

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0691488	(X3) Date Survey Completed 12/20/2021
Name of Provider or Supplier Biomat Usa, Inc	Street Address, City, State 3508 Ramill Road, Memphis, TN	
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
D2004	<p>ENROLLMENT CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicare Services CASPER Report 155, the laboratory's proficiency testing records, and staff interview, the laboratory failed to ensure participation in one proficiency testing program for one year before switching to a different proficiency testing program in 2021. The findings include: 1. Review of the CASPER Report 155 revealed the laboratory participated in proficiency testing for the total protein analyte with Accutest for 2021 event one and then switched to American Association of Bioanalysts (AAB) for 2021 events two and three. 2. Review of the laboratory's proficiency testing records revealed the following for the total protein analyte: 2021 event one-participation in proficiency testing with the Accutest proficiency testing program. 2021 events two and three participation in proficiency testing with the AAB proficiency testing program. 3. Interview with the center manager on December 20, 2021 at 3:30 pm confirmed the facility participated in proficiency testing for the total protein analyte with one proficiency testing program for 2021 event one and then switched to a different proficiency testing program for 2021 events two and three in 2021. The laboratory failed to ensure participation with one proficiency testing program for one year before switching to another proficiency testing program in 2021.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must</p>

attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records and staff interview, testing personnel failed to sign the proficiency testing attestation statement for 2021 event three (one of seven proficiency testing events). The findings include: 1. Review of the laboratory's proficiency testing records revealed the 2021 event three attestation statement was not signed by the person who performed the testing. 2. Interview with the center manager on December 20, 2021 at 3:30 pm confirmed testing personnel failed to sign the proficiency testing attestation statement for 2021 event three.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records and staff interview, the laboratory failed to retain the American Association of Bioanalysts (AAB) proficiency testing attestation statements for two years in 2021 (two of seven proficiency testing events). The findings include: 1. Review of the laboratory's AAB proficiency testing records revealed no attestation statements were present for 2021 event one for microhematocrit and 2021 event two for microhematocrit and total protein. 2. Interview with the center manager on December 20, 2021 at 3:30 pm confirmed the laboratory failed to retain the AAB proficiency testing attestation statements for 2021 events one and two.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

The laboratory director failed to have documentation of laboratory training or experience for performing technical consultant duties.(Refer to D6035)

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of

podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of laboratory records, personnel records and staff interview, the current technical consultant failed to have documentation of laboratory training or experience for performing technical consultant duties for patient testing in chemistry in 2021. The findings include: 1. Observation of the laboratory on December 20, 2021 at approximately 10:15 am revealed the performance of moderately complex testing for total protein using a digital refractometer. 2. Review of laboratory records revealed the current laboratory director assumed the duties of technical consultant when taking over as laboratory director on November 1, 2021. Technical consultant duties performed included review of proficiency testing results, refractometer comparisons/verifications and monthly quality assessment/director meetings. 3. Review of personnel records revealed no documentation that the laboratory director had the required laboratory training or experience to perform the technical consultant duties. 4. Interview with the center manager on December 20, 2021 at 3:30 pm confirmed the laboratory director began performing technical consultant duties beginning November 1, 2021. He also confirmed that personnel records did not include documentation of laboratory experience or training in the specialty of chemistry.