

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0711809	(X3) Date Survey Completed 07/14/2021
Name of Provider or Supplier Janet Shen Md Pc	Street Address, City, State 453 Colon 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
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:</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of laboratory records and an interview with the laboratory director/testing person, the laboratory failed to follow their written Quality Assessment (QA) policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problems that may occur in the laboratory testing for the calendar years 2019 and 2020. Refer to D5211.</p>