Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2132947	04/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma, Inc	2930 Sw 59th St, Oklahoma City, OK	

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	The recertification survey was performed on 04/25/2022. The findings were reviewed with center director, quality assurance back-up, and laboratory director during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the center director, the laboratory failed to ensure materials were not used beyond the open vial stability for one of one bottle of control material. Findings include: (1) On 04/25/2022 at 10:15 am the center director stated the following to the surveyor: (a) Plasma Total Protein was tested at five stations using the Reichert TS Meter DSP analyzers; (b) KOVA Refractrol SP high control material (green top) was used for monthly calibrations. (2) An observation at 10:20 am revealed the high control (lot# K304827), had been dated as open on 04/01 /2022 with an expiration date of 04/14/2022; (2) A review of the manufacturer's package insert for the control material stated, "KOVA Refractrol SP has an open vial stability of up to 14 days"; (4) The findings were reviewed with the center director, who stated on 04/25/2022 at 12:45 pm, that although the LIS (laboratory information system) would not allow the high control material to be used, it had not been discarded on or before the expiration date.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with center director and quality assurance back-up, the laboratory failed to evaluate the relationship between test results using seven different analyzers at least twice a year for one of three evaluations. Findings include: (1) On 04/25/2022 at 10:15 am, the center director stated to the surveyor: (a) Total protein testing was performed using seven different Reichert refractometers identified as R001, R002, R003, R004, R005, R006, R007. (2) A review of the written procedure manual titled, "Donor Center SOP" contained a policy titled, "Refractometer Semi-Annual Equipment Comparison". Under the section titled, "5. PROCEDURE" it stated: (a) "5.1 Review Requirements" (i) "5.1.1 At least twice per year, at six (6) month intervals, the refractometer semi-evaluation must be completed to perform a comparison of all active refractometers QC results when different refractometers are utilized to perform total protein test in the Donor Center.". (3) A review of the comparison records between 06/20/2020 through the day of the survey (04/25/2022) revealed a comparison had not been documented as performed after 03/11/2021; (4) The records were reviewed with the center director and quality assurance back-up. Both stated on 04/25/2022 at 11:52 am, a comparison of all the refractometers had not been documented as performed since 03/11/2021.