

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0625580	(X3) Date Survey Completed 05/22/2018
Name of Provider or Supplier Willamette Urology Pc	Street Address, City, State 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
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based upon discussion with one (1) of two (2) Technical Supervisors (TS) and review of testing personnel (TP) competency assessments, the Laboratory Director (LD) failed to fulfill the responsibilities of the LD. Findings include: 1. One (1) out of four (4) TP performing Microbiology had no twelve (12) month (annual) competency assessment for 2016, 2017 and 2018. 2. One (1) out of four (4) TP performing Microbiology had no twelve (12) month competency assessment for 2018. 3. Five (5) out of five (5) providers performing Potassium Hydroxide (KOH) wet mounts had no documentation of requisite bi-annual verification. This is a repeat citation.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based upon review of training records and discussion with the Technical Supervisor (TS), the Laboratory Director failed to ensure all testing personnel have bi-annual or annual competency training. Findings include: 1. See D-tag 6076</p>
<p>D6108</p>	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based upon review of training records and discussion with one (1) of two (2) Technical Supervisors, the TS failed to fulfill the responsibilities of the TS. Findings include: 1. One (1) out of four (4) TP performing Microbiology had no twelve (12) month (annual) competency assessment for 2016, 2017 and 2018. 2. One (1) out of four (4) TP performing Microbiology had no twelve (12) month competency assessment for 2018. 3. Five (5) out of five (5) providers performing Potassium Hydroxide (KOH) wet mounts had no documentation of requisite bi-annual verification. This is a repeat citation.</p>
<p>D6120</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based upon review of testing personnel (TP) training and competency records, the Technical Supervisor (TS) failed to ensure competency of TP performing Microbiology and Microscopy. Findings include: 1. See D-tag 6108.</p>