

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 38D0625580	<b>(X3) Date Survey Completed</b> 03/03/2020
<b>Name of Provider or Supplier</b> Willamette Urology Pc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6031</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(13)</p> <p>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based upon review of the procedure manual available for Medical Assistants (MA's) and interview with testing personnel (TP), the Laboratory Director (LD) failed to approve the procedure manual that contains the Urinalysis procedure. Findings include: 1. The last person to sign off on the Urinalysis procedure for macroscopic and microscopic analysis is no longer the LD. 2. The TP who is responsible for training the MA's in Urinalysis was interviewed during the survey 3/3/2020 at ~ 1400 and confirmed there was no other signature page by the current LD.</p>
<b>D6120</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> 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>

This STANDARD is not met as evidenced by:

Based on review of competency assessment of the two (2) testing personnel (TP) that perform high complexity Microbiology assays, the Technical Supervisor (TS) failed to ensure competency assessment was performed using the six (6) competency assessment criteria required. Findings include: 1. Upon review of competency assessments for Microbiology, no competency assessment for either TP could be produced for 2019. 2. The Microbiology TS confirmed that there was no competency assessment for either Microbiology TP for 2019 using the six (6) competency assessment criteria during interview on 3/3/2020 at ~ 1200.