

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2173410	(X3) Date Survey Completed 07/21/2021
Name of Provider or Supplier Biomat Usa, Inc	Street Address, City, State 419 E University Drive, Edinburg, TX	
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's total protein testing procedure, review of the total protein testing instruments' verification studies and interview with the staff it was determined the laboratory failed to document verification of total protein normal ranges for the facility's patient population. The findings were: 1. Review of the laboratory's "Total Protein Determination-Reichert" standard operating procedure (reviewed and signed by the Laboratory Director on Jun 09, 2020) revealed: "1. Total protein determination is performed on the donor prior to each donation. 2. Total protein results must be within acceptable limits: a. 6.0 gram to 9.0 grams." And "4. Donor Acceptability. a. Determine if the result is in the normal range of 6.0 - 9.0 grams." 2. Review of the laboratory's total protein testing instruments' performance verification studies revealed the studies were completed on 12/12/2019 on the</p>

following Reichert refractometers: Instrument Serial # 12171-0918, designated as #1 Instrument Serial # 12172-0918, designated as #2 Note: Both instruments were placed into use on 12/23/2019 3. Further review of the laboratory's instrument performance verification studies revealed the laboratory did not document verification of total protein patient normal ranges for this facility's tested population. 4. In an interview on 07/21/2021 at 1110 hours in the conference room Testing Person #8 (as described on CMS form 209 signed by the Laboratory Director on 07/20/2021) stated that per corporate recommendation the individual facilities no longer perform total protein patient normal range verification, and must follow the normal range as defined in corporate procedures. This confirmed the findings.