Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1054198	02/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Biomat Usa, Inc	4321 Summer Avenue, Memphis, TN	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the document titled "Equipment Qualification-Refractometer" for the Reichert TS Meter Plasma Protein Refractometer, the document titled "TS Meter-DSP Plasma Protein Refractometer User's Guide Reichert Technologies" and interview with the center manager, the laboratory failed to verify the upper reportable range for the total protein assay using the Reichert TS Meter in 2018. The findings include: 1. Observation of the laboratory on February 12, 2018 at 1:00 pm revealed the Reichert TS Meter Plasma Protein Refractometer in use for patient testing. 2. Review of the document titled "TS Meter-DSP Plasma Protein Refractometer User's Guide Reichert Technologies" page 3 revealed a range of 0.0-14.0 g/100ml for the total protein assay. 3. Review of the documents titled "Equipment Qualification-Refractometer" dated 01/22/2018 revealed that validation of the instrument did not span the high reportable range for ten of ten instruments (equipment id #s 0005110008, 0005110009, 0005110010, 0005110011, 0005110012, 0005110013, 0005110014, 0005110015, 0005110016, 0005110017). Highest level verified for any of the ten instruments was 10.4. 4. Interview with the center manager on February 12, 2018 at 5:30pm confirmed the laboratory began using

	the Reichert TS Meter Plasma Protein Refractometer for patient testing beginning February 8, 2018, and failed to verify the upper reportable range for the Reichert TS Meter Plasma Protein Refractometer prior to patient testing in 2018.