Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0625580	04/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Willamette Urology Pc	2973 12th Street 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
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the Laboratory's Microbiology records provided during on site survey, interviews with the Registered nurse (RN) nurse manager and testing personnel (TP #1), the laboratory failed to perform and document the Quality Control (QC) requirements for Microbiology testing. See D5471, D5477, D5507
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, lack of documentation, and interview with the Registered nurse (RN) nurse manager and testing personnel (TP #1), the laboratory failed to perform and document quality checks for the reagents and media used in Microbiology patient testing. Findings include: 1. Review of the Microbiology

	Quality Control (QC) procedure requires that reagents and biochemicals have daily or weekly QC. 2. The lab performs urine cultures on site, which require the use of Catalase, Oxidase, and Indole tests to identify specific strains of bacteria as defined in the Laboratory's Microbiology procedure manual. These reagents require QC to be performed each day when patient testing is performed. 3. A review of the Laboratory's QC records revealed the laboratory had not been performing QC on each day of use for the following reagents: a. Catalase last QC performed 11/03/2022 b. Oxidase last QC performed could not be located. c. Indole last QC performed 3/12/2023 4. A review of the MicroScan Identification system revealed the lack of weekly QC, as required in the Laboratory's Microbiology QC Control procedures. a. The last QC available for review for the biochemical reactions on both the Gram-negative and Gram-positive organism panels was performed on 03/12/2023. b. The last QC available for review for Gram negative and Gram positive organisms for minimal inhibitory concentration (MICs) or antimicrobial sensitivities was on 3/12/2023. 5. Interview with TP #1 on 04/16/2024, at 1:00 pm confirmed that she had not performed any QC for the requisite reagents while on site at this facility. 6. The laboratory reports performing 4839 cultures from 3/13/2023 - 4/15/2024.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Microbiology policies and procedures and interview with testing personnel (TP # 1), the laboratory failed to ensure that all Microbiology media received the appropriate Quality Control (QC) by inspection and confirmation of growth when received. Findings include: 1. Microbiology QC procedures state that all Microbiology media and reagents will be assessed for sterility, physical condition, contamination, and any other damage, such as cracked plates upon receipt. 2. Upon request for records of media and reagents received and QC performed, the laboratory lacked documentation demonstrating the evaluation of differential media characteristics and selective media's growth and inhibitory characteristics to demonstrate the appropriate biochemical responses of certain organisms. 3. The laboratory lacked current documentation of any physical assessment or lot numbers of media or reagents received, including expiration dates and QC performed. The last dated media QC was 12/29/2022. 4. TP # 1 confirmed during interview at 1:00 pm., that she did not perform QC on the microbiological media and reagents when new media and/or reagents were received, either before or concurrent with initial use. 5. TP # 1 also confirmed by interview at 1:00 pm., that she does not keep a log of the media or reagents received, lot numbers, expiration dates, or QC results. 6. The lab reports doing 11,332 cultures annually.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c)

	(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of microbiology test records, observation, and interview with testing personnel (TP#1), it was revealed that a lack of performance and documentation for Minimum Inhibitory Concentration (MIC's) quality control (QC), using the MicroScan plates for Gram-negative and Gram-positive organisms, the laboratory failed to perform QC prior to or concurrent with each day of patient testing. Findings include: 1. The laboratory's Microbiology QC procedure requires that QC be performed weekly on the MicroScan MIC plates using specific American Type Culture Collection (ATCC) strains of organisms and are to be recorded on "Form B". 2. Review of Microbiology test records involving MICs reported on patient specimens and requested MIC QC records for 2022, 2023 and 2024. the Laboratory failed to perform and document QC for MICs using the MicroScan plates for Gram-negative and Gram-positive organisms after 3/12/2023. 3. By observation during a tour of the laboratory on 04/16/2024, the Laboratory had no ATCC stock organisms on site, either on agar media plates or as lyophilized cultures. 4. The laboratory's established limits for MICs, which are required to be determined before reporting patient results, could not be determined during the survey as the last MIC QC of record was performed on 3/12/2023. 5. TP # 1 confirmed during interview on 04/16/2024, at 1:00 pm, the lack of performing MIC QC after 3/12/2023. 6. The laboratory reports performing 11,332 cultures annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of microbiology test records, observation, and interview with testing personnel (TP #1), the Laboratory Director (LD) failed to fulfill the duties of an LD. See D6079, D6087, D6100, D6103
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities

