Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2224882	09/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Biomat Holdings, Llc	6500 Quince Rd, Memphis, TN	

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
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on facility observation, a review of refractometer correlation studies, a review of testing personnel (TP) competency assessment records, and staff interviews, the laboratory failed to maintain complete quality assessment records for a period of two years when ownership changed on 07/01/24. The findings include: 1. Facility observation on 09/19/24 at 9:45 a.m. revealed the laboratory performed serum total protein using the Reichert TS Meter-DSP to determine donor eligibility for plasmapheresis. 2. A review of the "Refractometer Correlation Study" document dated 9/25/23 revealed "FAIL" for refractometer "Equipment ID # R7." The corrective action was not available on the survey date (09/19/24). 3. A review of testing personnel competency assessment records revealed the following: The person who performed 12 of 15 initial competency assessments (TP numbers three, four, five, six, seven, eight, ten, eleven, twelve, thirteen, fourteen, and fifteen) could not be determined. The person who performed 11 of 13 six-month competency assessments (TP one, two, three, five, six, seven, eight, ten, eleven, thirteen, and fifteen) could not be determined. The person who performed thirteen of thirteen annual competencies could not be determined (TP one, two, three, five, six, seven, eight, nine, ten eleven, thirteen, and fifteen). 4. An interview with the center manager and quality manager on 09/19/24 at 4:15 p.m. revealed the following: The refractometer that failed the correlation study was taken out of service. The corrective action was maintained electronically. The laboratory director/technical consultant performed the competency assessments. The documentation was maintained electronically. Transitions during an ownership change resulted in the center losing electronic record access to the previous owner's system for records prior to 07/01/24. This confirmed the survey findings.

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on facility observation, review of the refractometer user's guide, review of instrument records and lack of documentation, and staff interview, the laboratory failed to verify the calibration of the refractometers with three levels that covered the range of results reported at least every six months in 2022 and 2023. The findings include: 1. Facility observation on 09/19/24 at 9:45 a.m. revealed the laboratory performed serum total protein using the Reichert TS Meter-DSP to determine donor eligibility for plasmapheresis. 2. A review of the Reichert TS Meter-DSP User's Guide revealed that the "Zero Point" is verified using distilled or deionized water daily. If the verification fails, the CAL key is pressed to set the zero point. The stated measuring range was 0.0 - 15.1 g/100 ml. 3. A review of instrument records revealed that calibration verification across the measuring range was verified during initial instrument validations performed in August 2021 and on June 23, 2024. The laboratory could not provide documentation of refractometer calibration verification performed every six months in 2022 and 2023. 4. During an interview on 09/19/24 at 1:30 p.m., the center manager stated that the laboratory used the refractometers' measuring range and confirmed that the laboratory failed to verify the calibration of the refractometers using three levels that covered the measuring range at least every six months in 2022 and 2023.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by:

	Based on a review of testing personnel records and staff interviews, the technical consultant failed to ensure blind testing was included as part of competency assessments in 2022, 2023, and 2024 for 41 of 41 competency assessments performed for 15 testing personnel. 1. A review of testing personnel competency assessment records revealed that 41 of 41 competency assessments performed in 2022, 2023, and 2024 for 15 testing personnel did not include evaluation of blind test performance. 2. Interview with the center manager and quality manager on 09/19/24 at 4:15 p.m. confirmed that the technical consultant failed to ensure blind testing was included as part of competency assessments in 2022, 2023, and 2024.