

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1070212	(X3) Date Survey Completed 07/25/2019
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 813 W Michigan Avenue, Ypsilanti, MI	
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
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Quality Assurance Supervisor, the laboratory failed to ensure the final American Association of Bioanalysts (AAB) chemistry proficiency testing reports were reviewed by the appropriate testing personnel for 2 (July 2017 to July 2019) of 2 years. Findings include: 1. A record review of the AAB total protein proficiency testing reports revealed there was a lack of documentation to show appropriate testing personnel reviewed the proficiency testing final reports for 2017 (third quarter), 2018 (first, second and third quarters), and 2019 (first and second quarters). 2. An interview on 7/25/19 at 10:59 am with the Quality Assurance Supervisor confirmed proficiency testing reports were not reviewed by the appropriate testing personnel.</p>