

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0665504	(X3) Date Survey Completed 01/28/2020
Name of Provider or Supplier Virginia Urology Center,The	Street Address, City, State 8152 Pleasant Grove Road, Mechanicsville, 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 validation survey was conducted at The Virginia Urology Center on January 28, 2020 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 Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), procedure manual, split sample proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to verify twice annual accuracy of vaginal wet preparation microscopy testing in calendar year 2018 for testing personnel (TP) A. Findings include: 1. An entrance interview with the lab director (LD), at approximately 1:00 PM on 1/28/2020, included a review of the laboratory's CMS 209 form. During the interview, TP A was identified as performing patient vaginal wet preparation microscopy examination testing in 2018 and 2019. (See attached Testing Personnel Code Sheet.) 2. Review of the procedure manual revealed a policy titled "Vaginal Wet Preparation" that stated: "Internal comparison by split sample (2 person read) of 2-3 specimens are performed annually for proficiency testing". 3. Review of the available split sample PT records from January 2018 to the date of the survey on 1/28/20 revealed no documentation of vaginal wet preparation split sample testing by TP A in calendar year 2018. The inspector requested to review records of PT accuracy documentation for calendar year 2018 for TP A. No documentation was available for review. The LD stated "We</p>

overlooked getting the PT for wet preps in 2018". 4. In an exit interview with the lab director and technical consultant, at approximately 4:30 PM on 01/28/20, the above findings were confirmed.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of instrument maintenance logs, manufacturer's operations manual and bulletin, lack of documentation, and an interview, the laboratory failed to document performance of required annual Roche Cobas e411 chemistry analyzer maintenance in calendar years 2018 and 2019. Findings include: 1. Review of the laboratory's Roche Cobas e411 chemistry maintenance logs from January 2018 through the date of the survey (1/28/20) revealed the procedure "Replace 13 mm sample disk tube adapters" listed as "perform annually". The inspector noted no documentation of the maintenance was recorded during the twenty-four (24) months reviewed. 2. Review of the Cobas e411 operations manual revealed manufacturer's maintenance instructions on page 167 that read "incorrect results and errors due to misaligned sample tubes is possible". An attached Roche bulletin and maintenance log stated "perform replacement of the 13 mm sample disk tube adapters annually." The inspector requested to review additional documentation in 2018 and 2019 of performance of the maintenance procedure outlined above. No records were available. The lab director (LD) and technical consultant (TC) stated, at approximately 3:30 PM on 1/28/20, "We have had trouble ordering the parts from Roche to perform the maintenance. We have discussed with our field service representative". 3. In an exit interview with the LD and TC at approximately 4:30 PM on 1/28/20, the above findings were confirmed