

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2090204	(X3) Date Survey Completed 02/07/2018
Name of Provider or Supplier Biomat Usa Inc	Street Address, City, State 771 N College Rd, Twin Falls, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on personnel record review and an interview with the laboratory manager, the laboratory failed to establish a policy to assess the competency for the position responsibilities of the technical consultant since the last survey on March 23, 2016. Findings: 1. A record review of the technical consultant competency assessment revealed the laboratory failed to evaluate the position responsibilities for the technical consultant. 2. An interview on February 7, 2018 at 2:00 PM, with the laboratory manager, confirmed the laboratory failed to evaluate the technical consultant responsibilities.</p>
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 laboratory manager, the technical consultant failed to evaluate intermediate test results and preventive maintenance records as part of the annual competency assessment for all testing personnel since the last survey on March 23, 2016. Findings: 1. A record review of</p>

personnel competency assessments revealed the technical consultant failed to assess intermediate test results and preventative maintenance records for 14 out of 14 testing personnel listed on the CMS-209 form. 2. An interview on February 7, 2018 at 2:00 PM, with the laboratory manager, confirmed that intermediate test results and preventative maintenance failed to be documented.

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iv)

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.

This STANDARD is not met as evidenced by:
Based on personnel record review and an interview with the laboratory manager, the laboratory failed to evaluate the competency of testing personnel by direct observation of performance of instrument maintenance and function checks since the last survey on March 23, 2016. Findings: 1. A record review of personnel competency assessments revealed the technical consultant failed to evaluate testing personnel by direct observation of instrument maintenance and function checks for 14 out of 14 testing personnel listed on the CMS-209 form. 2. An interview on February 7, 2018 at 2:00 PM, with the laboratory manager, confirmed that performance of instrument maintenance and function checks failed to be documented.