

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0677964	(X3) Date Survey Completed 04/05/2024
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	<p>An announced CLIA recertification survey was conducted at Urology Associates of Fredericksburg on April 4, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The inspection also included a follow up offsite interview with the practice manager and technical support personnel on 4/5/24. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:</p>
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel form (CMS 209), proficiency testing (PT) records and interviews, the laboratory failed to rotate PT among personnel performing patient post vasectomy semen microscopy analysis for five (5) of 5 PT events reviewed (timeframe June 2022 to the date of the inspection on April 4, 2024). Findings include: 1. Review of the CMS Form 209 revealed the laboratory director (LD) identified eight (8) testing personnel (TP) qualified/responsible for performing patient vasectomy semen analysis microscopic examinations during the review timeframe of 6/3/22 to 4/4/24. 2. Review of the laboratory's American Proficiency Institute (API) PT documentation, a total of 5 events, revealed that TP #1 signed attestations and performed/reported: 2022 API Hematology Microscopy Event 3; 2023 API Hematology Microscopy Event 1; 2023 API Hematology Microscopy Event 2; 2023 API Hematology Microscopy Event 3; 2024 API Hematology Microscopy Event 1; TP #1 performed 5 of 5 PT events during</p>

the twenty-two months of review. (See Personnel Code Sheet.) 3. A follow up interview with the laboratory's technical support personnel and office manager on 4/5 /24 at 10:30 AM confirmed the above findings.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on a review of procedures, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to verify cytology pathology slide examination accuracy twice annually in calendar year 2023. Findings include: 1. A review of the laboratory's procedure manual revealed a lab director (LD) approved protocol "Urology Associates of Fredericksburg Cytology and FISH Peer Review" that outlined twice annual accuracy /PT verification by peer review of four samples twice annually. 2. During a review of the laboratory's PT binder (review timeframe June 2022 to the date of the inspection 4/4/24) the inspector noted no record of twice annual peer review recorded in calendar year 2023. The inspector requested to review twice annual peer review completed in 2023. The technical support personnel stated that the LD had sent out five cytology cases completed in calendar year 2023 for peer review on 1/22/24 : USC23-2909WW, USC23-2881WDW, USC23-2882LGSL, USC23-2751VAN, USC23-2752GAC. The technical support stated on 4/4/24 at 11:30 AM, "It appears that they did not perform the 2023 peer review until they pulled the five cases from last year on 1/22/24." 3. An exit interview with the laboratory's technical support personnel and office manager on 4/4/24 at 1:30 PM confirmed the above findings.