Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1010236	01/13/2022
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 13, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on American Proficiency Institute(API) Proficiency Testing (PT) record review and staff interview, the laboratory failed to document corrective action for the specialties Hematology and Chemistry. Findings include: 1. Review of the American Proficiency Institute (API) PT records revealed a score of 50% for the Urine sediment Microscopy for Event #1 in 2020 and Event #2 of 2021 for Hematology. 2. Review of the API PT records revealed a score of 50% for the Chemistry PSA analyte for Event #3 of 2021 for Chemistry. 3. During an interview with the Testing Personnel#6(CMS 209) on January 13, 2022 at approximately 4:20 PM, in the breakroom, confirmed the corrective actions were not documented for the PT results.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to

	identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) records and staff interview, the Laboratory Director (LD) failed to document corrective action with the Hematology and Chemistry results. Findings include: 1. Review of API(American Proficiency Institute) PT records revealed that the LD failed to document corrective action for the Urine Sediment Microscopy for Event #1 in 2020 and Event #2 in 2021 for Hematology. 2. Review of API PT records revealed that the LD failed to document corrective action for the Chemistry analyte, PSA for Event #3 in 2021. 3. During an interview with the Testing Personnel#6 (CMS 209) on January 13, 2022 at approximately 4:20 PM, in the break room, confirmed the corrective actions were not documented.