

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0893092	(X3) Date Survey Completed 04/10/2024
Name of Provider or Supplier Biolife Plasma Services	Street Address, City, State 14415 Owen Tech Blvd, Austin, TX	
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
D0000	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES 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 review of the laboratory's policies and procedures, competency evaluations, and interview, the technical consultant failed to ensure competency evaluations were performed at least annually for eight out of 14 testing personnel reviewed from 2022 and 2023. Findings follow. A. Review of the laboratory's policy and procedure titled Standard Operating Procedure-243894, effective date 05/15/2023, under 12.1 stated, "Competency of testing personnel must be assessed initially, and within 6 months from the initial certification, and then annually (within 12 months) from initial certification." B. Review of 14 annual competency evaluations revealed eight were missing a 2022 or 2023 evaluation: testing personnel #3 and 24 (as listed on the CMS-209) were missing the 2022 annual competency evaluation, and testing personnel #19, 20, 26, 27, 33, and 36 were missing the 2023 annual competency evaluation. C. Interview with the Quality Manager/Technical Consultant #2 (as listed on the CMS-209) on April 10, 2024 at 0955 hours in the conference room confirmed there was no competency evaluation in 2023 for testing person #19. Interview with the Plasma Center Group Manager/Technical Consultant #1 on April 10, 2024 at 1000 hours in the conference room acknowledged they were late on the competency evaluation for testing person #20 in 2023, and the competency evaluation was performed in 2024. Interview with Technical Consultant #1 on April 10, 2024 at 1020 hours in the</p>

conference room acknowledged testing person #24 was on medical leave and no competency evaluation was performed in 2022; further interview revealed testing person #24 was only on medical leave from 10/12/22 - 10/25/22 in 2022. Interview with Technical Consultant #1 on April 10, 2024 at 1050 hours in the conference room confirmed there was no competency evaluation for testing person #26 in 2023; and at 1105 hours confirmed there was no competency evaluation for testing person #27 in 2023; and at 1130 hours confirmed there was no competency evaluation for testing person #33 in 2023; and at 1145 hours confirmed there was no competency evaluation for testing person #36 in 2023, and acknowledged it was performed late.