

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1105352	(X3) Date Survey Completed 05/17/2022
Name of Provider or Supplier Biolife Plasma Services	Street Address, City, State 2301 E Hillside Drive, Broken Arrow, OK	
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	The recertification survey was performed on 05/17/2022. The findings were reviewed with the center manager and the quality manager at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the quality manager, the laboratory director or designee failed to sign a proficiency testing attestation statement for one of six events. Findings include: (1) The surveyor reviewed 2020, 2021, and 2022 proficiency testing records and identified the following for one of six events: (a) First 2021 Chemistry (Q1) Event - The attestation statement had not been signed by the laboratory director or designee. (2) The surveyor reviewed the findings with the quality manager who stated on 05/17/2022 at 02:05 pm, the attestation statement had not been signed by laboratory director or designee as shown above.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the quality manager and center manager, the technical consultant failed to ensure a semiannual evaluation for moderate complexity testing was performed for one of 27 testing persons. Findings include: (1) On 05/17/2022 at 11:30 am, the center manager stated the following: (a) Total Protein testing was performed using the Reichert TS Meter. (2) A review of 2021 and 2022 personnel records for 27 testing persons requiring a semiannual competency for the above testing, revealed the following: (a) Testing Person #4 - The initial training had been documented as performed on 03/04/2021 There was no evidence the semiannual competency had been performed (due 09/2021); (3) The findings were reviewed with the quality manager who stated on 05/17/2022 at 01:05 pm the semiannual competency had not been performed as indicated above.