

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0993305	(X3) Date Survey Completed 09/23/2025
Name of Provider or Supplier Biomat Usa Inc	Street Address, City, State 901 Yamato Road Suite 107, Boca Raton, FL	
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
D0000	An announced CLIA recertification survey was conducted at Biomat USA INC on August 27, 2025 to September 23, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a policy on how to perform competency assessments for general supervisors and technical supervisors and failed to perform annual competency assessments for technical supervisor and general supervisor for 2023 and 2024. Findings included: Review of Laboratory Personnel Report revealed Employee E was Technical Supervisor and General Supervisor. Review of Competency Assessments revealed no documentation of annual competency assessments for Technical Supervisor and General supervisor for 2023 and 2024. Review of Laboratory Services Compliance with CLIA Requirements signed by Laboratory Director on 10/17/2024, did not include a policy on how to perform competency assessments for Technical Supervisor and General Supervisor. Review of Laboratory Personnel Training Program signed by the Laboratory Director on 10/17/2024 read, "Each employee performs direct-observation competency assessments initially, 6 months and annually thereafter." On 8/28/2025 at 9:46 AM, the Technical Supervisor and Director of Operations confirmed there was no policy for competency for Technical Supervisor and General Supervisor and no annual competencies were performed for Technical Supervisor and General Supervisor in 2023 or 2024.</p>