

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2211201	(X3) Date Survey Completed 01/12/2022
Name of Provider or Supplier Biolife Plasma Services L P	Street Address, City, State 29959 Plymouth Road, Livonia, MI	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Quality Manager (QM) and the Center Manager (CM), the laboratory failed to follow their procedure for equipment /materials for 11 (February 23, 2021 to January 12, 2022) of 11months of use. Findings include: 1. During a tour of the laboratory on 1/12/2022 at 9:07 am the surveyor identified that only 1 (8) of 5 safepettes were labeled with a unique identifier. 2. Review of the "Daily Area Cleaning and Maintenance and Work Area Guideline" procedure states in section 1.0 Responsibilities and Procedure section 1.2 "Create a unique identifier (e.g. HID001) for equipment received without a serial number." 3. When queried on 1/12/2022 a 11:10 am, the CM stated that the pipettes did have a unique identifier at one time. 4. An interview on 1/12/2022 at 11:10 am with the QM and CM, they confirmed the pipettes no longer had a unique identifier.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value</p>

of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Quality Manager (QM), the laboratory failed to verify criteria for acceptability of control materials prior to use for 3 (10/29/2021 to 01/12/2022) of 3 months for the current batch lot in use. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of the verification of quality control criteria for 3 of 3 months for the current batch (10/29/2021) of the quality control material in use for the chemistry total protein testing . 2. The surveyor requested the verification for acceptability of control materials for the current batch in use on 1/12/2022 at 11:21 am and the "Verification History Report" revealed the testing was never entered into the computer system and the paper trail was not made available. 3. An interview on 1/12/2022 at 11:21 am, the GM confirmed the laboratory did not have the documentation of the quality control verification entered into the computer system prior to being put into use.