Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1010236	(X3) Date Survey Completed 10/28/2025
Name of Provider or Supplier North Georgia Urology Center	**Street Address, City, State** 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 October 28, 2025. 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:
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: A review of 2023 - 2025 API Proficiency Records confirmed that the laboratory had unsuccessful performance in the Proficiency Program. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 API Proficiency Records confirmed that the laboratory failed 2 of 3 consecutive testing events as follows: a. HEMATOLOGY - COAGULATION 2024 EVENT 3 received a score of 50% on the Urine Sediment Testing. b. in HEMATOLOGY - COAGULATION 2025 EVENT 2 received a score of 50% on the Urine Sediment Testing. 2. An exit interview, with the Laboratory Manager, on October 28, 2025, at 2:00pm, confirmed that the laboratory had unsuccessful proficiency performance in the speciality of hematology.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-

	step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A review of the procedure manual confirmed that the laboratory failed to provide procedures for all processes, tests, assays, and examinations performed by the laboratory THE FINDINGS INCLUDE: 1. A review of the current procedure manual confirmed the lack of the following procedures: Down Time, Specimen Handling. 2. A review of the procedure manual revealed a singular "procedure" containing all procedures collectively. There were no individual testing procedures, processes, or parameters available on the date of survey, 10/28/2025. 3. A review of the procedure manual revealed the lack of all required procedure manual components: a. patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; criteria for specimen acceptability and rejection. b. Microscopic examination, including the detection of inadequately prepared slides. c. STEP-BY-STEP performance of the procedure, including test calculations and interpretation of results. d. Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. e. The reportable range for all test results. f. Control procedures. g. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. h. Limitations in the test methodology, including interfering substances. i. Reference intervals (normal values). j. Imminently life-threatening test results, or panic or alert values. k. Pertinent literature references. l. The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values. 4. An exit interview, with the Laboratory Manager, on October 28, 2025, at 2:00pm, confirmed that the laboratory failed to provide procedures for all processes, tests, assays, and examination performed by the laboratory.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: A review of current Procedure Manual confirmed that the Laboratory Director failed to approve, sign and date the procedures before use. THE FINDINGS INCLUDE: 1. A review of the procedure manual revealed the procedure lacked evidence that the Laboratory Director had reviewed, approved, and signed the procedure prior to use. 2.

	A review of the procedure manual confirmed an addendum to the Quality Assurance Procedure that assigned quality assurance oversight to the physicians and employees of the facility. Quality Assurance oversight is a responsibility of the Laboratory Director and can only be delegated to the Technical Supervisor or the General Supervisor. 3. An exit interview, with the Laboratory Manager, on October 28, 2025, at 2:00pm, confirmed that the Laboratory Director failed to approve, sign and date the procedures before use.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: A review of the 2023 - 2025 Quality Control (QC) Records revealed that the laboratory's Quality Control System failed to meet the minimum requirements. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 QC Records for the Urine Microscopic procedures revealed that only a single low-level control was included in the sample runs, a high-level control was not performed. 2. Review of QC Records revealed that controls for the Semen Analysis process were not performed with the testing run. 3. An exit interview, with the Laboratory Manager, on October 28, 2025, at 2:00pm, confirmed that the laboratory's Quality Control System failed to meet the minimum requirements.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: A review of 2023 - 2025 Quality Control Records, 2023 - 2025 Personnel Records, 2023- 2025 Maintenance Records, 2023 - 2025 Temperature Records, and 2023 -

	2025 Proficiency Records confirmed that the Laboratory Director failed to provide oversight of the overall operations and administration of the laboratory. Refer to : D2130, D5403, D5407, D5441, D6087
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: A review of 2023- 2025 personnel records confirmed that the Laboratory Director failed to perform personnel competencies and assure that qualified testing personnel performed clinical laboratory testing. THE FINDINGS INCLUDE: 1. A review of 2023- 2025 personnel records confirmed that a portion of the competencies on Testing Personnel (TP1 - TP4) (see CMS Form 209) were performed by unqualified personnel. 2. A review of 2023- 2025 personnel Records confirmed that competencies for the General Supervisors 1 &2 and Technical Supervisor were not completed. . 3. An exit interview, with the Laboratory Manager, on October 28, 2025, at 2:00pm, confirmed that the Laboratory Director failed to perform personnel competencies on all personnel.