

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2219907	<b>(X3) Date Survey Completed</b>  02/05/2025
<b>Name of Provider or Supplier</b>  Biolife Plasma Services, Lp	<b>Street Address, City, State</b>  425 Ernest W Barrett Parkway, Nw, Suite 4000, Kennesaw, GA	
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>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 05, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D6032</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interviews, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of the Clinical Consultant. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of the Clinical Consultant. 2. Interviews with the facility's assistant manager and the quality manager representative in the front conference room on 02/05/25 at 1:00 p.m. confirmed the aforementioned finding.</p>