

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2092312	<b>(X3) Date Survey Completed</b>  06/13/2019
<b>Name of Provider or Supplier</b>  De Fazio Ob/Gyn Laboratory	<b>Street Address, City, State</b>  1301 82nd Street, Brooklyn, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on the surveyor's review of the College of American Pathologists (CAP) Proficiency Testing (PT) records, and an interview with the laboratory's technical consultants and the testing person, the laboratory failed to enroll in a PT program that meets the criteria in Subpart I and is approved by HHS for the sub-specialties of bacteriology, mycology, parasitology, general immunology, chemistry and endocrinology, and for the specialty of hematology testing for the 2018 calendar year. FINDINGS: The laboratory's technical consultants and testing person confirmed on June 13 at approximately 4:30 PM, that the laboratory failed to enroll in the 2018 CAP PT program. Approximately 500 patient specimens were tested and results were reported for bacteriology, mycology, parasitology, general immunology, chemistry and endocrinology sub-specialty, and for the hematology specialty testing.</p>
<b>D2005</b>	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results</p>

available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of proficiency testing (PT) reports and an interview with the technical consultants and the testing person, the laboratory failed to authorize the release of the College of American Pathologists (CAP) PT results for 2019 to the New York State Department of Health's Physician Office Laboratory Evaluation Program (POLEP). FINDINGS: Although the laboratory is enrolled in PT for all specialties for the 2019 calendar year, there was no indication that the laboratory has authorized the PT provider, (CAP), to release results to New York State Department of Health's POLEP Program.