Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2058191	08/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Biomat Usa Inc	815 Grant Street, Laredo, 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	An entrance conference was held 08/16/2018 with the laboratory staff. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 08/16/2018, this facility was found to be in substantial compliance for the specialties/subspecialties in which it was surveyed. An exit conference was held 08/16/2018 with the laboratory staff. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. An opportunity for questions and comments was provided.
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of AccuTest proficiency records from 2017 (Events 1 ,2 and 3) and 2018 (Events 1 and 2) for Routine Chemistry Urine Total Protein, laboratory records, and interview of laboratory staff, it was revealed that the laboratory failed to attain an overall testing event score of at least 80% for 1 of 5 events. Findings included: 1. Review of the AccuTest proficiency records from 2017 (Events 1,2 and 3) and 2018 (Events 1 and 2) for Routine Chemistry Urine Total Protein revealed that the laboratory received an unsatisfactory score of 0% for 1 of 5 events. The results entered by the laboratory and the acceptable range are as follows: a. 2017 Event 1 Sample A Laboratory Result 6.8 Acceptable Range 60-75 b. 2017 Event 1 Sample B Laboratory Result 10.5 Acceptable Range 95-117 c. 2017 Event 1 Sample C Laboratory Result 2.6 Acceptable Range 22-28 d. 2017 Event 1 Sample D Laboratory Result 8.8 Acceptable Range 80-98 e. 2017 Event 1 Sample E Laboratory Result 4.6 Acceptable Range 40-50 2. Review of laboratory records revealed the laboratory failed to enter the proper units of measure for the Urine Total Protein sample results. The laboratory record titled "CLIA Investigation Report" stated "When completing

	online form and recording the results in the computer, g/L was entered as unit instead of g/dL. 3. In an interview with laboratory staff on 08/16/2018 at 1141 in the conference room, the laboratory was asked, "Do you have documentation of self-grading the proficiency results?" The laboratory staff stated "No." The laboratory failed to provide documentation of self-grading 2017 Event 1 AccuTest proficiency testing. This confirmed the findings.
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 review of the laboratory's verification records for the Reichert Refractometers, quality control records and staff interview, it was revealed that the laboratory failed to have documentation of verifying the analyzers' precision and verifying the normal patient range prior to utilizing the refractometers for patient testing for the following refractometers: Findings included: 1. A review of the verification records for the Reichert Refractometer revealed the laboratory failed to have documentation of precision and verification of patient normal ranges for the following analyzers: a. Refractometer #10 (Serial Number 11895-0618) In Use b. Reichert Refractometer #11 (Serial Number 11896-0618) In Use c. Refractometer #1 (Serial Number Unidentified) Inactive d. Refractometer #2 (Serial Number Unidentified) Inactive e. Refractometer #3 (Serial Number Unidentified) Inactive f. Refractometer #4 (Serial Number Unidentified) Inactive g. Refractometer #5 (Serial Number Unidentified) Inactive h. Refractometer #6 (Serial Number Unidentified) Inactive i. Refractometer #7 (Serial Number Unidentified) Inactive j. Refractometer #8 (Serial Number Unidentified) Inactive k. Refractometer #9 (Serial Number Unidentified) Inactive 2. The laboratory was asked to provide documentation of precision verification and for patient normal range verification for ALL refractometers at the facility. No documentation was provided. 3. During an interview with laboratory staff on 08/16/2018 at 12:30 PM, the staff was asked to provide validation studies for precision and normal patient ranges for each refractometer at the facility. No documentation was provided. This confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

	system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration records from January 2017 through January 2018, the laboratory's quality control records, and staff interview, it was revealed that the laboratory failed to have documentation of performing calibration verification every 6 months with lot numbers of quality control material different from the lot numbers of quality control that were currently in use. 1. Review of the laboratory's quality control records revealed that every 6 months the laboratory performed Refractometer calibration verifications using Low, Normal and High control levels. 2. Review of the laboratory calibration record titled "Equipment Calibration and Maintenance" revealed the following lot numbers used for the calibration verification: 01/17/2017 a. Low Control Lot# K301008 b. Normal Control Lot# K301003 c. High Control Lot#K301001 07/17/2017 a. Low Control Lot# K301008 b. Normal Control Lot# K301003 c. High Control Lot#K301001 01/13/2018 a. Low Control Lot# K301008 b. Normal Control Lot# K301818 c. High Control Lot#K301001 The same lot number for low and normal controls used for calibration verification on 01/17/2017, 07/17/2017 and 01/13/2018 was also being used for the daily Refractometer quality control on those dates. 3. During an interview on 08/16 /2018 at 11:15 in the conference room, the laboratory staff was asked to provide documentation that lot numbers other than those lot numbers currently in use were utilized to perform the 6-month calibration verification. The laboratory staff stated "We use the same lot of controls for the 6-month verifications." This confirmed the above findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records and staff interview, it was revealed that the laboratory directory failed to ensure that verification studies for the Reichert Refractometers were completed prior to testing patient samples. (Refer to D5421)