Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0875247	01/20/2021
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 20, 2021. 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: 1. American Association of Bioanalysts (AAB) PT document review revealed the LD/TC did not sign the 2020 Nonchemicstry (Immunohematology) attestation statement for the 2020 Q2 event. 2. An interview in a medical office with Staff #1 (CMS 209) at approximately 3:15 p.m. confirmed the lack of LD/TC signature on the aforementioned PT document.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on maintenance document review and staff interview, the laboratory failed to monitor and document equipment temperature as required. Findings include: 1. Maintenance document review revealed no Barnstead Thermolyne Rh View Box temperature logs were available at the time of survey for: 2018 -- September through December; 2019, 2020, and 2021 thus far. 2. An interview with Staff #1 (CMS 209) in a medical office on 1/20/2021 at approximately 3:45 p.m. confirmed the lack of the aforementioned temperature logs at the time of survey.
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: Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to delegate responsibilities to qualified TP as required. Findings include: 1. TP competency document review revealed the 2021 annual competency for Staff #2 (CMS 209) was performed by unqualified TP due to failure to meet TC educational requirements. 2. An interview with Staff #1 (CMS 209) on 1/20/2021 in a medical office at approximately 2:00 p.m. confirmed the aforementioned annual TP competency was performed by unqualified TP.
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 test (PT) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to ensure all PT reports received were reviewed by appropriate staff as required. Findings include: 1. American Association of Bioanalysts (AAB) document review revealed the LD/TC did not review

	Nonchemistry (Immunohematology) PT reports for the following events: 2019 -- Q2 and Q3; 2020 -- Q1, Q2, and Q3. 2. An interview with Staff #1 in a medical office on 1/20/2021 at approximately 3:00 p.m. confirmed the lack of LD/TC review of the aforementioned PT events.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to evaluate and document the performance of TP responsible for moderate complexity testing at least semiannually during the first year the TP tested patient specimens. Findings include: 1. TP competency document review revealed a six-month competency was not performed for Staff #2 (CMS 209) in 2018. 2. An interview with Staff #1 (CMS 209) in a medical office on 1/20/2021 at approximately 2:30 p.m. confirmed the lack of a six-month competency evaluation and performance for the aformentioned TP.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to evaluate and document the performance of TP responsible for moderate complexity testing at least annually after the first year as required. Findings include: 1. TP competency document review revealed annual competency documentation was not available at the time of survey for staff #1 (CMS 209) for 2018. 2. TP competency document review revealed annual competency documentation was not available at the time of survey for Staff #1 (CMS 209) and Staff #2 (CMS 209) for 2019 and 2020. 3. An interview with Staff #1 (CMS 209) in a medical office on 1/20/2021 at approximately 2:30 p.m. confirmed the lack of annual competency evaluation and performance for the aformentioned TP for 2018, 2019, and 2020.