

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  28D2006976	<b>(X3) Date Survey Completed</b>  04/19/2022
<b>Name of Provider or Supplier</b>  Octapharma Plasma, Inc	<b>Street Address, City, State</b>  4640 South 25th Street, Omaha, NE	
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>D6063</b>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation the laboratory failed to have proof of education on testing personnel #11, as listed on the CMS-209, performing moderate complexity testing. Refer to D6065.</p>
<b>D6065</b>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the center director, assistant</p>

manager, quality assurance supervisor, and leadership trainer the laboratory failed to have acceptable proof of education on one out of 26 testing personnel listed on the CMS-209. Findings are: 1. No acceptable proof of education documentation for testing personnel #11, as listed on the CMS-209, performing moderate complexity testing was presented at time of survey. 2. Interview on 4/19/202 at 11:39AM with the center director, assistant manager, quality manager assurance supervisor, and leadership trainer confirmed no acceptable documentation was available.