

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2109675	(X3) Date Survey Completed 10/25/2019
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 1700 N Rolling Road, Baltimore, MD	
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
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the personnel evaluations and interview with the quality supervisor (QS), the laboratory director (LD) did not ensure that the technical consultants (TC's) were being evaluated. Findings: 1. The laboratory's training and evaluation records for 2018 were reviewed. The documentation that was reviewed showed that the current LD did not perform the evaluation of the TC's listed on the Laboratory Personnel Report (CLIA) (CMS-209) . 2. According to the QS the location identification number (ID#) for the laboratory being surveyed is ID#450. The evaluation documents for the two TC's listed on the CMS-209 had a different location ID#. The QS explained that the TC's for the laboratory also work as the TC in several other laboratories in the system. 3. The evaluations of the two TC's listed on the CMS-209 that was reviewed did not have the ID#450 and were not signed by the LD of the laboratory being surveyed. The evaluations were being performed by a person not listed on the CMS-209 for the laboratory being surveyed. 4. During the survey on 10 /25/19 at exit interview at 11:00 AM the QS confirmed that the laboratory records did not show that the evaluation of the TC's were performed by the LD of the laboratory being surveyed.</p>