Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2116886	01/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma, Inc	6228 Hulen Bend Blvd, Fort Worth, TX	

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	Laboratory representatives were present at the entrance conference conducted 01/26 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 01/26 /2021. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, calibration verification records, quality control (QC) records and in interview with staff, the laboratory failed to ensure a different lot number from calibration material was used for QC for Total Protein (TP) on the TS Meter -DSP refractometer. Findings: 1. Review of the laboratory's procedure "Planned Deviation" stated, "5.8. Obtain essential items and review requirements for Calibration Verification. 5.8.1. Refractrol Abnormal, Normal and High Serum Protein Reference Control...Trained Donor Center staff will test all three (3) levels of Refractrol Serum Protein Reference Controls." 2. Review of "Calibration Verification Quality Control Data Sheet" records from 01/2020 and 07 /2020 revealed the following quality control material was used for calibration verification for refractometers R001, R002, R003, R004, R005, R006, R007, and

	R008 on the following dates: 01/15/2020 Kova Refractrol Lot #K302384 (expiration date 03/31/2020) - High Level Kova Refractrol Lot #K303960 (expiration date 04/30 /2022) - Normal Level Kova Refractrol Lot #K303250 (expiration date 07/31/2021) - Low Level 07/15/2020 Kova Refractrol Lot #K303119 (expiration date 07/31/2021) - High Level Kova Refractrol Lot #K303960 (expiration date 04/30/2022) - Normal Level Kova Refractrol Lot #K303250 (expiration date 07/31/2021) - Low Level 3. Review of a random sampling of days in 01/2020 and 07/2020 revealed K303960 and K303250 were used for day-to-day QC acceptability on 01/15/2020, 01/16/2020, and 07/15/2020. The same lot number of QC material was used for both daily quality control and for calibration verification. 4. During an interview on 01/26/2021 at 11:29 am, the Quality Assurance Supervisors confirmed the above findings.