

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0722307	(X3) Date Survey Completed 03/23/2022
Name of Provider or Supplier Biomat Usa, Inc	Street Address, City, State 2053 22nd Ave, Kenosha, WI	
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 surveyor review of proficiency testing (PT) records, federal Certification and Survey Provider Enhanced Reports (CASPER), and interview with the center quality manager, the laboratory changed proficiency testing (PT) providers for refractometer protein testing after one event in 2021 and did not participate in a single approved proficiency testing program for all of 2021. Findings include: 1. Review of PT records and reports for refractometer protein testing in 2021 showed the laboratory participated in the Accutest PT program for event one. Records for event two and three in 2021 showed the laboratory tested samples and received reports from the AAB (American Association of Bioanalysts) PT program. 2. Review of the CASPER 155D 'Individual Laboratory Profile' report showed this laboratory received scores from two providers in 2021. The report showed Accutest Inc. reported scores for the first and second events and AAB reported scores for the second and third events. 3. Interview with the center quality manager (staff A) on March 15, 2022 at 9:15 AM confirmed the laboratory submitted refractometer protein results to Accutest Inc. for the first event in 2021 then submitted results to AAB for the second and third events and did not submit results to Accutest for the second and third events to complete the 2021 year.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification</p>

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:

Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form CMS-209) and personnel records, and interview with the center quality manager, the laboratory has not had a qualified technical consultant since September 27, 2021. Findings include: 1. The laboratory's previous technical consultant has not been employed in that role since September 27, 2021. The laboratory did not have documentation to show the current identified technical consultant met the qualification requirements of 493.1411 of this subpart. See 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 surveyor review of the CMS (Center for Medicare and Medicaid Services) Form 209 Laboratory Personnel Report and personnel records, and interview with the center quality manager, the laboratory has not had a qualified technical consultant

since September 27, 2021. Findings include: 1. Review of the CMS Form 209 submitted by the laboratory for the March 15, 2022 survey showed the laboratory director is identified as the technical consultant on the form. 2. Review of personnel records including certificates of laboratory director training and medical degree transcripts submitted by the laboratory through email on March 16 and 23, 2022 did not show evidence of one year of clinical laboratory training and experience in non-waived testing in chemistry. 3. Interview with the center quality manager on March 15, 2022 at 9:10 AM confirmed the previous technical consultant has not filled the responsibilities of technical consultant since September 27, 2021. Documentation was not available on site or after the survey that showed the laboratory director had one year training or experience in clinical chemistry to meet the qualification requirements for a technical consultant for the chemistry specialty.