

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2278338	(X3) Date Survey Completed 02/24/2025
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 4400 North Fwy #H100, Houston, 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	An announced survey of the laboratory was conducted on 02/24/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory's director failed to attest PT samples were tested in the same manner as patients' samples for one of five PT events reviewed from 2023 and 2024. Findings included: 1. Review of laboratory's PT records revealed the laboratory used American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) as its PT provider. 2. Review of AAB-MLE instructions to laboratories revealed: "The attestation statements must be signed for each analyte by the analyst performing the procedure and kept in your files for inspection purposes. In addition to the analysts' signatures, the director or the director's designee must sign only once for each reporting form." 3. Further review of laboratory's PT records revealed AAB-MLE Chemistry M2 2024 Event (tested 05/27/2024) did not have laboratory director's or designee's PT attestation signature. 4. In an interview on 02/24/2025 at 1125 hours in the conference room, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, personnel records and staff interview, the laboratory's Technical Consultant failed to document semiannual competency assessment for five of forty-four testing personnel (TP) employed by the laboratory in 2023 and 2024, TP numbers twenty-six (TP26), twenty-seven (TP27), twenty-eight (TP28), thirty-nine (TP39) and forty (TP40). Findings included: 1. Review of laboratory's policy "Moderate Complexity CLIA Testing Requirements" (document SOP-243894, last approved 11/05/2024) revealed: "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." 2. Review of the laboratory's personnel records revealed the following personnel (as indicated on submitted Form CMS 209) did not have their competency assessed within six months from initial competency assessment: TP26 Initial competency assessment documented: 04/19/2023 Next competency assessment documented: 04/11/2024 TP27 Initial competency assessment documented: 04/19/2023 Next competency assessment documented: 08/16/2024 TP28 Initial competency assessment documented: 04/19/2023 Next competency assessment documented: 04/11/2024 TP39 Initial competency assessment documented: 05/31/2023 Next competency assessment documented: 03/28/2024 TP40 Initial competency assessment documented: 09/06/2023 Next competency assessment documented: 08/14/2024 3. In an interview on 02/24/2025 at 1050 hours in the conference room, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid