

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0958050	<b>(X3) Date Survey Completed</b> 04/27/2023
<b>Name of Provider or Supplier</b> Biomat Usa Inc	<b>Street Address, City, State</b> 630 Greenwich Street #3, Reading, PA	
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>D5301</b>	<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 review of laboratory CMS 116, patient's record and interview with the Quality Systems Manager (QSM), at the time of the validation survey, the laboratory failed to have a written or electronic request for 41,033 of 41,033 patient specimens tested for Total Protein from 2022 through the time of survey. Findings include: 1. On the day of survey, 04/27/2023, the lab could not to provide test requisitions for 41,033 of 41,033 patient specimens analyzed for Total Protein using the Reichert Digital Refractometer. 2. The CMS 116 form submitted at the time of the survey indicated an annual volume of 41033 number of patient specimens analyzed. 3. QSM confirmed the above findings on 04/27/2023 around 11:25am.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory procedure manual/Biomat USA Donor Center Document record review, interview with Quality Systems Manager (QSM) and former Laboratory Director (LD) listed as Clinical Consultant (CC) on CMS 209 form on 04/27/2023 during the validation survey, the laboratory failed to ensure that the 1 of 1 laboratory procedure manual in use for Total Protein testing was approved, signed and dated by</p>

the current laboratory director. Findings include: 1. At the time of survey, the QSM stated that some changes were made to the Total Protein laboratory procedure manual that required the LD to sign. 2. The electronic Laboratory procedure manual /Biomat USA Donor Center Document reviewed at the time of inspection (10:14am) revealed the procedures were approved, signed and dated by the former LD. The procedure manual was not signed by the current LD. 3. The CMS 209 form submitted by the lab on the day of inspection 04/27/2023, had a different name listed as the Lab Director. 4. According to ASPEN Web (CMS 116) the director's name was changed by the Accrediting Agency (COLA) on 03/15/2023 from the former director's name to the new director's name listed on the CMS 209 form. 5. According to the QSM, a total of 5250 patient specimens were tested for Total Protein from 03/15/2023 to the date of survey (04/27/2023). 6. The former LD on 04/27/2023 at 10:36 am confirmed that he signed the documents.