Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2158499	04/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma, Inc	7379 W 25th St, North Riverside, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policies, procedures and interview; the procedures manual did not include the following: *Description of the course of action to take if the test system were to go down. 1. Review of the laboratories down time procedures did not include instructions for how it would perform and or report patients' total protein results if the lab's test system were to become inoperable. 2. At 11:30 AM on April 11, 2019, the Quality Assurance Supervisor confirmed the surveyor's findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of written procedures, laboratory records, survey forms and interview with the Quality Assurance Supervisor; the laboratory director failed to ensure that verification procedures used were adequate to determine the accuracy and precision of the method used to test for total protein. Findings include: 1. A written procedure titled, "Digital Refrafctometer Equipment Validation" was reviewed by the surveyor. 2. Section 3.1 of the validation procedure states that Donor Center Staff performs validation and documents the information on the validation form. 3. Section 3.2 of the validation procedures sates that Donor Center Management reviews and approves the validation and provides guidance for out of range controls. 4. Review of Laboratory Personnel Report (FORM CMS 209) revealed that there is a total of 13 persons listed as testing personnel on the form. 5. Review of validation records revealed that none of the 13 testing personnel listed on Laboratory Personnel Report (FORM CMS 209) were included in the performance of the validation process. 6. At 10:40 AM on April 11, 2019, the Quality Assurance Supervisor confirmed the surveyor's findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of survey forms, laboratory policies, procedures, personnel records and interview with the Quality Assurance Supervisor; the laboratory director failed to specify in writing the responsibilities and duties of each consultant. Findings include: 1. Review Laboratory Personnel Report (FORM CMS 209) revealed that the person listed as the laboratory director is also the person listed as both Clinical Consultant and Technical Consultant. 2. Review of laboratory policies and procedures revealed that there was a chart titled, "Donor Center Reporting Structure." The chart did not include personnel assigned to positions applicable to CLIA regulation which included the following: a. Laboratory Director b. Clinical Consultant c. Technical Consultant d.

	Moderate Complexity Testing Personnel 3. Review of personnel records revealed that the laboratory director was not assigned the positions of Clinical Consultant and/or Technical Consultant. 4. At 10:30 AM on April 11, 2019, the Quality Assurance Supervisor confirmed the surveyor's findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's Standard Operating Procedures (SOPs), survey forms, personnel records and interview with the Quality Assurance Supervisor; the technical consultant failed to be responsible for evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. Findings include: 1. In section 4.3.2 of the SOP it reads as follows: "The CLIA Laboratory Director/Designee reviews performance of staff conducting TP determination initially, at 6 month and annually. Employees must be observed on the refractometer. The CLIA technical consultant is also qualified to evaluate the competency of testing personnel. 2. Review Laboratory Personnel Report (FORM CMS 209) revealed that the person listed as the laboratory director is also listed as both Clinical Consultant and Technical Consultant. 3. There were a total of 13 persons listed as Moderate Complexity Testing Personnel on survey FORM CMS 209 (Laboratory Personnel Report). 4. Review of personnel records revealed that the laboratory director was not the person responsible for evaluating the competency of 13 of 13 testing personnel listed on FORM CMS 209. 5. AT 11:00 AM on April 11, 2019, the Quality Assurance Supervisor confirmed the surveyor's findings.