

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 10D2112788	<b>(X3) Date Survey Completed</b> 02/12/2025
<b>Name of Provider or Supplier</b> Biomat Usa Inc	<b>Street Address, City, State</b> 2364 W Oak Ridge Rd, Orlando, FL	
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>	An announced CLIA validation survey was conducted at Biomat USA Inc on 2/12 /2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The laboratory was found out of compliance with the following conditions: D6063 - LABORATORY TESTING PERSONNEL
<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 record review, and interview, the laboratory failed to have qualified Testing Personnel for 2 out of 33 testing personnel sampled for testing for total protein, (A and B). See D6078.</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 of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50</p>

weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review, and interview, the laboratory failed to have qualified Testing Personnel for 2 out of 33 testing personnel sampled for testing for total protein, (Testing Personnel A and B). Findings included: 1. Review of Laboratory Personnel Report CMS 209 (signed by the Laboratory Director 02/10/2025) revealed Testing Personnel A and B were listed as Testing Personnel. 2. Review of employment form revealed Testing Personnel A received their diploma at a foreign high school. There was no foreign equivalence documentation for comparing a foreign degree to United States education High school standard. 3. Review of employment form revealed Testing Personnel B received their diploma at a foreign high school. There was no foreign equivalence documentation for comparing a foreign degree to United States High school education standard. 4. Review of Initial Competency assessments revealed Testing Personnel A had an initial competency assessment done on 7/17/2023 and Testing Personnel B had an initial competency assessment done on 11/25/2024. Initial competency assessment involved observation of running a donor sample for total protein. 5. On 2/12/2025 at 6:43 PM, the Center manager confirmed Testing Personnel A and B were not qualified for moderate complexity testing due to lack of foreign equivalences.