Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2004817	07/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Potomac Urology Center, Pc	2296 Opitz Boulevard - Suite 350, Woodbridge, 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 remote CLIA recertification survey was conducted for Potomac Urology Center, SC on July 15, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on June 15, 2021 and virtual record review conducted on July 12, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the laboratory's daily temperature/environment logs, manufacturer's user guides, lack of documentation, and interview, the laboratory failed to monitor the daily relative humidity percent (RH%) to ensure manufacturer's operating and storage requirements were followed for two (2) Qualigen FastPack analyzers utilized for Prostatic Specific Antigen (PSA) testing for one (1) of fourteen months reviewed (January 2019 to February 2020). Findings include: 1. Review of the laboratory's "Daily Environmental Log" revealed a statement, "Take the refrigerator, room temperature readings along with the relative humidity readings daily." 2. Review of the laboratory's "Daily Environmental Log" from January 2019 until February 2020 revealed a lack of documentation of the RH% for June 2019 (20 days). On July 15, 2021 at approximately 10:35 AM, the inspector requested documentation

	of the June 2019 RH%. The laboratory provided no documentation of the RH% for June 2019 for review. 3. Review of the Qualigen FastPack IP analyzer's product specifications revealed the following "Operating Humidity 10% to 80% relative humidity." 4. In an exit interview with the office manager and testing personnel on July 15, 2021 at approximately 10:45 AM, the findings were confirmed.