

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2179413	(X3) Date Survey Completed 06/09/2022
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 7708 Pershing Road, Kenosha, WI	
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
D6063	<p>LABORATORY TESTING PERSONNEL 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 surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209 "Laboratory Personnel Report (CLIA)" and personnel records and interview with the center director, the laboratory did not have documentation showing one of six new testing personnel reviewed met the academic qualification requirements for moderate complexity testing personnel at 493.1423. Findings include: 1. The laboratory did not have documentation before June 7, 2022 showing one of six reviewed new testing personnel had met the academic qualification requirements for moderate complexity testing. See D 6065.</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS 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</p>

high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209 "Laboratory Personnel Report (CLIA)" and personnel records and interview with the center director, the laboratory did not have documentation showing one of six reviewed new testing personnel met the qualification requirements for moderate complexity testing personnel at 493.1423 from March 26, 2022 through June 7, 2022. Findings include: 1. Review of academic credentials for six of the new testing personnel identified on the Form CMS-209 submitted for the survey showed the high school transcripts for one testing person (staff A) did not show the individual received a high school diploma and did not include a graduation date. 2. Review of training and competence evaluation records for staff A showed the technical consultant signed the competence evaluation for staff A on March 26, 2022. 3. The center director (staff B) emailed a copy of Staff A's diploma on June 9, 2022 at 2:00 PM . The diploma showed staff A was given the diploma on June 7, 2022. 4. Interview with the center director on June 7, 2022 at approximately 1:45 PM confirmed staff A had performed moderate complexity testing since March 26, 2022. Further interview confirmed the transcript did not show staff A had earned a high school diploma.