

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2165273	(X3) Date Survey Completed 02/27/2024
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 7538 E Hampton Ave, Mesa, 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
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the facility personnel, the laboratory failed to provide documentation of academic credentials to qualify one out of 26 testing personnel for moderate complexity testing (Refer to D6065).</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with facility personnel, the</p>

laboratory failed to provide documentation of academic credentials to qualify one out of 26 testing personnel (TP-17) for moderate complexity testing. Findings include: 1. The laboratory performs 79,893 patient tests annually under the subspecialty of Routine Chemistry. 2. Review of the personnel records for one out of 26 testing personnel for the subspecialty of Routine Chemistry revealed the laboratory failed to have academic credentials to qualify TP-17. 3. No documentation was presented for review during the survey to indicate the laboratory had the diploma and corresponding transcripts of the testing personnel indicated above evaluated by a foreign transcript evaluation agency to ensure the equivalent education requirements. 4. Interview with facility personnel on 2/27/24 at 11:20 AM confirmed the laboratory failed to provide the required documentation to qualify TP-17 for moderate complexity testing.