Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2002134	**(X3) Date Survey Completed** 05/23/2018
Name of Provider or Supplier Octapharma Plasma, Inc	**Street Address, City, State** 4085 E Lancaster Avenue, 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	An entrance conference was held 05/23/2018 with the Field Quality Manager and the Quality Assurance Technician. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 05/23 /2018, this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1421 Testing Personnel (moderate complexity) An exit conference was held on 05/23/2018 with the Field Quality Manager and the Quality Assurance Technician. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory policy manual, manufacturer's instructions and confirmed in interview with staff, the laboratory failed to label the in use KOVA Refractol High Level control with the open date and new expiration date. Findings Included: 1. During the tour of the facility storage area on 05/23/2018 at 10: 25am, one vial of Refractrol High Level Control (Lot number K302384, expiration date 2020/03) was observed on the shelf with other supplies. The laboratory did not label the control vial with the open date and new expiration date. 2. Review of the laboratory policy manual for Refractometer Quality Control stated, "Obtain a new vial of high-level serum protein reference control. Enter vial open date, including your

	initials on the vial. Enter vial expiration date, including your initials on the vial. Calculate the expiration date by counting fourteen calendar days including the date of opening the vial used." 3. Review of manufacturer's instructions for KOVA Refractol Serum Protein Reference Control stated, "KOVA Refractol SP has an open vial stability of up to 14 days." 4. The findings were confirmed on 5/23/2018 at 03:15pm by the laboratory staff.
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 direct observation, 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 included: 1. During a tour of the facility on 05/23/2018 at 10:48 am, the following in-use control material was observed to be stored in the supply room: Kova Refractrol Lot #K302384 (expiration date 03/2020) - High Level Kova Refractrol Lot #K302383 (expiration date 07/2020) - Normal Level Kova Refractrol Lot #K301822 (expiration date 11/2019) - Low Level 2. Review of the laboratory's procedure "Planned Deviation" stated, "5.7. Obtain essential items and review requirements for Calibration Verification. 5.7.1. 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." 3. Review of "Calibration Verification Quality Control Data Sheet" records from 05/2018 revealed the following control material used for refractometers 56319 and 53739 on 05/22/2018: Kova Refractrol Lot #K302384 (expiration date 03/2020) - High Level Kova Refractrol Lot #K302383 (expiration date 07/2020) - Normal Level Kova Refractrol Lot #K301822 (expiration date 11/2019) - Low Level The material used for calibration verification was the same lot number used for QC. 4. Review of a random sampling of days in 05/2018 revealed K302383 and K301822 were used for day-to-day QC acceptability on 05/20/2018, 05 /21/2018, 05/22/2018, and 05/23/2018. 5. During an interview on 05/23/2018 at 3:30 pm, the Field Quality Manager and QA Specialist confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to ensure employed individuals met qualification requirements for moderate complexity testing. The laboratory failed to have documentation that 1 of 81 testing persons

	(TP#1) met the qualifications for performing moderate complexity testing. (Refer to D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 1 of 81 testing persons (TP#1) met the qualifications required to perform moderate complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person #1 listed to perform moderate complexity total protein testing on the Reichert Refractometer. 2. Review of testing person #1 records did not include an evaluation of education to determine foreign equivalency to United States education. No other education documents were provided for testing person #1. 3. During an interview on 05/23/2018 at 10:00am, with the Field Quality Manager, the above findings were confirmed.