Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0870858	06/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
All Women's Medical Office Based Surgery Pllc	120-34 Queens Boulevard, Suite 420, Kew Gardens, NY	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor's review of 2019, 2020 American Proficiency Institute (API) proficiency testing (PT) attestation statements and an interview with the practice manager, the laboratory failed to rotate the testing of PT samples among four personnel, who routinely perform ABO/RH testing. FINDINGS. The practice manager confirmed on June 8, 2021 at approximately 10:00 AM, the surveyor's findings that the attestation forms for 2019 and 2020 were not signed by the testing personnel, therefore the surveyor could not determine if the PT samples were rotated among the four testing personnel, who routinely perform ABO/RH testing.
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 surveyor's review of API Immunohematology PT records for 2019 and 2020

	and confirmed in an interview with the practice manager, the four testing personnel failed to sign the attestation forms attesting that the PT samples were tested in the same manner as patient specimens.
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 surveyor's review of the laboratory's temperature logs for 2020, laboratory temperature procedure for the Slide Viewbox and an interview with the practice manager, the laboratory failed to follow the laboratory's temperature procedure to monitor and document the Slide Viewbox from August 1, 2020 through January 1, 2021. FINDINGS: The practice manger confirmed on June 8, 2020 at approximately 11:00 AM, the laboratory failed to follow their established temperature procedure for the Slide Viewbox to monitor and document the temperature from August 1, 2020 through January 1, 2021. a. The Slide Viewbox temperature procedure requires temperatures to be recorded each day of testing. b. The established temperature range is 40-50C.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor's review of the Clay Adams Hematocrit (Hct) Maintenance log sheets, the laboratory's maintenance procedures for the Hct centrifuge and an interview with the practice manager, the laboratory failed to followed their established maintenance procedures for the Hct centrifuge and perform and document monthly checks using the Biorad Meter Trax Controls for the calendar year 2020. FINDINGS: The practice manager confirmed on June 8, 20221 at approximately 11;00 AM, the surveyor's findings that the laboratory failed to followed their established maintenance procedures for the Hct centrifuge and perform and document monthly checks using the Biorad Meter Trax Controls for the calendar year 2020. a. The last date for the HCT checks was 12/11/19 and resumed again on 1/26/21.