Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2108295	04/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma Inc	9203 Stella Link Rd, 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 at the entrance and exit conferences. The facility representative was 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.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies and staff interview, it was revealed the laboratory failed to have documentation of verifying patient normal

	ranges for total protein. The findings were: 1. A review of the laboratory's verification studies performed in March 2016 revealed the laboratory performed studies on eight (8) Reichert refractometers. They were: serial number 09376 serial number 09418 serial number 09422 serial number 09428 serial number 09437 serial number 09460 serial number 09461 serial number 09462 2. Further review of the laboratory's verification studies revealed the laboratory failed to have documentation of verifying its patient normal range for total protein. 3. The laboratory's patient normal range for total protein was 6.0 - 9.0. 4. The laboratory was asked to provide documentation of verifying it patient normal range. No documentation was provided. 5. An interview with the center director on 04/16/2018 at 1000 hours in the training room revealed the laboratory did not verify the total protein normal range. This confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from 2017, and staff interview, it was revealed the laboratory failed to have documentation of verifying new lots of control material prior to use. The findings were: 1. A review of the laboratory's quality control records from 2017 revealed the laboratory utilized the following control materials: a) Low control: lot: K301008 in use: January 2017 to December 2017 b) Normal control: lot: K301003-08 in use January 2017 to August 2017 lot: K301003-11 in use August 2017 to December 2017 c) High control: lot: K301001 in use January 2017 to December 2017 2. The laboratory was asked to provide documentation of verifying the controls prior to placing the control into use. No documentation was provided. 3. An interview with the center director on 04/16 /2018 at 1030 hours in the training room revealed the laboratory did not verify the controls. This confirmed the findings.