

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2061664	(X3) Date Survey Completed 02/14/2022
Name of Provider or Supplier Biolife Plasma Services - Boise	Street Address, City, State 4120 N Eagle Rd, Boise, ID	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory polices and procedures and an interview with the laboratory quality representative on 2/14/2022, the laboratory failed to list acceptable ranges in the "Donor Screening" procedure. The finding include: 1 A review of the "Donor Screening" procedure identified that the laboratory failed to include the acceptable range for total protein testing performed using the Reichert refractometer. 2. An interview with the laboratory quality representative on 12/14/2022 at 5:24 pm</p>

confirmed that the acceptable range for total protein was not listed in the approved "Donor Screening" procedure. 3. The laboratory reports performing 157,494 total protein tests annually.