

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2118960	<b>(X3) Date Survey Completed</b>  04/14/2022
<b>Name of Provider or Supplier</b>  Octapharma Plasma Inc	<b>Street Address, City, State</b>  6394 Silver Star Rd, Orlando, FL	
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>D0000</b>	A recertification survey was conducted on April 14, 2022. Octapharma Plasma Inc clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to complete competency evaluation for 1 (F) of 13 (A - M) Testing Personnel for 2021. Findings: Review of the Laboratory Personnel Report, signed by the Laboratory Director on 04/11/2022 showed there were 13 Testing Personnel and the Laboratory Director. The Laboratory Director was also listed as the Clinical Consultant and the Technical Consultant. Review of Testing Personnel F's competency evaluation records revealed the competency evaluation for 2021 was missing. On 04/14/2022 at 11:59 AM, the Center's Director stated they were unable to find the competency evaluation for Testing Personnel F for 2021.</p>