

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  29D2188526	<b>(X3) Date Survey Completed</b>  08/24/2021
<b>Name of Provider or Supplier</b>  Octapharma Plasma, Inc	<b>Street Address, City, State</b>  2101 S Decatur Blvd Ste 25, Las Vegas, NV	
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>	<p>This Statement of Deficiencies was created as a result of an on-site initial CLIA certification survey conducted at your facility August 24, 2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory personnel training and competency assessment records, and an interview with the Quality Assurance Supervisor, and an interview with the Center Director, the laboratory director failed to ensure that initial training and competency assessment was completed at the laboratory for five of twenty testing personnel prior to the performance of donor testing. Findings include: 1. A review of the testing personnel training and competency assessment records revealed that five of twenty testing personnel did not have initial training and competency assessment at the donor center laboratory prior to testing donor samples for total protein. The training documents revealed that the personnel were transferred from a separate donor center laboratory within the company. The laboratory presented the initial training</p>

documents from the laboratory where the personnel were previously employed. Review of the initial training and competency assessment records revealed that the documents were completed between the dates of June 11, 2015, and November 22, 2019. 2. The laboratory began donor testing on August 26, 2020. 3. The findings were confirmed during an interview conducted with the Quality Assurance Supervisor, and the Center Director on August 24, 2021 at approximately 10:45 AM. The laboratory performs approximately 6399 chemistry tests annually.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory personnel training and competency assessment records, and an interview with the Quality Assurance Supervisor, and an interview with the Center Director, the technical consultant failed to ensure that semi-annual training and competency assessment during the first year of employment was completed at the laboratory for five of twenty testing personnel prior to the performance of donor testing. Findings include: 1. A review of the testing personnel training and competency assessment records revealed that five of twenty testing personnel did not have semi-annual training and competency assessment at the donor center laboratory during the first year of employment at the laboratory. The training documents revealed that the personnel had been transferred from a separate donor center laboratory within the company. The laboratory presented the semi-annual training documents from the laboratory where the personnel were previously employed. The semi-annual training and competency assessment records revealed that the documents were completed between the dates of August 11, 2016, and May 8, 2020. 2. The laboratory opened for business and began donor testing on August 26, 2020. 3. The findings were confirmed during an interview conducted with the Quality Assurance Supervisor, and the Center Director on August 24, 2021 at approximately 10:45 AM. The laboratory performs approximately 6399 chemistry tests annually.