

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D1072559	(X3) Date Survey Completed 07/26/2021
Name of Provider or Supplier Octapharma Plasma Inc	Street Address, City, State 907 North Hillside Street, Wichita, KS	
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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Digital Refractometer quality control (QC), and interview with the quality assurance supervisor the laboratory failed to evaluate the laboratory quality control ranges necessary to detect immediate errors and monitor over time the accuracy and precision of test performance. Findings: 1. Review of Digital Refractometer quality control (QC) revealed that the manufacturer ranges were put in place without on-site evaluation for test performance and therefore appropriate ranges were not established. 2. The quality assurance supervisor stated that the quality control materials were placed into use utilizing the manufacturer ranges without further evaluation prior to use for patient testing. 3. Interview with the quality assurance supervisor on 7/26/2021 at 1:40 pm confirmed, the laboratory failed to evaluate the laboratory quality control ranges necessary to detect immediate errors and monitor over time the accuracy and precision of test performance.</p>