Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2133144	07/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma Inc	3150 Burke Road, Pasadena, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory verification records, laboratory records, and confirmed in interview, the laboratory failed to document a complete verification study for Total Protein testing on the Reichert Refractometer. (normal reference range study) Findings were: 1. Review of the laboratory verification records for the 4 Reichert refractometers in use (serial number 55897, 55898, 55899, 559900) revealed no documentation of the normal reference range study for 4 of 4 of the Reichert refractometers. 2. Review of the laboratory records revealed the laboratory utilized the reference interval (normal values) of 6.0-9.0 g/100 ml. 3. Review of the CMS116 revealed the laboratory annual volume for Total Protein testing as 35170 annually. 4.

	An interview with the QA supervisor on 7/09/19 at 1015 hours in the training room confirmed the above findings. She was able to provide the normal reference range established for the other facilities, but it did not include this facility.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records and confirmed in interview, the laboratory failed to have documentation of monitoring quality control values over time for the quality control for Total Protein on the Reichert Refractometer. Findings were: 1. Random review of the quality control from January 2018 to July 2019 revealed no documentation of the laboratory monitoring quality control values over time for the following quality control for Total protein for 4 of 4 Reichert Refractometers. Control Lot K301818, exp 7/31/19 Lot K301822, exp 11/30/19 Lot K302382, exp 10/31/20 Lot K302383, exp 7/31/20 Lot 301818, exp 7/19 2. Review of the CMS116 revealed the laboratory annual volume for Total Protein testing as 35170 annually. 3. An interview with the QA supervisor on 7/9/19 at 1101 hours in the training room confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory verification records, laboratory quality control records, and confirmed in interview, the laboratory quality assurance policies failed to monitor and correct problems in the analytic systems. Refer to D5421, D5441
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory verification records, laboratory records, and confirmed in interview, the laboratory director failed to ensure the laboratory documented a complete verification study for Total Protein testing on the Reichert Refractometer. Refer to D5421
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 the laboratory quality control records and confirmed in interview, the laboratory director failed to ensure a quality control program was established and maintained for Total Protein patient testing on the Reichert Refractometer. Refer to D5441