Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0627962	02/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Womens Health Center Of Southern Oregon	1075 Sw Grandview Ave Ste 200, Grants Pass, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the attestation forms for 2023 and 2024 Proficiency Testing (PT) events from American Proficiency Institute (API) and interview with the office manager, the laboratory failed to ensure that the Laboratory Director (LD) and the testing personnel (TP) attested to the performance of these PT samples. Findings include: 1. Upon review of the PT records from API for 2023, for the specialty Bacteriology, it was noted that the person signing off as the LD on the attestation form was not the LD, but a Medical Assistant (MA), with a high school (HS) diploma (also TP#4) for events one (1), two (2) and three (3) in 2023. 2. Upon review of the PT records from API for 2024, for the specialty Bacteriology, it was noted that there was no LD or TP signature for any of three (3) events in 2024. 3. The Office manager confirmed during interview at 1:30pm that the signature on the attestation forms for the three (3) events in 2023 belonged to TP #4 and not the LD. 4. The Office manager confirmed during interview at 1:30pm that the signature on the attestation forms for the three (3) events in 2024 were lacking for both the LD and the TP performing testing. 5. The laboratory reports performing 3000 moderate complexity Bacteriologic assays annually.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient

	identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the test report for the five (5) bacteriologic infectious agents tested for using the Cepheid Gen-Xpert instrument, and interview with the Office manager (also listed on the CMS 209 form as the Technical Consultant (TC) and Testing personnel (TP #1), the laboratory failed to ensure the final patient test report included pertinent information. Findings include: 1. The name and address on the test report is incomplete and reads as WHC 1075 SW Grandview. There is no city, state or zip code. 2. The tests performed are stated in vague acronyms, with no key included on the test report for interpretation of these acronyms. Atop gp - meaning unknown Mega1- meaning unknown Cgroup - standing for Candida species Cglab-krus- standing for Candida species TV - standing for Trichomonas vaginalis Rule 1 - meaninng unknown CT1 standing for Chlamydia trachomatis NG2 - standing for Neisseria gonorrhea NG4 - Standing for Neisseria gonorrhea 3. There is no ordering provider on the test report. 4. There is no specimen source or time of collection on the test report. 5. Interview with the Office manager (also listed as the TC and TP #1 on the current CMS 209 form) at 2:00 pm confirmed that the test report did not include the items stated above. 6. The laboatory reports performing 3000 tests annually for bacteriologic infectious agents.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the Proficiency testing (PT) results from the American Proficiency Institute (API) for 2023 and 2024 and interview with the Office manager (also listed as the Technical Consultant (TC) and testing personnel (TP #1), the Laboratory Director (LD) failed to review all PT events from API for 2023 and 2024. Findings include: See D2009
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on review of the sample report submitted for review during current survey and interview with the Office manager, also listed on the CMS 209 for as the Technical Consultant (TC) and testing personnel (TP #1), the Laboratory Director failed to

	ensure the test report for the five (5) bacteriologic infectious agents contained pertinent information required for test report interpretation. Findings include: 1. See D5805
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 the review of laboratory documents presented at survey, interview with the Office manager, also Testing Personnel #1 (TP #1) and email communications received from her 02/19/2025 at 9:18 am, the Laboratory Director (LD) failed to specify, in writing, what laboratory personnel were approved to perform what laboratory activities in all three (3) phases of laboratory testing. Findings include: 1. Upon request for a current document approved and signed/dated by the LD, with designation of duties for all laboratory personnel listed on the current CMS 209 form, none could be produced. 2. Upon request again for an approved and signed/dated designation of duties by the LD, via email on 02/18/2025 at 10:05 pm, the Office Manager/TP #1 responded on 02/19/2025 at 09:18 am "I don't believe this exists". 3. The current CMS 209 form lists nine (9) TP, who perform moderate complexity testing for vaginal infectious agents on site. These infectious agents include: Gardnerella. vaginalis Trichomonas vaginalis Candida species Chlamydia trachmatis Neisseria gonorrhae 4. The laboratory reports performing 3000 vaginal infectious agent assays annually.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS 209 form submitted for review during survey 02/18 /2025, review of personnel records for those listed on the current CMS 209 form and interview with the Office Manger, also listed as the Technical Consultant (TC) and testing personnel (TP #1) on the current CMS 209 form, the Laboratory Director (LD) failed to ensure a qualified TC was employed to oversee training and competency assessment for moderate complexity testing for bacteriologic infectious agents. Findings include: 1. See D6034
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education

	and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of personnel listed on the current CMS form submitted at survey, review of personnel education records and interview with the Office Manager, also listed as the Technical Consultant (TC) and testing personnel (TP #1) on the CMS 209 form, the laboratory failed to ensure a qualified TC was employed by the laboratory as required for moderate complexity testing. Findings include: 1.Upon review of the educational documents for the person listed on the current CMS 209 form, as TC, also testing personnel (TP #1), it was noted that TC / TP#1 did not have educational documentation beyond a High School degree from Grants Pass High School, graduation June 2005. 2. Interview with designee TC, also TP #1, at 1:30 pm, confirmed that she did not have any secondary education beyond High School. 3. The laboratory reports performing 3000 vaginal infectious agent assays annually.