

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1018520	(X3) Date Survey Completed 03/31/2022
Name of Provider or Supplier Women For Women Obstetrics And Gynecology Llc	Street Address, City, State 1 Hollow Lane, Suite 315, Lake Success, 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
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: Base on review of the American Proficiency Institute (API) Proficiency Testing (PT) summary reports, the laboratory failed to review and evaluate the API hematology PT results for second events in 2021. FINDINGS: 1. The API PT summary report was not signed as reviewed and evaluated. 2. Confirmed on an interview with laboratory supervisor on 3/31/2022 approximately 11:00am.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory's API PT record second event of year 2021, the laboratory failed to document evaluation and verification activities including review of all unsatisfactory scores and the corrective action taken. Finding: 1. The API PT summary report did not have corrective action taken for mycology score of 60% and parasitology of 80%. 2. Confirmed on an interview with laboratory supervisor on 3/31/2022 approximately 11:00am.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p>

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 the review of API PT summary reports and an interview with the laboratory supervisor, the laboratory director failed to review the scored proficiency testing reports received from API to evaluate the laboratory's performance for second event in 2021. Refer to D5211.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on surveyor's review of the laboratory's API PT records and an interview with the laboratory supervisor, the laboratory director failed to ensure that corrective action was performed and documented for the laboratory's unsatisfactory PT performance for the second event of 2021. Refer to D5221.