

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2039576	<b>(X3) Date Survey Completed</b>  10/30/2018
<b>Name of Provider or Supplier</b>  Biomat Usa Inc	<b>Street Address, City, State</b>  3280 W 87th St, Chicago, IL	
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>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's records, employee files, and an interview with the testing personnel (TP), the technical consultant (TC) failed to evaluate the competency of all TP and assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently in the subspecialty of Routine Chemistry, affecting 30 out of 33 TP. Findings: 1. The CMS 209 lists 33 TP who perform Total Protein analysis in the laboratory. 2. Review of employee records showed that 30 out of 33 TP competency evaluations were performed by other TP, whose education and experience does not meet the requirements of a TC. 3. On a Validation survey conducted on 10/30/2018 at 12:00 PM, to a COLA accredited lab, whose survey was conducted on 09/18/2018; the laboratory managers confirmed the above findings.</p>
<b>D6051</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS 209),</p>

records, manual, and an interview with the laboratory managers, the laboratory failed to document the test performance of individuals responsible for moderate complexity testing, through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples, affecting 33 out of 33 testing personnel (TP) . Findings: 1. The CMS 209 lists 33 TP who perform Total Protein analysis in the laboratory. 2. Review of employee records showed that 33 out of 33 TP were authorized to perform Total Protein analysis. Also included in each TP's file is a statement page signed by the TP and their observer (another TP) which states that the TP has been assessed and is competent to perform testing. No documentation was provided as evidence that the use of previously analyzed specimens, or internal blind testing samples or external proficiency testing samples were included in the laboratory's competency procedure to assess each TP's test performance. 3. The laboratory's competency policy and procedure (which is called the "Proficiency Testing") describes how the TP's test performances are to be implemented, however it does not instruct the assessors to document this process. 4. On a Validation survey conducted on 10/30/2018 at 12:00 PM, to a COLA accredited lab, whose survey was conducted on 09/18/2018; the laboratory managers and regional manager via teleconference, confirmed the evaluation of each TP did not include testing previously analyzed specimens, internal blind samples or external proficiency testing samples.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on the surveyor's review of the Laboratory Personnel Report (CMS-209) and employee files, the laboratory failed to employ individuals who meet the qualification requirements of 493.1423 for testing personnel (TP). Finding: 1. The laboratory failed to ensure laboratory personnel meet the education qualification requirements for performing moderately complex testing in the subspecialty of Routine Chemistry. See D6065.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), employee files, records, and an interview with the laboratory managers, the laboratory failed to ensure laboratory employees meet the education qualification requirements for performing moderately complex testing in the subspecialty of Routine Chemistry. Findings: 1. The CMS 209 lists 33 TP performing Total Protein analysis in the laboratory. 2. Employee PJB (listed on page 2, line 1) files included the following: a). A diploma from Greece, written in Greek; b). A translation of the diploma which had been notarized; and c). A document from the laboratory's credentialing service which states that TP-PJB attended the "Technological Educational School of Athens" and that TP-PJB graduated in 2010 with a Bachelor Degree in Midwifery. No documentation was provided as proof that Employee PJB or the credentialing service had TP-PJB's Bachelor Degree in Midwifery evaluated for its US equivalency. 3. On a Validation survey conducted on 10/30/2018 at 12:00 PM, to a COLA accredited lab, whose survey was conducted on 09/18/2018; the laboratory managers confirmed the above findings.