Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2238590	05/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma, Inc	10945 Fm 1960 West, Houston, 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 a review of the laboratory's quality control records for the seven Reichert Refractometers from 2022, the laboratory's records, and staff interview, it was

	revealed that the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for total protein testing on the seven Reichert Refractometers from February to May 2022. Findings include: 1. A review of the laboratory's quality control records for the seven Reichert Refractometers (Analyzer numbers: R001, R002, R003, R004, R005, R006, R007) from 2022 revealed the laboratory ran three quality control materials each day of patient testing: distilled water, Kova Refractrol Low (lot K305444, exp 08/2024), and Kova Refractrol Normal (lot K304604, exp 03/2023). 2. Further review of the quality control records from February to May 2022 revealed the laboratory failed to have a method in place for monitoring and evaluating quality control results over time on the Reichert Refractometers. 3. A review of the laboratory's records revealed the laboratory started patient testing in February 2022 and estimates performing 1,999 total protein tests annually. 4. An interview with the center director on 5/17/22 at 9:45 a.m. in the conference room revealed the laboratory only assessed quality control values on the day they are run and did not monitor or evaluate values over time for shifts or trends. This confirmed the above findings.