

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2061664	(X3) Date Survey Completed 02/20/2018
Name of Provider or Supplier Biolife Plasma Services - Boise	Street Address, City, State 4120 N Eagle Rd, Boise, ID	
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
D6049	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on personnel record review and an interview with the plasma center manager, the technical consultant failed to evaluate the competency of preventive maintenance records as part of the biannual and annual competency assessment for all testing personnel since the last survey on April 29, 2016. Findings: 1. A record review of personnel competency assessments revealed the technical consultant failed to assess the competency of preventative maintenance records for 66 out of 66 testing personnel listed on the CMS-209 form. 2. An interview on February 7, 2018 at 2:00 PM, with the plasma center manager, confirmed that the assessment of preventative maintenance failed to be documented.</p>
D6050	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.</p> <p>This STANDARD is not met as evidenced by: Based on personnel record review and an interview with the plasma center manager, the technical consultant failed to evaluate the competency of testing personnel by direct observation of performance of instrument maintenance and function checks as</p>

part of the biannual and annual competency assessment for all testing personnel since the last survey on April 29, 2016. Findings: 1. A record review of personnel competency assessments revealed the technical consultant failed to evaluate by direct observation instrument maintenance and function checks for 66 out of 66 testing personnel listed on the CMS-209 form. 2. An interview on February 7, 2018 at 2:00 PM, with the plasma center manager, confirmed the direct observation of performance of instrument maintenance and function checks failed to be documented.