Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0259153	05/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Atlanta Center For Medicine	2801 North Decatur Rd Ste 300, Decatur, 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 May 27, 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:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: A review of the Personnel Assessment Procedure confirmed that the Technical Consultant (TC) failed to follow the laboratory competency procedure. THE FINDINGS INCLUDE: 1. A review of the Personnel Assessment Procedure, adopted by the facility, revealed that personnel competencies were to be performed at six months and annually intervals from the date of hire. 2. A review of personnel records revealed personnel competencies were not completed for years 2023 - 2025 by the TC for all personnel, as required by the laboratory procedure manual. 3. An exit interview with the TC and Testing Personnel #2 (See CMS-209 Personnel form) on May 27, 2025, at 3:30pm, in the Laboratory Conference area, confirmed that the TC failed to follow the competency procedure for the facility
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory

	location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A review of the in-house test result report, of a random patient, confirmed that the patient test report failed to provide the name, address, contact information, or Laboratory Director for the testing location. THE FINDINGS INCLUDE: 1. A review of a random, in-house test report, revealed that the report did not identify the facility in which testing was performed. 2. An exit interview, with the Technical Consultant and Testing Personnel #2 (see CMS-209 personnel form), on May 27, 2025, at 3: 30pm, in the Laboratory Conference area, confirmed that the patient test report failed to provide the name, address, contact information or Laboratory Director for the itesting location.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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 Laboratory Records, confirmed that the Laboratory Director (LD) failed to provide overall oversight of the laboratory operations to assure quality laboratory services. THE FINDINGS INCLUDE: 1. An interview with Testing Personnel 1 (see CMS-209 Personnel Form) confirmed that the LD also assumed the positions of Laboratory Director (LD), Clinical Consultant (CC), and Technical Consultant (TC). 2. A review of the 2023 - 2025 Quality Assurance Records confirmed that QA review was conducted by Testing Personnel 1, as listed on the Form 209. A letter of delegation of duties was not available, at the time of inspection, from the Laboratory Director. 3. An exit interview conducted with the Technical Consultant and Testing Personnel #2 (see CMS-209 personnel form), on May 27, 2025, at 3:30pm, in the Laboratory Conference area, confirmed the LD failed to provide overall oversight of the laboratory operations to assure quality laboratory services.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is

	authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: A review of the current Laboratory Procedure Manual (SOP) confirmed that the Personnel SOP failed to provide, in writing, the qualifications, responsibilities, and duties for each consultant and testing personnel for all phases of laboratory testing. THE FINDINGS INCLUDE: 1. A review of the Personnel Procedure Manual revealed that the procedure contained qualifications and responsibilities for the Medical Technologist position. The Laboratory Director, Clinical Consultant, and Technical Consultant positions were not included in the procedure. 2. An exit interview, conducted with the Technical Consultant and Testing Personnel#2 (See CMS-209 form), on May 27, 2025, at 3:30pm in the Laboratory Conference area, confirmed that the Laboratory Director failed to ensure that the Personnel SOP included qualifications, responsibilities, and duties for each consultant and testing personnel for all phases of laboratory testing. .
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) (b)(8)(ii) Monitoring the recording and reporting of test results; This STANDARD is not met as evidenced by: A review of the 2023 - 2025 Quality Assurance (QA) Records, confirmed that the Technical Consultant (TC) failed to monitor the electronic test results delivery for accuracy. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 QA Records confirmed that the electronic results delivery from the chemistry and hematology analyzers were audited to assure accurate results from the analyzer to the patients' charts. 2. An exit interview conducted with the TC and Testing Personnel #2 (See CMS-209 personnel form) on May 27, 2025, at 3:30pm, in the Laboratory Conference area confirmed that the TC failed to monitor the electronic transfer of test results from the chemistry and hematology analyzers for accuracy.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: A review of 2023 - 2025 American Proficiency Institute Proficiency Testing (API-PT) records, confirmed that investigation and corrective actions for proficiency test scores less than 100% were not performed. THE FINDINGS INCLUDE: 1. A review of the API-PT records confirmed that for 2023 Chemistry Event 2, a score of 80% was received for the IRON analyte. No corrective actions were documented for this 80% score as required. 2. A review of the API-PT records confirmed that for 2024 Chemistry Event 2, a score of 80% was received for the IRON analyte. No corrective actions were found for this 80% score as required. 3. A review of the API-PT records confirmed that for 2024 Endocrinology Event 2, a score of 80% was received for the

	TSH analyte. No corrective actions were available for the 80% score as required. 4. An exit interview conducted with the Technincal Consultant and Testing Personnel#2 (See CMS-209 personnel form) on May 27, 2025, at 3:30pm, in the Laboratory Conference area, confirmed that the Laboratory Director failed to ensure that investigations or corrective actions for proficiency test scores, of less than 100%, were performed.