

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2190107	<b>(X3) Date Survey Completed</b>  02/18/2025
<b>Name of Provider or Supplier</b>  Biolife Plasma Services, L P	<b>Street Address, City, State</b>  11569 12 Mile Road, Warren, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Based on record review and interview with the Technical Consultant, the Laboratory Director failed to ensure compliance with 493.51 Notification requirements for laboratories issued a certificate of compliance for 24 of 24 months (February 2023 to February 2025). Findings include: 1. On 02/18/2025 at 9:05 am, the surveyor arrived at the address listed in the QIES database, 11569 12 Mile Road, Warren, MI 48088, and discovered that another business, Facility A, was located at the address. The surveyor performed an internet search for the laboratory. The internet search resulted with the address of the laboratory as 13710 East 14 Mile Rd, Warren, MI 48088. The surveyor was unable to reach the laboratory at the phone number listed in the QIES database to confirm the location of the laboratory. 2. On 02/18/2025 at 9:20 am, the surveyor arrived at 13710 East 14 Mile Rd, Warren, MI 48088 and confirmed it was the location of the laboratory. 3. On 02/18/2025 at 9:45 am, the surveyor requested documentation the laboratory had submitted to the State Agency (SA) notifying the SA of the laboratory's change in location in accordance with notification requirements listed at 493.51: a. "Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory ' s certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance." 3. An interview with the Technical Consultant on 02/18/2025 at 9:45 am revealed the laboratory had been located at 13710 East 14 Mile Rd, Warren, MI 48088 since the last survey in 2023. However, a review of the 2023 Form CMS 116 revealed that 11569 12 Mile Road, Warren, MI 48088 was listed as the laboratory's physical address.
<b>D6035</b>	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant, the laboratory failed to ensure the Technical Consultant met the qualification requirements at 493.1411 for 1 of 1 Technical Consultant listed on Form CMS-209. Findings include: 1. Review of the laboratory's Form CMS-209 completed for the survey revealed one individual identified as Technical Consultant. 2. A review of personnel credentials for the Technical Consultant revealed the individual's education documentation did not meet requirements to perform the duties of Technical Consultant. 3. An interview on 02/18/2025 at 1:20 pm with the Technical Consultant confirmed that the education documentation did not meet CLIA requirements.