

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2253325	(X3) Date Survey Completed 11/30/2023
Name of Provider or Supplier Biolife Plasma Services, Lp	Street Address, City, State 640 Fellsway, Medford, MA	
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
D0000	An initial CLIA survey was conducted for the laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D6084	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)</p> <p>The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview on 11/30/2023 with the Quality Management Representative (QMR) and the Plasma Center Manager (PCM) the laboratory director (LD) failed to ensure that the physical plant and environmental conditions provided a safe environment in which employees were protected from physical, chemical, and biological hazards as evidenced by the following: Emergency Eyewash Stations: The surveyor toured the laboratory space on 11/30/2023 and reviewed the maintenance documentation for the four (4) eyewash stations. The review revealed that the documentation for all four (4) eyewash stations being checked weekly was only documented for January, September, and October 2023, only two (2) weeks in March 2023 (3/7 and 3/31), only one (1) week in April (4/14), July (7/11), August (8/4), and November (11/30) of 2023. There was no documentation that the eyewash stations were checked weekly in February, May, and June of 2023. The PCM stated that there was a change in which staff would be responsible for this task and therefore the task was not completed weekly. The QMR and PCM confirmed in an interview on 11/30/2023 at 12:35 PM that documentation was not being appropriately maintained that the four (4) emergency eyewash stations were being routinely checked and maintained on a weekly basis.</p>