

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2031758	(X3) Date Survey Completed 02/08/2018
Name of Provider or Supplier Patricia McCormack, Md	Street Address, City, State 515 North Wood Avenue, Linden, NJ	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Biannual Assessment (BA) records and interview with the Laboratory Consultant (LC), the laboratory failed to perform BA twice a year in the calendar years 2016 and 2017. The LC confirmed on 2/8/18 at 10:00 am that BA was not performed.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Laboratory Consultant (LC), the laboratory failed to assess and correct problems on the FR from 1/13/16 to the date of the survey. The finding includes: 1. A review of the FR with an Addendum stated "Deeper levels support the above diagnosis" but the diagnosis was below the Addendum. 2. The LC confirmed on 2/8/18 at 10:30 am the laboratory failed to correct problems on the FR.</p>