	to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP), Technical Supervisor (TS) and General Supervisor (GS) competency records, review of Microbiology Quality Control (QC) records and interview with the Registered nurse (RN) nurse manager and TP # 1, the LD failed to ensure that all laboratory personnel were qualified and competent to perform high complexity Microbiology patient testing. Findings include: 1. Record review of the Laboratory's form CMS-209 submitted during survey 04/16/2024 identified one individual as the TS / GS for the laboratory and two testing personnel (TP) performing high complexity Microbiology patient testing. The following was revealed: TS / GS- unable to determine start date. Last competency assessment record by the LD for the TS/GS was 08/09/2021. TP # 1 Start Date - 08/05/2023 TP # 2 Start Date - 05/07/2021 2. The request for and lack of documentation of competency assessments for the TS / GS revealed no competency assessments were performed for the years 2022, 2023, 2024. 3. The request for and lack of documentation revealed that TP # 1 had not had an initial competency assessment by a qualified TS/GS. TP #1's 6 month competency assessment was not performed, which was due 2/2024. 4. The request for and lack of documentation revealed that TP # 2 had not had an annual competency assessment performed in 2023 or 2024 to date of survey by a qualified TS /GS. 5. Further review of form CMS-209 submitted at the time of survey, revealed that a qualified GS was not available on site to provide daily supervision and oversight of TP performing Microbiology testing after 03/2023. 6. TP #1 confirmed during interview 04/16/2024 at 1:00 pm that no GS was on site while she performed high complexity Microbiology testing on site at this facility.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of Microbiology testing personnel (TP) competency records, Quality Control (QC) records, the media IQCP control procedure and interview with testing personnel (TP #1), the Laboratory Director (LD) failed to ensure that TP were performing patient testing in accordance with CLIA regulations and the laboratory's policies and procedures. See D5471, D5477, D5507 and D6079
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4). This STANDARD is not met as evidenced by:

	Based on review of form CMS-209 submitted during survey 04/16/2024 and interview with the Registered nurse (RN) nurse manager and testing personnel (TP #1), the Laboratory Director (LD) failed to ensure a qualified General Supervisor (GS) was on site to provide technical oversight and supervision of TP performing high complexity Microbiology testing. Findings include: 1. A review of form CMS-209 revealed that a qualified GS was not on-site during microbiology testing performed by TP # 1 and TP # 2, who do not qualify as a TS or GS or as TP to perform high complexity microbiology testing unsupervised. 2. TP #1 confirmed during interview on 04/16 /2024 at 1:00 pm, that no GS was on site while TP #1 worked at the facility since she was hired 08/05/2023. 3. The facility reports performing 11,332 cultures annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, patient record review, testing personnel (TP) training and competency records, Technical Supervisor (TS) and General Supervisor (GS) competency records, proficiency testing (PT) records, and the laboratory's Quality Control (QC) records, the Laboratory Director (LD) failed to ensure all individuals were annually assessed to demonstrate competency and ensure remedial training was provided if needed. See D6079
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of Microbiology testing records, interview with Registered nurse (RN) nurse manager and testing personnel (TP # 1), the Technical Supervisor (TS) failed to fulfill the duties of a TS. See D6118, D6120.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of Microbiology work records, the lack of Quality Control (QC)

