

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2166143	<b>(X3) Date Survey Completed</b>  06/02/2021
<b>Name of Provider or Supplier</b>  Octapharma Plasma, Inc	<b>Street Address, City, State</b>  9124 E Apache Trail Suite 1, Mesa, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5469</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(10)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records, lack of QC lot verification documentation and interview with the facility personnel, the laboratory failed to verify the criteria for acceptability of quality control materials used on the Reichart Refractometers. Findings include: 1. The laboratory began Total Protein testing using 7 separate Reichart Refractometers on September 11, 2019, with an approximate annual test volume of 17,191. 2. It is the practice of the laboratory to test two levels of QC material (Normal and Low) each day prior to patient testing. A third level of QC (High) is performed on a monthly basis. 3. During the survey conducted on June 2, 2021, facility personnel interviewed confirmed that the laboratory uses the stated values of the commercially assayed control material. 4. No documentation was presented for review during the survey to indicate the laboratory verified the stated values of the commercially assayed control material (Normal, Low and High) for each lot of controls used by the laboratory. 5. The number of different QC lots for each</p>

level of control material (L, N, H) used by the laboratory since patient testing began could not be determined at the time of the survey. 6. The facility personnel confirmed that the laboratory could not produce documentation during the survey to show how each lot of control material was verified by the laboratory.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on lack of policy for review and interview with the facility personnel, the laboratory failed to establish policies and procedures for verifying each new lot of control material used for Total Protein testing. Findings include: 1. The laboratory began Total Protein testing using 7 separate Reichart Refractometers on September 11, 2019, with an approximate annual test volume of 17,191. 2. No established policy or procedure was presented for review during the survey conducted on June 2, 2021 to indicate the laboratory's process for verifying each new lot of Quality Control material used for Total Protein testing. See D5469 for additional findings. 3. The facility personnel confirmed that the laboratory failed to have an established policy or procedure in place at the time of the survey regarding the process of verifying each new lot of control material used for Total Protein testing.