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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>34D2080660    | <b>(X3) Date Survey Completed</b><br><br>06/20/2023 |
| <b>Name of Provider or Supplier</b><br><br>Octapharma Plasma, Inc  | <b>Street Address, City, State</b><br><br>10644 Westlake Drive, Charlotte, NC |   |
| 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>   |
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| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the Director of Laboratory Operations 6/20/23, the laboratory failed to establish and follow written policies and procedures for technical supervisor competency for 6 of 6 technical supervisors. Findings: Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for evaluating the competency of technical supervisors, including how evaluations are conducted, the frequency, the criteria used for evaluation, the steps to take if the criteria are not met, and who is responsible. Review of personnel records revealed the laboratory had evaluated the competency of their general supervisors, but there were no competency evaluations available for 6 of 6 technical supervisors. During interview at approximately 10:10 a.m., the Director of Laboratory Operations confirmed that the laboratory did not have a policy describing the process for evaluating the competency of technical supervisors, and there were no technical supervisor competency evaluations available for 6 of 6 technical supervisors. He stated they had not evaluated the competency of technical supervisors because they were unaware technical supervisor competency evaluations were required.</p> |