

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0677964	(X3) Date Survey Completed 02/06/2018
Name of Provider or Supplier Urology Associates Of Fredericksburg	Street Address, City, State 1051 Care Way, Fredericksburg, VA	
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
D0000	An announced CLIA recertification survey was conducted at Urology Associates of Fredericksburg on February 6, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a review of the Laboratory Personnel Report form (CMS 209), policy manual, proficiency testing (PT) documentation, and an interview, the laboratory failed to verify the accuracy of qualitative semen analysis and microscopic urine examinations for 2017. Findings include: 1. Review of the CMS Form 209: Laboratory Personnel Report revealed that there are seven (7) TP performing patient testing. 2. Review of the policy manual revealed a PT policy for microscopic examination of urine and qualitative semen analysis. The policy stated "each testing personnel will have a minimum of two (2) specimens per year sent for comparative analysis". 3. Review of the laboratory's 2015, 2016, and 2017 PT documentation revealed no semen analysis and urine sediment comparative analysis for all seven (7) providers during calendar year 2017. The documentation was not available for review upon request. 4. An interview with the office manager at 11:00 AM on 2/6/18 confirmed that the lab failed to verify the accuracy of qualitative semen analysis and microscopic urine examinations at least twice a year for 2017.</p>