

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0870858	(X3) Date Survey Completed 04/05/2018
Name of Provider or Supplier All Women's Medical Office Based Surgery Pllc	Street Address, City, State 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory competency records and an interview with the laboratory Office Manager/testing person, the laboratory failed to follow their written policies and procedures to assess the competency of the laboratory testing personnel semi-annually for the first year of patient testing. Findings Include: It was confirmed by the laboratory office Manager/testing person on April 5, 2018, at approximately 11:00 am, that the director acting as the technical consultant failed to have documentation of semi-annual competency for two of two testing personnel who perform ABO/RHO Blood Typing.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute Proficiency Test(API PT) reports and an interview with the laboratory office manager/testing person, the laboratory did not evaluate, perform and document remedial action for the PT scores less than 100% for the 1st event in 2017 for ABO/RH Blood typing. Findings Include:</p>

It was confirmed with the laboratory office manager/testing person at approximately 11:15 am, that the laboratory failed to evaluate the results received for: 2017 first event ABO/RHO = 80%

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on a review of personnel records and an interview with the laboratory office manager/testing person, the laboratory director failed to ensure that appropriate training was documented for two of two new testing personnel who perform moderate complexity testing for ABO/RHO Blood Typing in year 2016.

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 a review of the personnel records and an interview with the office manager /laboratory testing person, the laboratory director, acting as the technical consultant, failed to perform the semi-annual evaluation for the two of two testing personnel during the first year of patient testing in calendar year 2016. Refer to D5209.