

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2084770	<b>(X3) Date Survey Completed</b> 10/19/2021
<b>Name of Provider or Supplier</b> Biomat Usa, Inc	<b>Street Address, City, State</b> 220 E Rio Grande Street, Eagle Pass, TX	
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>D0000</b>	The laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D6063 - 42 C.F.R. 493.1240 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
<b>D6063</b>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview it was determined the laboratory failed to have documentation of education for personnel performing moderate complexity testing (refer to D6065).</p>
<b>D6065</b>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor</p>

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 review of the laboratory's personnel records and staff interview it was determined the laboratory failed to have documentation of qualifications for moderate complexity testing for 1 of 27 testing personnel. The findings were: 1. Review of the laboratory's personnel records revealed Testing Person number 10 did not have documentation of qualifications for moderate complexity testing on file. 2. The laboratory was asked to provide education documents qualifying Testing Person number 10 to perform moderate complexity testing and no such documentation was provided. 3. In an interview on 10/19/2021 at 1125 hours in the training room Testing Person number 1 (as Described on CMS Form 209 signed by the laboratory director on 10/12/2021) confirmed the findings.