

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2130618	<b>(X3) Date Survey Completed</b>  04/10/2019
<b>Name of Provider or Supplier</b>  Biomat Usa, Inc	<b>Street Address, City, State</b>  3570 South Mendenhall Rd, Memphis, TN	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 review of the laboratory procedure manual, the forms used for assessing employee competency, and interview with the quality assurance manager, the laboratory failed to have a procedure that included all six criteria for assessing personnel competency in 2017, 2018, and 2019. The findings include: 1) Review of the laboratory procedure titled "CLIA PROFICIENCY TESTING, TOTAL PROTEIN COMPETENCY, AND HEMATOCRIT COMPETENCY EVALUATION" under the section titled "TOTAL PROTEIN QUALITY CONTROL COMPETENCY" revealed that competency will be assessed using quality control materials and observations. The procedure failed to include all six criteria as specified in Subpart M to include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Review of the forms used for documenting competency assessment revealed that blind testing is not included as part of the competency assessment documentation. 3) Interview on April 10, 2019 at 4:30 p.m. with the quality assurance manager confirmed the testing personnel competency procedure did not include all six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS) and the form used for competency documentation failed to include blind testing in 2017, 2018 and 2019.</p>