

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0229791	(X3) Date Survey Completed 09/18/2019
Name of Provider or Supplier Urology Of Virginia, Pllc- Clinical Lab	Street Address, City, State 225 Clearfield Avenue, Virginia Beach, 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 of Virginia, PLLC (Clinical Lab) on September 19, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of policies, equipment calibration/maintenance records, and interviews, the laboratory failed to document annual calibration verification for nine (9) of 9 thermometers according to the laboratory's procedure in calendar year 2018. Findings include: 1. During a tour of the laboratory at approximately 11:30 AM, the inspector noted the following thermometers in use for monitoring the storage temperature of patient samples, reagents/supplies, culture incubation, environmental requirements for instrumentation (one Phoenix M50 microbiology analyzer and two Roche Cobas e411 chemistry analyzers): ERTCo SN DB080R (incubator) ERTCo SN 6313 (room temperature) Cardinal Health SN 33316 (Freezer A) Cardinal Health SN 1228 (Freezer B) Cardinal Health SN 14991 (Freezer C) Cardinal Health SN 32317 (Freezer D) Streck SN 8433 (Refrigerator A) Streck SN D10770 (Refrigerator B) Streck SN D11344 (Refrigerator C) 2. A review of the facility's Laboratory Quality Assurance Equipment Maintenance Manual revealed a procedure (title: Thermometer</p>

Calibration) that stated, "To ensure thermometers used in procedures, incubators, refrigerators, and freezers, are accurate when compared to a certified thermometer such as a National Institute Standards and Technology (NIST) reference unit; thermometer calibrations are to be verified once per year." 3. Review of the laboratory's equipment calibration/maintenance record book revealed two (2) Thermometer Calibration Verification Record forms, for the identified thermometer serial numbers (SN) outlined above. The verifications were performed on 5/25/17 and 9/11/19 and were approved by the lab director's (LD) signature of review. The inspector requested to review thermometer verification documentation for calendar year 2018. No records were available for review. The technical supervisor (TS) confirmed that the laboratory policy was to verify the calibration of all thermometers once per year. The TS stated, at approximately 1:15 PM, "We had a tech who routinely did the thermometer verifications for us. She left in 2017 and we overlooked getting it done in her absence". 4. In an interview with the LD, Director of Laboratory Services and TS at approximately 2:30 PM, the above findings were confirmed