

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0625580	(X3) Date Survey Completed 07/26/2022
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
D6092	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)</p> <p>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) results for 2022, the Laboratory Director (LD) failed to perform and document corrective action (CA) for analytes missed or found unacceptable for PT event #1 in 2022. Findings include. 1. Review of the PT event #1 2022 from College of American Pathologists (CAP) revealed that the laboratory missed one (1) of three (3) microscopic urine sediment challenges. (Specimen is coded CMP-06) 2. When ask to provide written documentation of CA for this missed specimen, none could be provided during survey 7/26/2022. 3. During an interview with the nurse manager at approximately 12:00 pm during survey 7/26 /2022, she confirmed that there was no written documentation of CA for this PT event, #CMP-06.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and discussion with the Nurse Manager, the Laboratory Director (LD) failed to ensure that a Quality Assessment (QA) plan /program outside of contracted Microbiology was established and being followed.</p>

Findings include: 1. During survey 07/26/2022, this surveyor asked to review the QA Policy and Procedures for the laboratory. The contracted Microbiology Company (Clinical Micro-Stat dba CMS) was able to produce their QA plan and documentation during survey but the Laboratory/Nurse Manager could not produce a QA Plan for other areas of the laboratory yielding patient results, for review. 2. The Nurse Manager confirmed that there was no written QA Plan for other areas of the lab that she was aware of during interview at ~ 1:30 pm 07/26/2022.