Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1010236	07/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
North Georgia Urology Center	1434 Broadrick Drive, Dalton, GA	

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	A recertification survey was performed on July 26, 2023. An entrance conference was held with the laboratory representatives. The survey process was discussed, along with review of the survey forms that was sent to the facility, previous to the survey. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficencies, but none were provided. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of refrigerator and freezer temperature records of 2022-2023 (to date) and testing personnel (TP) interview, the laboratory failed to document corrective actions when temperatures (temp) exceeded acceptable limits. Findings : 1. Review of 2022 freezer records revealed temps were out of range 231 days of 231 days without corrective actions documented. Review of 2023 freezer records revealed temps were out of range 145 days of 145 days (to date) without corrective actions documented. Noted referance range: 0 to -12 degrees Celsius. 2. Review of 2022 freezer records revealed temps were not recorded 22 days of 231 days without corrective actions documented. Review of 2023 freezer records revealed temps were not recorded 2 days of 145 days (to date) without corrective actions documented. 3. Review of 2022 refrigerator records revealed temps were out of range 111 days of 231 days without corrective actions documented. Review of 2023 refrigerator records

	revealed temps were out of range 119 days of 145 days (to date) without corrective actions documented. Noted reference range: 2 to 5 degrees Celsius. 4. Review of 2022 refrigerator records revealed temps were not recorded 26 days of 251 days without corrective actions documented. Review of 2023 refrigerator records revealed temps were not recorded 2 days of 145 days (to date) without corrective actions documented. 5. Interview with testing personnel #5 (CMS 209 form) on 7/26/23 at 12:18 PM in a providers office, confirmed the corrective actions were not documented.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of refrigerator and freezer temperature records of 2022-2023 (to date) and testing personnel (TP) interview, the laboratory director failed to ensure corrective actions were documented when temperatures (temp) exceeded acceptable limits. Findings : Refer to: D5785