

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2191156	(X3) Date Survey Completed 03/01/2023
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 1655 N 107th Ave, Avondale, AZ	
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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on lack of education credentials for review and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience for the type and complexity of services offered. Findings include: 1. No evidence of appropriate education documentation was presented for review for one testing personnel who began patient testing on December 22, 2022. 2. During the survey conducted on March 1, 2023, the laboratory presented evidence of a 'Credit Report Card' for the testing personnel indicated above but the documentation did not satisfy the minimum educational requirement for testing personnel who perform moderate complexity testing. 3. The facility personnel interviewed on 3/01/2023 at 10:15am confirmed that the laboratory failed to provide documentation of appropriate education credentials for the testing personnel indicated above. 4. The laboratory began patient testing in the specialty of Chemistry with an approximate annual test volume of 82,402.</p>