Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2179413	01/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma, Inc	7708 Pershing Road, Kenosha, WI	

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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on surveyor review of Certification and Surveyor Provider Enhanced Reporting (CASPER) records and proficiency testing (PT) results, and interview with the quality assurance supervisor and assistant manager, the laboratory did not authorize the proficiency test program to release to Health and Human Services (HHS) the laboratory's proficiency test results. Findings include: 1. Review of the CASPER report 0155D (Individualized Laboratory Profile) for the laboratory on January 7, 2021 shows no proficiency testing data was available for review. 2. Review of the PT records showed the report for the laboratory did not include the Clinical Laboratory Improvement Amendments (CLIA) identification number for the laboratory. 3. Interview with the quality assurance supervisor and assistant manager, Staff A and Staff B, on January 7, 2021 at 1:35 PM, confirmed the laboratory did not provide the CLIA identification number to the PT provider to authorize the program to release the laboratory's results to HHS.