

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2274583	(X3) Date Survey Completed 07/22/2025
Name of Provider or Supplier Biolife Plasma Services, Lp	Street Address, City, State 239 Memorial Ave, Unit A, West Springfield, MA	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to rotate proficiency testing (PT) samples amongst all testing personnel who routinely perform patient testing. Findings include: 1. Record review on 7/17/2025 of the laboratory's CMS form 209, 'Laboratory Personnel Report' signed by the laboratory director (LD) on 7/15/2025 revealed the laboratory has 19 TP. 2. Record review on 7/17/2025 of the laboratory's CMS form 209, 'Laboratory Personnel Report' signed by the LD on 3/16/2023 revealed the laboratory had 13 TP. 3. Record review on 7/17/2025 of the laboratory's American Association of Bioanalysts/Medical Laboratory Evaluation (AAB/MLE) Event 3:2023, Events 1,2,and 3:2024, and Events 1 and 2 of 2025 Chemistry PT records revealed: a. In 2023 only 3 of 13 TP participated in PT. b. In 2024 only 3 TP participated in PT. c. In 2025 only 3 of 19 TP participated in PT. 4. record review on 7/17/2025 of the laboratory's, 'Proficiency Testing' procedure SOP-243904 revealed: a. Section 2.0: "Select the testing analyst (Management). The testing analyst must not have been an analyst for the previous six testing events." 5. During staff interview on 7/17/2025 at 9:50 AM with the Center Manager (CM) and the Quality Manager (QM), the CM and QM confirmed the above findings. The QM stated, "One TP performs PT on all samples in an event and there aren't enough PT samples for the number of TP. We follow our SOP and that is the way it tells us to do it." 6. The laboratory performs 64,455 tests annually in the specialty of Chemistry.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p>

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on record review and confirmed by staff interview with the Center Manager (CM) the laboratory director (LD) failed to ensure new testing personnel (TP) received training prior to performing patient testing. Findings include: 1. Record review on 7/17/2025 of the laboratory's CMS form 209, 'Laboratory Personnel Report' signed by the laboratory director on 7/15/2025 revealed the laboratory has 12 new TP. 2. Record review on 7/17/2025 of the laboratory's TP records revealed 2 of 12 new TP did have documented training prior to testing patient samples. 3. Record review on 7/17/2025 of the laboratory's 'Initial Training' procedure, DOC # QM-200145, revealed: a. "Scope: The trainee is not allowed to perform procedures independently until final evaluation is completed by a Designated Trainer, and the corresponding Statement of Task Understanding (STU) is signed off." 4. Record review on 7/17/2025 of the laboratory's 'Moderate Complexity CLIA Testing Requirements' procedure, SOP-243894, revealed: a. Section 10.0: "Train testing personnel on procedures related to total protein determination." 5. During an interview with the CM on 7/17/2025 at 10:49 AM, the CM confirmed the laboratory did not have documented training for 2 of 12 new TP. The CM stated, "Both new TP were transfers from other facilities and the SOP doesn't say they must be trained." 6. The laboratory performs 64,455 tests annually in the specialty of Chemistry.