Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2192217	06/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Biomat Holdings, Llc	1302 Lititz Pike, Lancaster, PA	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Center Manager (CM), the laboratory failed to retain quality control (QC) records for 4 of 4 Reichert TS Meters used to perform total protein (TP) examinations for at least 2 years from 6/10/2023 to 06/10/2025. Findings include: 1. On the day of survey, 6/10/2025 at 11:00 am, the laboratory failed to provide requested QC records for 4 of 4 Reichert TS Meters used to perform total protein examinations from 6/10/2023 to 6/10/2024. 2. The laboratory performed 45,079 Total Protein examinations in 2024 (CMS 116 annual volume). 3. The CM confirmed during interview on 6/10/2025 at 1:00 pm, the laboratory changed ownership (June 2024) and failed to retain all QC records for the last 2 years.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on lack of documentation, review of American Associates of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and interview with the center manager (CM), the laboratory failed to document the evaluation and verification activities performed for 1 of 3 AAB-MLE Chemistry

	events for 2023. Findings Include: 1. On the day of survey, 06/10/2025 at 10:00, a review of AAB-MLE PT records revealed the laboratory received a score of 80% for 1 of 3 AAB-MLE PT events (Chemistry M3 2023) for total protein testing performed in 2023. 2. The laboratory's Technical Consultant Review of Proficiency Testing Results for Q3 2023 Quadrimester memo stated, "DON-102 requires the center to score no less than 100%. Center to take corrective action and preventative action for receiving a score of less than 100%." 3. The laboratory failed to provide documentation for the corrective and preventative action taken when receiving a PT score of less than 100%. 4. The CM confirmed the findings above on 06/10/2024 at 12: 30 pm.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the center manager (CM), the laboratory failed to indicate the open date for 1 of 1 quality control (QC) material and the expiration date for 1 of 1 reagent currently being used to perform total protein (TP) testing in June 2025. Findings include: 1. On the day of survey, 06/10/2025, observation of the laboratory revealed the laboratory failed to indicate the following for 1 of 1 reagent and 1 of 1 control material currently being used to perform TP testing in June 2025: - KOVA Refractol Normal Level: No open date indicated - Pure Life, Deionized Water (DI H20): No expiration date indicated. 2. The CM confirmed findings above on 06/10/2025 at 12:30 pm.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 record review, lack of documentation, and interview with the Center Manager (CM), the laboratory failed to perform calibration verification at least once every six months for 4 of 4 Reichert TS Meter-DSP Refractometers used for total protein testing (TP) in 2024. Findings include: 1. On the day of the survey, 6/10/2025 at 12:00 pm, the laboratory failed to provide documentation for the calibration verfication performed at least once every six months (due 12/2024) for the following 4 of 4 Reichert TS Meter-DSP Refractometers used for TP testing in 2024: - S/N: E86821 - S/N: E86808 - S/N: E87036 - S/N: E87206 2. The CM confirmed the findings above on 6/10/2025 at 12:00 pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Center Manager (CM), the laboratory failed to evaluate, twice a year, the relationship between test results for 4 of 4 Reichert TS Meter-DSP Refractometers used for total protein (chemistry) testing performed from 06/10/2023 to the date of survey. Findings include: 1. On the day of the survey, 6/10/2025 at 11:30 AM, the laboratory failed to provide documentation of the comparison of test results evaluated twice a year between 4 of 4 Reichert TS Meter-DSP Refractometers used for Total Protein testing performed from 06/10/2023 to 6/10/2025. 2. The laboratory performed 45,079 chemistry tests in 2024 (CMS-116 estimated annual volume). 3. The CM confirmed the findings above on 6/10/2025 at 11:30 AM.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with the center manager (CM), the Laboratory Director failed to ensure a Quality Assessment (QA) program was established and maintained to assure the quality of laboratory services and to identify failures in quality as they occur for chemistry testing performed for 24 of 24 months from 6/14/2023 to 6/10/2025. Findings include: 1. On the day of the survey, 6/5/2025, the laboratory failed to provide documentation for the QA activities performed and reviewed by the LD for total protein testing performed for 24 of 24 months from 6/10 /2023 to 6/10/2025. 2. The CM confirmed above findings on 6/10/2025 at 12:30 pm.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)

	(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on lack of documentation, record review, and interview with the Center Manager (CM), the Laboratory Director (LD) failed to specify in writing the responsibilities and duties of 12 of 12 testing personnel (TP) involved in the preanalytic, analytic, and postanalytic phases of moderate complexity chemistry testing from 6/10/2023 to 6/10/2025. Findings include: 1. On the day of survey, 6/10 /2025, the laboratory failed to provide the written list of responsibilities for 12 of 12 TP (CMS-209 TP # 1, through TP# 12) involved in the preanalytic, analytic, and postanalytic phases of moderate complexity chemistry testing from 06/10/2023 to 6/10 /2025. 2. The laboratory could not provide documentation that identified which examinations each TP was approved to perform, and whether supervision is required for specimen processing , test performance or result reporting, or if consultant/director review is required prior to reporting patient results. 3. The CM confirmed the above findings on 6/10/2025 at 11:30 am.