

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2184406	(X3) Date Survey Completed 07/23/2024
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 11620 Coursey Blvd, Baton Rouge, LA	
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
D0000	A Recertification survey was performed at BioLife Plasma Services, LP, CLIA ID 19D2184406, on July 23, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, calibration verification records, and interview with personnel, the laboratory failed to perform their calibration verification</p>

procedures semi-annually in 2023. Findings: 1. Review of the laboratory's "Control Verification of Refractometer" procedure revealed "Testing Name: Calibration verification; Controls used: low, normal, high; Frequency: semi-annually based on date of Precision & Specification; Documentation: Quality Control Record-Refractometer Calibration Verification." 2. Review of the laboratory's "Refractometer Calibration Verification, Precision and Specification Testing" procedure revealed "Complete calibration verification for all in-service and back up refractometers semi-annually on the first business day of the semi-annual period + ten (10) calendar days." 3. Review of the laboratory's 2023 calibration records revealed the laboratory did not perform calibration verification semi-annually: a) Refractometer 14024-0320: performed January 18, 2023 and April 2023; due October 2023 b) Refractometer 14007-0320: performed April 7, 2023; due October 2023 c) Refractometer 14025-0320; performed April 7, 2023; due October 2023 d) Refractometer 13972-0320; performed April 7, 2023; due October 2023 e) Refractometer 13976-0320; performed April 7, 2023; due October 2023 f) Refractometer 14017-0320: performed April 11, 2023; due October 2023 4. In interview on July 23, 2024 at 12:03 pm, the Quality Manager stated the calibration verification procedures should be done six months from date last performed. 5. In further interview on July 23, 2023 at 12:03 pm, the Senior Operations Manager Trainee confirmed the laboratory did not perform calibration verification procedures semi-annually in 2023.

D5447

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(i)(g)

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on observation by surveyor, review of quality control (QC) records, patient test logs, and interview with personnel, the laboratory failed to perform two (2) levels of controls for total protein testing for forty six (46) of forty nine (49) days reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 23, 2024 at 9: 35 am revealed the laboratory utilizes Reichart TS refractometers for total protein testing. 2. Review of the laboratory's QC records revealed the laboratory did not perform two (2) levels of QC for the following dates on Refractometer 14024-0320: May 29, 2024 May 30, 2024 May 31, 2024 June 1, 2024 June 2, 2024 June 4, 2024 June 5, 2024 June 6, 2024 June 7, 2024 June 9, 2024 June 11, 2024 June 12, 2024 June 13, 2024 June 14, 2024 June 15, 2024 June 16, 2024 June 18, 2024 June 19, 2024 June 20, 2024 June 21, 2024 June 22, 2024 June 25, 2024 June 26, 2024 June 27, 2024 June 28, 2024 June 29, 2024 June 30, 2024 July 2, 2024 July 3, 2024 July 4, 2024 July 5, 2024 July 6, 2024 July 7, 2024 July 9, 2024 July 10, 2024 July 11, 2024 July 12, 2024 July 13, 2024 July 14, 2024 July 16, 2024 July 17, 2024 July 18, 2024 July 19, 2024 July 20, 2024 July 21, 2024 July 23, 2024 3. Review of patient test logs ("Refractometer Details Report") for Refractometer 14024-0230 from May 29, 2024 through July 23, 2024 revealed the following five (5) randomly selected patients were tested without documentation of QC: May 29, 2024: Patient A11657733 Patient A10874733 Patient A10697733 Patient A05620671 Patient A05358733 4. Further review of patient test logs for Refractometer 14024-0230 from May 29, 2024 through July 23, 2024 revealed a total of 1,626 patients were tested without QC performance.

5. In interview on July 23, 2024 at 3:39 pm, the Quality Manager stated the laboratory did not have documentation of QC performed for the identified dates. 6. In further interview on July 23, 2024 at 3:42 pm, the Senior Operations Manager Trainee stated he thought the laboratory had an out of service refractometer still linked to the computer. The Senior Operations Manager Trainee confirmed the laboratory's documents showed the refractometer as still in use without QC performed.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on observation by surveyor, review of the laboratory's policies, quality control records, patient test logs, and interview with personnel, the laboratory failed to perform corrective actions when quality control (QC) was unacceptable for one (1) of six (6) randomly selected dates reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 23, 2024 at 9:35 am revealed the laboratory utilizes the Reichart TS refractometer for total protein testing. 2. Review of the laboratory's "Control Verification of Refractometer" procedure revealed controls are to be performed "daily before refractometer is used." 3. Further review of the laboratory's "Control Verification of Refractometer" procedure revealed the following corrective actions for unacceptable QC: "Review results to ensure all are within the manufacturer's acceptable assay range. If results from testing are not within the control manufacturer's range, dispose of the protein control sample in a puncture-resistant biohazard waste container. Repeat the testing with a control sample prepared from a new vial of the same case. If the repeat results are still not within the manufacturer's acceptable assay range, dispose of the second protein control samples in a puncture-resistant biohazard waste container. Repeat the control testing with a new case of controls. If the repeat results are still not within the manufacturer's acceptable assay range, notify management to open a non-conforming materials report as per Nonconforming Material Report." 4. Review of QC records for randomly selected dates revealed QC was not acceptable without performance of corrective actions for the following: May 28, 2024: Refractometer 14024-0320 Low Control Reading: 45.20 (Retake 3) Low Comment Code: New vial, same lot (acceptable range 5.60-6.40) High Control Reading: N/A High Comment Code: Fuzzy Image/No Sample Results (acceptable range 8.60-9.40) 5. Review of patient logs revealed the following three (3) patients were reported on May 28, 2024 from Refractometer 14024-0320 without acceptable QC: Patient A17336733 Patient A18344733 Patient A19233733 6. In interview on July 23, 2024 at 3:30 pm, the Senior Operations Manager Trainee stated the laboratory did not have documentation of acceptable QC for Refractometer 14024-0320 for May 28, 2024.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the laboratory's established quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's "Moderate Complexity CLIA Testing Requirements" revealed "Complete all items addressed on Quarterly Moderate Complexity Review form and include a review of any associated events." 2. Review of the laboratory's "Quarterly Moderate Complexity Review" form revealed the following items are reviewed: a) "Follow-up items from last meeting" b) "Proficiency Testing" c) "Refractometer Verifications, Control Testing, and Daily Cleaning and Maintenance Records" d) "Refractometer Calibration Verification, Precision Testing, and Variability Testing (if applicable)" e) "Competency Evaluation Checklists" f) "Infection Control Procedures" g) "Audit Findings" h) "Other" There are signature and date lines for the Management Representative, Technical Consultant and Laboratory Director. 3. Observation by surveyor, review of the laboratory's records, and interview with personnel revealed the laboratory did not identify the following issues with the analytic system: a) The laboratory failed to perform their calibration verification procedures semi-annually in 2023. Refer to D5439. b) The laboratory failed to perform two (2) levels of controls for total protein testing for forty six (46) of forty nine (49) days reviewed. Refer to D5447. c) The laboratory failed to perform corrective actions when quality control (QC) was unacceptable for one (1) of six (6) randomly selected dates reviewed. Refer to D5783.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5439.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and

	<p>maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5447.</p>
<p>D6022</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.</p>
<p>D6024</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D5783.</p>
<p>D6036</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5439.</p>

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5447.

D6043

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(5)

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.