

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2090204	(X3) Date Survey Completed 12/02/2021
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from Accutest, refractometer comparison forms and an interview with the center manager on 12/2/2021, the laboratory failed to test the total protein PT samples in the same manner as patient samples are tested. The findings include: 1. A review of PT records for total protein testing from Accutest for 2021 event one and the laboratory refractometer comparison forms identified that the laboratory testing personnel performed PT testing on March 26, 2021 and performed refractometer comparison testing on March 27, 2021 using the 2021 event one PT samples. The laboratory failed to test the PT samples in the same routine manner as used for testing patient samples. 2. An interview with the center manager on 12/2/2021 at 1:45 pm confirmed that the laboratory failed to test the PT samples in the same manner that patient samples are tested. 3. The laboratory reports performing 25,000 total protein tests annually.</p>