

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1079459	<b>(X3) Date Survey Completed</b>  12/03/2020
<b>Name of Provider or Supplier</b>  Octapharma Plasma Inc	<b>Street Address, City, State</b>  605 Bessemer Super Highway, Midfield, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6054</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the Quality Assurance Supervisor, the surveyor determined the Technical Consultant (also serves as the Laboratory Director) failed to ensure Testing Personnel (TP) #4 and TP #9's competency was evaluated at least annually, following their first year of employment. This affected two of twelve testing personnel, who perform moderate complexity testing. The findings are: 1) A review of the personnel records for the testing personnel failed to include annual competency evaluations for TP #4 and TP #9 after the first year of the initial training. TP #4 had annual competency evaluations performed in 2016 and 2017, which were reviewed on the previous survey (3/21/2018). TP #9 was initially trained on 7/28/2018. 2) In an interview on 12/03/2020 at 1:00 PM, the Quality Assurance Supervisor (QAS) stated she had deviation reports for the missing competency evaluations for TP #4 and TP #9, who would sit for their evaluations on December 8. When the surveyor asked when the errors were noted and deviation reports started, the QAS stated December 2. The surveyor inquired of how often the training/competency needs were monitored. The QAS officer stated, since her transfer to this location, as well as the Training Coordinator, a daily report was printed and reviewed. This process began around November 2, 2020. The QAS explained the report shows what training is due, however the report did not indicate any missing training/competency needs for TP #4 or TP #9, because the former employee had signed off on the report, removing the testing personnel. Additionally,</p>

the Training Coordinator performs five weekly audits of training files. These audits also began in November, 2020, however, the missed competency evaluations were not realized until a day prior to the survey.