

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1105426	(X3) Date Survey Completed 10/23/2018
Name of Provider or Supplier Carolina Urology Healthcare, Pllc	Street Address, City, State 1021 Beaman Street, Clinton, NC	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review 2017 Daily Environmental Log records, manufacturer's instructions, and staff interview on 10/23/18, the laboratory failed to establish and document acceptable criteria for conditions required for accurate and reliable test systems operations. Findings: Review of Carolina Urology Healthcare, PLLC's Qualigen Package Insert REF:25000040 for Prostate Specific Antigen (PSA), and REF:25000041 for Testosterone, it reads "...the refrigerator temperature for proper storage of the reagent kits must be maintained between 2 Degrees to 8 Degrees Celsius...". During review of recorded 2017 Daily Environmental Log for January, February and March the refrigerator temperature readings were above the manufactures acceptable range for kit storage. Findings: January 2017 11 of 21 the temperatures were above 8 Degrees C: 1/3, 1/10-1/12, 1/23-1/27, and 1/30-1/31/17. February 2017 17 to 20 of the temperatures were above 8 Degrees C: 2/1-2/3, 2/6-2/10, 2/13-2/17, and 2/20-2/23/17. March 2017 2 of 23 of the temperatures were above 8 Degrees C: 3/1, and 3/3/17. During interview at 11:30 a.m. of the practice manager interview and testing personnel, it was revealed that the testing personnel failed to acknowledge that the refrigerator temperatures were above the manufacturer's package insert instructions.</p>