

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2018622	<b>(X3) Date Survey Completed</b>  01/24/2019
<b>Name of Provider or Supplier</b>  Potomac Urology Center, Pc	<b>Street Address, City, State</b>  3700 Joseph Siewick Dr Ste 300, Fairfax, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Potomac Urology Center on January 24, 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 deficiencies cited are as follows:
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Qualigen FastPack analyzers' performance verification records, patient test logs and an interview, the laboratory failed to verify reference (normal) ranges for Prostatic Specific Antigens (PSA) performed on the Qualigen FastPack analyzer prior to reporting patient results from February 1, 2018 until January 24, 2019. Findings include: 1. Review of the laboratory's Qualigen FastPack analyzers' (serial numbers 0984 and 0294 installed February 1, 2018) performance verification documentation revealed the documentation did not include verification of the reference (normal) ranges for PSAs. The surveyor requested to review documentation of the verification and evaluation of the reference (normal) ranges for PSAs on the Qualigen FastPack analyzers' prior to patient testing. The laboratory provided no documentation for review. 2. An interview with the Office</p>

Manager and Testing Personnel A, at approximately 10:30 AM, confirmed that the laboratory failed to document the verification of PSA reference (normal) ranges prior to patient testing.