Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2086283	09/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma, Inc	8780 Pershall Road, Hazelwood, MO	

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
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 review of 2017, 2018 instrument comparison documentation and interview with the laboratory staff, the laboratory failed to perform instrument comparisons for two of eight Reichert refractometers two times a year. Findings: 1. Review of the Reichert refractometer total protein semi-annual evaluation forms showed the laboratory failed to include two of the eight analyzers in the comparison studies two times a year for 2017 and 2018. Analyzers #47645 and #47647 were not included in the comparison studies for 2017 and to date 2018. 2. Interview with the laboratory staff on September 4, 2018 at 11:30 AM confirmed, the laboratory failed to perform instrument comparisons for two of eight analyzers two times a year for 2017 and to date 2018.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's inserts, quality control(QC) logs, and interview with laboratory staff, the laboratory director failed to ensure the quality control program was maintained to assure laboratory quality. Findings" 1. Review of the Kova Refractometer serum protein QC assay sheet for lot number K301432 for the high level revealed the value 10.3 +/- 0.4 for a range of 9.9-10.7. 2. Review of the QC logs and established ranges documented in the laboratory information system(LIS) showed the ranges were entered as 9.8-10.6. Review of the high QC values for September 1, 2018 revealed a value of 9.8. The LIS system assigned a value of "PASS". 3. Interview with the laboratory staff on September 4, 2018 at 11:30 AM confirmed the laboratory director failed to ensure the QC program was maintained to assure the quality of total protein testing.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel documentation and interview with the laboratory staff, the technical consultant failed to perform 1 of 14 competency evaluations for 2017. Findings: 1. Review of 2017 employee competencies revealed the technical consultant failed to perform 1 of 14 competencies for testing personnel of moderate complexity testing. 2. Interview with the laboratory staff on September 4, 2018 at 11:30AM confirmed the technical consultant failed to perform 1 of 14 annual competencies for 2017.