

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0135499	(X3) Date Survey Completed 05/01/2019
Name of Provider or Supplier Mary M Hanna Md	Street Address, City, State 1812 Richmond Avenue, Staten Island, 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
D2000	<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 a Proficiency Testing (PT) desk review of Center for Medicaid and Medicare Services (CMS) PT records, the laboratory failed to enroll in an approved PT program for the subspecialty Bacteriology/throat cultures for the calendar year 2019. THIS IS A RECITED DEFICIENCY FROM THE PT DESK REVIEWS CONDUCTED ON AUGUST 24, 2018 AND NOVEMBER 17, 2016.</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p>

This STANDARD is not met as evidenced by:

Based on a PT desk review of CMS PT records, the laboratory director failed to ensure that the laboratory is enrolled in an approved PT program for the subspecialty Bacteriology/throat cultures for the calendar year 2019. Refer to D2000.