

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0668897	(X3) Date Survey Completed 09/16/2020
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 2325 Mounds View Blvd, Mounds View, MN	
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 documents and interview with laboratory personnel, the laboratory failed to ensure staff performing moderate complexity testing meet the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the complexity of testing performed. Findings are as follows: The laboratory failed to obtain an equivalency evaluation of foreign credentials for 1 testing personnel performing moderately complex Chemistry testing. See 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>

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to obtain an equivalency evaluation for 1 of 3 new testing personnel with foreign education credentials who were hired between April 2018 and September 2020. Findings are as follows: 1. The laboratory performed moderate complexity Total Protein Chemistry testing as confirmed by the Center Manager (CM) during a tour of the testing area at 10:10 a.m. on 09/16/20. Reichert digital refractometers were observed as present and available for use during the tour. 2. Testing Personnel 41 (TP41) was listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as an employee performing moderate complexity testing. Laboratory records indicated TP41 completed training and was approved for test performance in March 2019. 3. Education credentials found in personnel records indicated TP41 completed education in Ethiopia. 4. An equivalency evaluation of foreign credentials was not found in personnel records. The laboratory was unable to provide an equivalency evaluation upon request. The Center Manager (CM) acknowledged the lack of educational equivalency evaluation at 1:15 p.m. on 09/16/20 and was given 2 days to produce the document. 5. An equivalency evaluation completed by Education Perspectives and dated 09/18/20 was provided by the CM via email at 4:09 p.m. on 09/18/20. 6. The equivalency evaluation of TP41's foreign education credentials did not occur prior to test performance.