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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>52D0961971         | <b>(X3) Date Survey Completed</b><br><br>10/19/2023 |
| <b>Name of Provider or Supplier</b><br><br>Biolife Plasma Services Lp  | <b>Street Address, City, State</b><br><br>3325 Business Park Dr, Stevens Point, WI |   |
| 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>D2006</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of American Association of Bioanalysts (AAB) proficiency testing (PT) records and laboratory records and interview with the quality manager, staff A, and the center manager, staff B, the laboratory did not examine or test the proficiency testing samples in the same manner as it's patient specimens for total protein performed for three of three events in 2022 and two of two events in 2023. Findings include: 1. Review of AAB PT records from 2021 showed the laboratory received a score of eighty percent on total protein for event 3 in 2021. 2. Review of the "Deviation (Event) Detailed Report" showed under heading "CAPA Assessment" the laboratory stated, "Our corrective actions will include a member of management observing the testing analyst performing their proficiency testing at every cycle". 3. Interview with staff A and staff B on October 19, 2023, at 1:47 PM confirmed a member of management does not observe the testing analysts performing testing on donors on a daily basis. Further interview confirmed the laboratory did not examine or test the proficiency testing samples in the same manner as it's patient specimens in 2022 and 2023.</p> |