

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0668904	(X3) Date Survey Completed 05/22/2019
Name of Provider or Supplier Biomat Usa, Inc	Street Address, City, State 501 Sable Blvd, Aurora, CO	
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
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES 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 a review of laboratory policy, competency assessment records and staff interview, the technical consultant failed in 2018 and 2019 to evaluate the competency of 36 of 36 testing personnel who performed non-waived testing and approximately 73,000 patient specimens are analyzed annually. Findings include: a. The laboratory tests patient specimens for total protein determination using a Reichert digital refractometer. b. The laboratory policy states that, "With the exception of centers located in California and Houston, Texas, the Laboratory Director may approve "assessors" in the center to assist in performing employee assessments. For the centers in California and Houston, Texas, Technical Consultants may be approved to assist the Laboratory Director, but these individuals must meet the criteria of 42 CFR Chapter IV 493.1411, Technical Consultant qualifications." c. Competency assessment records showed that testing personnel were evaluated for competency in 2018 and 2019 by laboratory staff who are not qualified to serve as a technical consultant (#8 on page 1 of Form CMS-209, and #4 and #5 on page 3 of Form CMS-209) . d. On 5-22-19 at about 10 a.m., staff stated that the Laboratory Director had approved these three testing personnel as assessors who had not earned at a minimum a Bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution. e. On 5-22-19 at about 10 a.m., staff confirmed that none of the testing personnel were assessed by the Laboratory Director /Technical Consultant in 2018 or 2019 as required by the federal CLIA regulation.</p>
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on a review of the competency assessment records and staff interview, the laboratory's Performance Observation Checklist failed to include all required components of competency of testing personnel who perform moderate complexity total protein determinations using a refractometer in 2018 and 2019 and approximately 73,000 patient specimens are tested annually. Findings include: a. The Performance Observation Checklist (Document #80-01B, Rev. 5.0) included the following: "Was the refractometer used properly? Was the total protein determined properly? Was the proper dry-wet-dry cleaning of refractometer used? Was the employee able to verbalize what to do if RBCs were dispensed onto the prism? Did the employee commit the value in BECS once the results were obtained? Were the soiled wipes immediately properly disposed of? Was the employee able to verbalize the steps for performing the daily operational standardization of the device? Was the employee able to verbalize the steps for handling a failure of the daily operational standardization of the device?" b. The Performance Observation Checklist failed to include the direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of quality control (QC) records, proficiency testing (PT) results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; and the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. c. On 5-22-19 at about 11 a.m., staff stated they were unaware of this regulatory requirement for competency assessment, and confirmed all elements of competency were not included in the Performance Observation Checklist as required by the federal CLIA regulations.