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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 13D2090204 | (X3) Date Survey Completed 06/11/2025 |
| Name of Provider or Supplier Biomat Usa Inc | Street Address, City, State 771 N College Rd, Twin Falls, ID | |
| 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 | A validation survey was conducted by the Idaho CLIA state agency at the facility on June 11, 2025. The laboratory was found out of compliance with the following standard: |
| 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 a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory procedures, training and competency assessment records and an interview with the Quality Systems Manager on 6/11/2025, the laboratory failed to establish a procedure for competency assessments for the technical consultant (TC) in 2023, 2024 and 2025. The findings include: 1. The CMS 209 identified 22 testing personnel (TP) performing moderate complexity testing and one TC. 2. A review of laboratory procedures identified that the laboratory established a procedure to assess TP initial training, semiannual and annual competency but failed to establish a procedure for competency assessment performance for the TC. 3. A review of training and competency assessment records identified that the laboratory failed to have a competency assessment for the TC in 2023, 2024 and 2025. 4. An interview with the Quality Systems Manager on 6/11/2025 at 10:38 am confirmed the above findings. 5. The laboratory reports performing 38,400 tests annually.</p> |