Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 14D2120214	**(X3) Date Survey Completed** 09/19/2018
Name of Provider or Supplier Octapharma Plasma Inc	**Street Address, City, State** 16845 Torrence Ave, Lansing, IL	
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 direct observation, review of laboratory records, and interview with the quality assurance technician; the laboratory failed to demonstrate precision for total protein testing on Reichert digital refractometers prior to reporting patient test results. Findings Include: 1. Direct observation of laboratory testing equipment on 9-19-2018, at 9:45am, identified 5 Reichert digital refractometers in use total protein testing. Reichert Digital Refractometer Identification Numbers 53879 53905 53907 53908 53909 2. Review of digital refractometer equipment validation documentation for the above mentioned refractometers found no precision documentation for 5 of 5 digital refractometers. 3. Review of non-waived test volume worksheets indicate 29,689 patients were tested for total protein in 2017. 4. On survey date 9-19-2018, at 12:20 pm, the above findings were confirmed by the quality assurance technician.