

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1004873	(X3) Date Survey Completed 04/01/2019
Name of Provider or Supplier Octapharma Plasma Inc	Street Address, City, State 418 Hill Ave, Aurora, IL	
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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 record review and interview with the Quality Assurance Supervisor, the laboratory director failed to ensure that prior to testing patient's specimens, all personnel have the appropriate education and experience. Findings include: 1. There were a total of 13 testing personnel listed on Laboratory Personnel Report (FORM CMS 209). 2. Review of personnel records revealed that 1 of 13 testing personnel lacked educational credentials that show she had at least a high school diploma. See D6065 3. At 10:30 AM on 04/01/2019, the Quality Assurance Supervisor confirmed the surveyor's findings.</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</p>

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 record review and interview with the Quality Assurance Supervisor, testing personnel failed to meet the minimum educational requirement for performing moderate complexity testing. Findings include: 1. There were a total of 13 testing personnel listed on Laboratory Personnel Report (FORM CMS 209). 2. On 04/01/2019 at 10:30 AM, review of personnel records revealed that 1 of 13 testing personnel's educational documents was not legible. The surveyor told the Quality Assurance Supervisor that she must submit a legible copy of the educational document by the close of business, Monday, April 8, 2019. 3. On 04/08/2019 at 8:00 AM, the surveyor received and reviewed a legible copy of 1 educational transcript emailed to her on 04/01/2019. Review of the transcript revealed that that this person lacked the minimum educational requirement of a high school diploma for performing moderate complexity testing. 4. On 04/08/2019 at 8:12 AM, the surveyor relayed this in a follow-up email to the Quality Assurance Supervisor.