Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1004873	02/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma Inc	418 Hill Ave, Aurora, IL	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to retain all proficiency testing (PT) records for at least two years. Findings include: 1. The laboratory's standard operating procedures (QPM-201) for proficiency testing and electronic records for PT events from October 11, 2019 (Event #3, 2019) through September 25, 2021 (Event #3, 2021) were reviewed. 2. The QPM-201 PT retention policy stated the following: "4.6.4. A KwikTag scanned document is a "True and Accurate Copy of the Original". "4.6.5. Original copies may be discarded after scanning into KwikTag and the scanned record is verified according to procedure requirements". 3. The scanned PT documents from event 3 of 2019 through event 3 of 2021 retrieved from the KwikTag electronic system revealed the following: *From event 3 of 2019, the entire PT event packet had been scanned, which included the laboratory's address, date the PT package was received in the laboratory, deadline date for the laboratory to report PT results, PT program instructions, PT program result recording forms, the PT program's attestation statement form, and the laboratory's scores from the PT program for the event. *From events 1, 2, 3 of 2020 and event 1,2, 3 of 2021, the packets included the PT program's attestation statement form, electronic reporting confirmation forms, and the laboratory's PT scores for each event. 4. The laboratory failed to retain all PT records for six out of six events during the years of 2020 through 2021. 5. On a Recertification survey conducted on February 24, 2022 at 4:15 PM, the laboratory Staff managers confirmed the above findings.