

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1040835	(X3) Date Survey Completed 03/19/2024
Name of Provider or Supplier Biomat Usa, Inc	Street Address, City, State 6530 N 76th St, Milwaukee, 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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory documents and interview with the Center Quality Manager (Staff A), the laboratory does not have a request from an authorized person for 23,932 of the 23,932 total protein tests performed annually at this laboratory. Findings include: 1. Review of documents provided by the laboratory showed no evidence the laboratory director or other authorized person had approved an order for total protein testing. 2. Review of the "Application for Certification" CMS (Centers for Medicare and Medicaid Services) Form 116 signed by the laboratory director on March 12, 2024, showed the laboratory performed approximately 23,932 chemistry tests annually. 3. Interview with Staff A on March 19, 2024, at 12:45 PM confirmed the only chemistry testing the laboratory performed was total protein testing by refractometer. Further interview at 2:00 PM confirmed the laboratory did not have a standing order for the total protein testing performed on donors in the laboratory.</p>