

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2101691	(X3) Date Survey Completed 04/19/2022
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 8602 W Brown Deer Rd, Milwaukee, 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
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of procedures and laboratory records and interview with the quality manager, the laboratory director has not approved the Planned Deviation document that delegated responsibilities to the technical consultant. Findings include: 1. Review of proficiency testing (PT) records from 2020 (event three) through 2022 (event one) showed the technical consultant signed the attestation statements and review of PT results for five of five events. The records showed no evidence of review or signature of the laboratory director. 2. Review of procedures showed the laboratory director is responsible for PT review. The procedure did not reference the 'Planned Deviation for Technical Consultant Responsibilities' or otherwise provide for delegation of these responsibilities to the technical consultant. 3. Review of the list of approved procedures signed by the laboratory director did not include the 'Planned Deviation for Technical Consultant Responsibilities'. The Planned Deviation document did not show the laboratory director had approved the document. 4. Interview with the quality manager (staff B) on April 19, 2022 at approximately 11:00</p>

AM confirmed the laboratory director did not sign the 'Planned Deviation for Technical Consultant Responsibilities' to document approval of the delegation of responsibilities to the technical consultant.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

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.

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 quality manager, 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. Findings include: 1. The laboratory did not have documentation showing one of six reviewed new testing personnel had graduated from high school. See D 6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(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

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 quality manager, 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. 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. Interview with the quality manager (staff B) on April 19, 2022 at approximately 10:00 AM confirmed the transcript did not show staff A had earned a high school diploma.