling and handling, performing controls, and reporting was made but documentation was not available. 3. An on-site interview with TP1 on 10/8/25 at 12:00 PM confirmed the findings. 4. The laboratory reports performing 1945 patient tests annually for BD Affirm VPIII, Fern testing, and Wet Mounts.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)

	(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of room temperature and refrigerator thermometers, and an interview with testing personnel one (TP1), the laboratory failed to ensure temperature readings are accurate for BD Affirm VPIII testing area and reagent storage. The findings include: 1. Observation on 10/8/2025 at 10:00 AM showed the refrigerator and room temperature thermometers did not have a verification or calibration date indicated on the thermometers and the room temperature thermometer used was a "Sunbeam refrigerator-freezer". 2. An on-site interview with TP1 on 10/8/2025 at 11: 00 AM confirmed the thermometers were used for taking daily temperatures. 3. The laboratory reports performing 1860 BD Affirm VPIII patient tests annually, including Trichomonas vaginalis, Gardnerella vaginalis, and Candida species.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of quality control logs and procedures Individualized Quality Control Plan (IQCP), and an interview with testing personnel one (TP1) the laboratory failed to ensure control procedures were performed using negative and positive control material for the BD Affirm VPIII since September 2023. Findings Include: 1. Review of quality control logs from BD Affirm VPIII showed the laboratory did not perform an external negative control with the positive control. 2. Review of the IQCP for BD Affirm VPIII revealed the laboratory did not list a negative control to be used. 3. In an on-site interview with TP1 on 10/8/25 at 11:00 AM, the TP1 confirmed the findings. 4. The laboratory reports performing 1860 BD Affirm VPIII patient tests annually, including Trichomonas vaginalis, Gardnerella vaginalis, and Candida species.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of temperature charts and an interview with testing personnel one (TP1), the laboratory failed to document corrective actions for refrigerated temperatures out of acceptable range where BD Affirm VPIII reagents are stored. The findings include: 1. A review of refrigerator temperature logs for August and October 2024 and March 2025 showed the refrigerator temperature out of range in 16 out of

	131 readings with 1 temperature not taken. 2. A request was made for documentation of corrective actions taken for the temperatures out of range and no documentation was available. 3. An on-site interview with the TP1 10/8/25 at 11:00 AM confirmed that ranges on the temperature log were out of range and no documentation was made. 4. The laboratory reports performing 1860 BD Affirm VPIII patient tests annually, including Trichomonas vaginalis, Gardnerella vaginalis, and Candida species.
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 review of competency assessment forms and an interview with testing personnel one (TP1), the Technical Consultant failed to evaluate the competency for five (5) of five (5) staff using the BD Affirm VPIII since September 2023. Findings include: 1. Review of the "Competency Assessment for Laboratory Testing Personnel" form for five (5) of five (5) staff revealed: a. A staff member who did not meet the CLIA qualifications as a Technical Consultant evaluated the competency of staff as satisfactory or unsatisfactory b. The laboratory director reviewed and signed off on the competency forms. 2. In an on-site interview with TP1 on 10/8/25 at 11:00 AM confirmed the findings. 3. The laboratory reports performing 1860 BD Affirm VPIII patient tests annually, including Trichomonas vaginalis, Gardnerella vaginalis, and Candida species.