Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2154152	07/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma, Inc	1234 W Francisquito Ave, West Covina, CA	

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
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's validation records for an unmodified FDA-cleared or approved Reichert TS (TS) Refractometer implemented, and interview with the laboratory Quality Assurance supervisor (QAr) and the Center Director (CR), it was determined that the laboratory did not follow and adequately perform "Verification of performance specifications" for TS including Accuracy, Precision, Reportable range of the procedure, and the Reference interval of this TS system in 493.1253 (b)(1): Verification of performance specifications. The findings included: a. The laboratory is responsible for verifying the performance specifications of each non-waived unmodified FDA-cleared or approved test system that the laboratory introduced, prior to reporting patient test results. b. The verification of method performance should provide documents and support Accuracy, Precision, and Reportable range of the procedure and Reference interval of the TS and ensure validations were adequate to meet the clients' needs, as determined by the laboratory director, and claimed by the manufacturer. c. The laboratory introduced and implemented TS to perform blood Total Protein for its clients. d. At the time of survey (7/11/2019 @ 11:45 AM), the laboratory QAr provided a total of 10 pages validation records (VD), titled "Digital Refractometer Equipment Validation Test Case". e. The VD included three (3) levels of quality control (low, normal, and high) test data, indicating that the laboratory

	performed each level of control materials for five (5) times (total of 15 test results) on the same day of 8/29/2019. f. The laboratory concluded the verification of performance specifications for TS based on these 15 test result data. g. The laboratory did not adequately perform and address for Accuracy, Precision, Reportable range and Reference interval and to verify the manufacturer's performance specifications based on the 15 test result data performed within the same day. h. Further, the laboratory QAr probably misunderstood the requirements of the verification of performance specifications and provided documents of "Planned Deviation", which was for "Verifying Quality Control Ranges for Refractrol" performed between Sept 05, 2018 and Sept 10, 2018 to support the laboratory has performed adequately for verification of performance specifications for the TS instrument. i. The laboratory's TS validation was not acceptable and did not adequately address Accuracy, Precision, and Reportable range of the procedure and Reference interval, and failed to meet the requirements in CFR 493.1253 (b)(1).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's validation records for an unmodified FDA-cleared or approved Reichert TS (TS) Refractometer implemented, and interview with the laboratory Quality Assurance supervisor (QAr) and the Center Director (CR), it was determined that the laboratory director failed to be responsible for the overall operation and administration of the laboratory, including the employment of personnel who were competent to perform test procedures, and proficiently for assuring compliance with the applicable regulations. The findings included: a. It appeared to the Examiner and based on interview with the QAr and CR, and the documents provided on site when request at the time of survey (7/11/2019 @ 11:45 AM), the personnel involved in laboratory operations appeared lack knowledge of CLIA compliance (see D-5421).