	records for all Microbiology testing performed in this lab in the past year, lack of training and competency records for testing personnel (TP #1 and TP #2) and interview with the Registered nurse (RN) nurse manager and TP # 1, the Technical Supervisor (TS) failed to ensure that daily, weekly and media end user QC were performed according to laboratory policy and procedure. Findings include: 1. The TS failed to verify the performance of the MicroScan test systems, stock organisms, reagents and media. See D5471, D5477, D5507. 2. Establish and monitor QC and quality assurance (QA) appropriate for the testing systems in use; the TS failed to monitor QC and QA monitors. See D5471, D5477, D5507 3. Evaluate the competency of personnel performing all aspects of Microbiology testing; The TS failed to perform competency assessments for two (2) of two (2) TP in 2023 and 2024. See D6079. 4. Identify the training needs of TP and ensure that appropriate training was received; the TS failed to perform initial and 6 month competency training for TP #1 in 2023 and 2024 and assess TP # 2's competency by annual review for 2023 and 2024 to date. See D6079 5. The facility reports performing 11,332 cultures annually.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency records and interview with the Registered Nurse (RN) nurse manager and TP # 1, the Technical Supervisor (TS) failed to ensure that competency assessments including initial training, 6 month competency assessment, 12 month competency and annual competency assessments thereafter were conducted on all TP. Findings include: 1. Document review revealed that TP # 1 did not have record of initial training or 6 month competency assessment by a CLIA qualified TS. 2. Document review revealed that TP # 2 had not had annual competency assessment for 2023 or 2024 year to date by a CLIA qualified TS. 3. TP #1 confirmed during interview 04/16/2024 at 1:00 pm that she had not had any training or competency assessment by the Technical Supervisor / General Supervisor (TS / GS) listed on the CMS 209 form at time of survey since her date of hire 08/05 /2023. 4. The laboratory reports performing 4839 cultures between 03/13/2023 and 04 /15/2024.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on a review of form CMS-209 submitted during survey 04/16/2024 and interview with the Registered Nurse (RN) nurse manager and testing personnel (TP

	#1), the Laboratory failed to ensure a General Supervisor (GS) was on site to ensure supervision and oversight of TP performing high-complexity Microbiology testing. Findings include: 1. TP #1 confirmed during interview on 04/16/2024 at 1:00 pm that a qualified GS was not on site when she was performing all phases of Microbiology testing. 2. The laboratory reports performing 11,332 cultures per year.
D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) listed on form CMS-209 submitted during survey 04/16/2024, interview with the Registered nurse (RN) nurse manager and TP #1, the laboratory failed to ensure a General Supervisor (GS) was on site when TP were performing all phases of Microbiology testing. Findings include: 1. TP #1 confirmed during interview 04/16/2024 at 1230 pm that no GS was on site when she was performing Microbiology testing at this facility. 2. TP #1 and TP #2 do not qualify as a GS, due to lack of years of experience and performance. See D6175, D6177. 3. The laboratory reports performing 11,332 cultures per year.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on the review of Microbiology testing personnel (TP) educational and competency records, it was determined that TP #1 and TP #2 do not qualify to perform the duties of a high complexity Microbiologist without direct oversight and supervision by the Technical Supervisor (TS) or General Supervisor (GS). See D6175 and D6177.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel (TP), the laboratory failed to follow the laboratory's policies and procedures for high complexity microbiological testing. Findings include: 1. Record review revealed TP failed to

	follow established policies and procedures for performing Quality Control (QC) activities for Microbiology culture identification and antimicrobial sensitivities. See D5471, D5477, D5507. 2. Based on lack of documentation, TP failed to follow established policies and procedures for performing QC and/or recording of lot numbers and expiration dates for reagents and media. See D5471, D5477, D5507 3. Review of TP #1 and TP #2 educational documents and training records revealed TP #1 and TP #2 do not qualify as a General Supervisor (GS) and cannot work in high complexity Microbiology testing unsupervised by a CLIA qualified GS. See D6079.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) procedures for performing and documenting QC, interview with testing personnel (TP # 1), TP failed to follow and document the laboratory's QC activities for all culture media, all Micro Scan Identification and MIC plates, all stock cultures and all reagents used in Microbiology testing before reporting patient results. See D5471, D5477, D5507