Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0691445	(X3) Date Survey Completed 07/20/2022
Name of Provider or Supplier Biomat Usa, Inc	**Street Address, City, State** 2585 Barclay Street Suite C, Muskegon, MI	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: . Based on record review and interview with the Center Manager, the laboratory failed to follow its policy to assess testing personnel competency for 1 (Testing Personnel #13) of 20 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Moderate Complexity Competency Assessments" policy on 7/20/22 revealed a section stating, "This procedure applies to all donor center staff / employees that perform Moderate Complexity Testing. The Moderate Complexity Competency Assessments timeframes are as follows: o Initially upon completion of training and certification to perform Moderate Complexity testing o Six-Months after initial assessment o Twelve Months after initial assessment, and o Annually thereafter." 2. A review of the laboratory's testing personnel competency records revealed Testing Personnel #13 had been hired in July 2021 and the initial competency assessment was dated 9/9/21. 3. The surveyor requested the Testing Personnel #13's semiannual competency assessment performed after the initial competency assessment dated 9/9/21 on 7/20/22 at 10:06 am and it was not made available. 4. An interview on 7/20/22 at 10:15 am with the Center Manager confirmed the laboratory had not assessed Testing Personnel #13's competency according to its policy.