Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2187695	09/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma Inc	6806 Riverdale Road, Riverdale, MD	

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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory did not verify the stated values of commercially assayed control reagents (the normal and the abnormal quality control reagents) used each day of donor testing, for the blood plasma protein test performed using the refractometer. Findings: 1. The laboratory did not have quality control records to show that the manufacturer's assayed values for each new lot of quality control reagents or each shipment of quality control reagents received by the laboratory was verified prior to use for donor testing. 2. The written procedure did not include instructions for the donor center located in Riverdale, MD to verify the manufacturer's assayed values for each new lot of quality control reagent or each shipment of quality control reagents received by the laboratory prior to use for donor testing. 3. During interview with the donor center manager on September 18, 2025 at 11:30 am, it was confirmed that the laboratory did not have written procedures to verify the manufacturer's assayed values for each new lot or shipment of quality control reagents prior to use for donor testing.