

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2235531	(X3) Date Survey Completed 06/23/2022
Name of Provider or Supplier Octapharma Plasma, Inc.	Street Address, City, State 5301 Bosque Blvd., Suite 320, Waco, 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 deficiency and plans of correction were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification is recommended.
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 quality control records and interview, the laboratory failed to monitor over time the accuracy and precision of the KOVA Refractrol-SP daily quality control for Total Protein using the Reichert refractometer for six of six months reviewed. Findings follow. 1. Random review of the quality control records from Feb 2022 and May 2022 showed the daily results. Further review of quality control records showed statistical data, i.e., mean, standard deviation, and coefficient of variation were not calculated to determine the accuracy and precision of each refractometer for Total Protein. 2. Statistical data such as mean, standard deviation, and coefficient of variation was requested for the daily quality control on June 23, 2022 at 1315 hours but not provided. 3. Interview with the Sr. Quality Assurance</p>

Supervisor with the initials RM on June 23, 2022 at 1325 hours confirmed statistical data was not calculated for the daily quality control. 4. The center began reporting Total Protein on Dec 15, 2021.