Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0870858	08/17/2023
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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of spun hematocrit quality control (QC) records, Bio-Rad Meter Trax control assay sheets, and an interview with the testing person, the laboratory failed to ensure the spun hematocrit hematology QC test results were not within acceptable range prior to testing patient specimens. FINDINGS: 1. Review of the spun hematocrit form titled, "Centrifuge Calibration Record" had established QC ranges without validating, the following: low level 20.2-23.6 ; mid-level 34.1/39.9 and high level 38.5-45.7. 2. Review of the Bio-Rad Meter Trax QC assay sheets for the spun hematocrit had different ranges for each lot tested. 3. The testing person confirmed August 17, 2023, at 10:00 AM that the assay sheets revealed the calculated ranges did not match the ranges recorded the lag sheet. The laboratory failed to calculate the ranges for each new lot of Bio-Rad Meter Trax hematocrit controls. The following QC ranges for the eight lots were not calculated from 710/2021 through current lot in use8 /17/2023 and no corrective action was performed. Lot # Low Lot # Mid Lot# High Expiration Date 92821 92822 92823 8/21/21 92831 92832 92833 11/6/21 92851 92852 92853 4/23/22 92861 92862 92863 7/23/22 92871 92872 92873 10/8/22 92891 92892 92893 3/25/23 94301 94302 94303 6/24/23 94311 94312 94313 9/22/23 4. Approximately 380 patient specimens were tested, and results reported for hematocrit testing during this time.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of hematocrit QC records, control assay sheets, lack of corrective action documentation, and an interview with the testing person, the laboratory failed to document corrective action measures when the Bio-Rad Meter Trax QC test results were not within acceptable ranges from 710/2021 through current lot in use 8/17/2023 and no corrective action was performed. FINDINGS: 1.The following hematocrit controls were out of range a. Low 92821 Exp. 8/21/21 (17.5-20.9) out 3 days greater than 23.0 Mid 92822 " (31.4-37.2) out 3 days greater than 39.0 b. Low 92851 Exp. 4 /23/22 (17.4-20.8) out 4 days greater than 22.0 c. Low 92861 Exp.7/23/22 (17.5-20.9) out 3 days greater than 22.0 Mid 92862 " (30.8-36.4) out 3 days greater than 37.0 d. Low 92891 Exp.3/25/23 (18.5-21.9) out 3 days greater than 22.0 e. Low 94301 Exp. 6 /24/23 (19.2-20.6) out 3 days greater than 21.0 d. Low 94311 Exp. 9/22/23 (16.9-20.3) out 2 days greater than 21.0 2. Approximately 380 patient specimens were tested, and results reported for hematocrit testing during this time.