

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0867504	(X3) Date Survey Completed 10/28/2019
Name of Provider or Supplier Oregon Urology Institute	Street Address, City, State 2400 Hartman Lane, Springfield, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency records, the laboratory failed to ensure that TP had the required biannual verification for tests requiring such. Findings include: 1. Four randomly selected TP competency records were reviewed for biannual verification documentation for microscopic urinalysis and post vasectomy wet mounts. Zero out of four selected had documentation of biannual verification. 2. The Technical Consultant (TC) confirmed that biannual verification was not currently being done during interview 10/28/2019 at approximately 1400.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures (SOP's) and discussion with testing personnel, the laboratory failed to establish a written Quality Assurance (QA) SOP. Finding include: 1. No written evidence of QA activities could be produced during the survey conducted 10/28/2019. 2. The Technical Consultant (TC) and Microbiology Technical Supervisors (TS) confirmed there was no written procedure or policy for</p>

Quality Assurance (QA) activities during interview on 10/28/19 at approximately 1300.