

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2090149	(X3) Date Survey Completed 02/27/2020
Name of Provider or Supplier Octapharma Plasma Inc	Street Address, City, State 4570 Memorial Drive Suite A, Decatur, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 27, 2020. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 proficiency test (PT) document review and staff interview, the laboratory failed to perform and document corrective action for all unsatisfactory scores as required. Findings include: 1. American Association of Bioanalysts PT report review revealed the laboratory did not perform corrective action for Total Protein results of 80% (eighty percent) for 2018 Chemistry Events Two and Three. 2. An interview with the quality assurance supervisor in the training coordinator's office on 2/27/2020 at approximately 1:30 p.m. confirmed the lack of corrective action for Total Protein scores of 80% for the aforementioned PT events.</p>