

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2173319	(X3) Date Survey Completed 10/27/2020
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 3472 Macon Road, Columbus, 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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on October 27, 2020. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of the PT samples into the patient workload using the laboratory's routine methods as required. Findings include: 1. Review of American Association of Bioanalysts (AAB) PT documents revealed the LD did not sign the attestation statement for 2020 Chemistry Event Q1(One). 2. An interview with the Quality Control Manager on 10/27/2020 at approximately 2:30 p. m. in the conference room confirmed the lack of LD signature on the aforementioned PT document.