

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2209520	<b>(X3) Date Survey Completed</b>  01/04/2023
<b>Name of Provider or Supplier</b>  Biolife Plasma Services Lp	<b>Street Address, City, State</b>  1450 Clements Bridge Road, Deptford, NJ	
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>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Group Quality Manager (GQM) the laboratory failed to ensure that the FR included the name and address of the laboratory where testing was performed from March 2021 to the date of survey. The GQM confirmed on 1/4/23 at 12:00 pm that the FR did not have name and address of the laboratory where testing was performed.</p>
<b>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Report (FR) and interview with the Group Quality Manager (GQM), the laboratory failed to have a Reference Range (RR) for</p>

Total Protein results from March 2021 to the date of the survey. The GQM confirmed on 1/4/23 at 11:15 am that the above test did not have a RR on the FR.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the Group Quality Manager (GQM), the Laboratory Director (LD) failed to ensure that PS procedures performed for Total Protein tests performed on the Reichter digital refractometer were adequate from March 2021 to the date of survey. The findings include: 1. There was no evidence that linearity was performed on six out of six analyzers. 2. There was no evidence that a Reference Range was verified on six out of six analyzers. 3. There was no evidence that precision and accuracy were performed on six out of six analyzers 4. The GQM confirmed on 1/4/23 at 11:15 am that PS records were not adequate.