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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D0877321 | (X3) Date Survey Completed 07/12/2021 |
| Name of Provider or Supplier All Women's Medical Office Based Surgery Pllc | Street Address, City, State 222 Mamaroneck Ave, White Plains, 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 |
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| D1001 | <p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the Clay Adams Hemocrit (Hct) Centrifuge maintenance procedure, Hct Quality Control (QC) procedure, Hct controls records and an interview with the laboratory testing person, the laboratory failed to follow their established Hct QC procedures for performing quality control testing on the Clay Adams Hct centrifuge from January 1, 2019 through July 10, 2021. FINDINGS: 1. The laboratory testing person confirmed on July 12, 2021 at approximately 1:30 PM that the laboratory failed to follow their established Hct QC procedures for performing quality control testing on the Clay Adams Hct centrifuge from January 1, 2019 through July 10, 2021. 2. The laboratory's Hct QC procedures requires three levels of controls (Low/Mid/High) of Biorad Meter Trax controls to be performed on a monthly basis, however the laboratory did not retain the Biorad Meter Trax control assay sheets for the following lots: a. #92743 expiration date 10/19/19; #92813 expiration date 5/22/21. b. The surveyor could not determine if the control results were within the acceptable ranges for these lot numbers, since the assay sheets were not retained. c. Failure to define the lot numbers used for testing dates from January 1, 219 through July 10, 2021. d. The worksheet used for recording the records did not define the control materials levels as Low, Mid, High, it define the minutes only 2 ,3, 4 minutes. d. Approximately 327 patients were tested and reported from January 1, 219 through July 10, 2021.</p> |