

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0663650	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 321 West Beaver Avenue, State College, PA	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the center manager (CM), the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which tests were performed from 08/23/2022 to the day of survey. Findings include: 1. The PA regulations (5.23(b)(1) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. On the day of the survey, 02/15/2024 at 10:30 am, review of the laboratory personnel report (PA State) and personnel credentials revealed that the laboratory failed to ensure that the PA regulations were met regarding having a qualified supervisor on site during all hours of patient testing from 08/23/2022 to 02/15/2024. 3. The laboratory's hours of operation are Monday 10:00 am to 07:00 pm, Tuesday to Thursday 08:00 am to 07:00 pm, Friday 08:00 am to 06:00 pm and Saturday 10:00 am to 04:00 pm. 4. The CM confirmed the findings above on 02/15/2024 at 11:55 pm.</p>