Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0875247	01/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Atlanta Womens Medical Center	235 West Wieuca Road, Ne, Atlanta, 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 5, 2023. 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: Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish the 6-step criteria for the competency assessment as required for CLIA regulations. The Findings includes: 1. SOP review revealed the competency policy and procedure did not follow the 6-step criteria for competency assessment during the time of survey. 2. Lack of TP competency documents revealed there was no annual competency for Testing Personnel #2 for 2021. 3. During an interview with Testing Personnel#2(CMS-209) and Office Manager on January 5, 2023 at 1:15PM in an office near the laboratory, confirmed that the competency did not follow the 6-step criteria for competency for testing the staff.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The

	laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA document review revealed the lack of a QA checklist documentation from 2021 to the date of the survey, January 5, 2023. 2. During an interview with the Testing Personnel#2(CMS 209) on January 5, 2023 at 12:25 PM in an office, near the laboratory, confirmed the lack of a QA checklist documentation from 2021, 2022, and thus far 2023.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the general laboratory standard operating procedure manual (SOP) and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. A review of the SOP confirmed that a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, or how to obtain additional assistance) was not available for staff to follow when sending specimens to reference laboratory (Quest Diagnostics). 2. During an interview on January 5, 2022 at 1:10 PM with Testing Personnel#2(CMS-209) in an office near the laboratory, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to reference laboratories.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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: Based on the review of the laboratory records, procedure manual(SOP) review, and staff interview, the Laboratory Director(LD) failed to review, approve, sign, and date the current procedures. The Findings include: 1. The laboratory procedure document revealed that the Laboratory Director(LD) failed to review the procedures, approve the current procedures, and date the procedures. The laste date the procedure manual was signed was in 2018. 2. During an interview with Testing Personnel#2(CMS-209) on January 6, 2023 at 1:10PM in an office near the laboratory, confirmed that the Laboratory Director(LD) did not reivew, approve, and sign the date the current procedures.

D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory records, procedure manual (SOP), and staff interview, the laboratory director failed to ensure that the external quality control (QC) and quality assessment(QA) programs are established and maintained to identify failures in the laboratory. Findings include: 1. Review of the SOP revealed the lack of a written Quality Assessment Checklist(QA) for the overall laboratory from 2021 to the date of the survey, January 6, 2023. 2. Review of the laboratory's records revealed no documentation of pre-analytic, analytic, or post-analytic monitors for the overall laboratory. 3. During an interview with Testing Personnel#2(CMS-209) on January 6, 2023 at 1:15PM , in an office, near the laboratory, confirmed that the laboratory did not have records for QA for 2021 and to the date of the survey January 6, 2023.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of personnel competency assessment records and staff interview, the Laboratory Director(LD) failed to include the six required competency assessment criteria when evaluating competency for the Testing Personnel(TP). The findings include: 1. Review of testing personnel competency assessment records for 2021 and 2022 on 2 of 2 employees revealed the assessment did not include the six competency assessment criteria required by CLIA. 2. During an interview with Testing Personnel#2(CMS-209) and Office Manager on January 5, 2023 at 1:15PM in an office near the laboratory, confirmed that the Laboratory Director was not include the 6-step competency assessment criteria required by CLIA.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on laboratory record review and staff interview, the Laboratory Director failed to ensure that an approved procedure for competency followed the 6-step critera. The Findings include: 1. Laboratory document review revealed that the Laboratory Director(LD) failed to approve a 6-step critera for competency. 2. During an interview with Testing Personnel#2(CMS-209) and the Office Manager on January 5, 2023 in an office near the laboratory, confirmed that the Laboratory Director failed to approve a 6-step critera for competency.