

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2163917	(X3) Date Survey Completed 03/03/2021
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 7535 State Ave, Kansas City, KS	
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: Required credentials are not available for 1 of 35 testing personnel (TP) who perform 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 high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: Review of 2019-2020 testing personnel (TP) records, and interview reveals that the laboratory failed to have the credentials required for 1 of 35 TP to perform moderate</p>

complexity laboratory test procedures (See CMS Form 209). Findings: 1. No documentation of qualification for TP #23 was available at the time of survey. 2. The Associate Regional Director (TP #4) provided evidence the TP #23 performed non-waived testing during their employment period of 2/24/2020 to 6/25/2020. 3. In interview on 3/3/21 at 1:20 p.m. TP#4 confirmed, the laboratory failed to have the credentials required for 1 of 35 TP to perform moderate complexity laboratory test procedures. (See CMS Form 209).