Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1075051	11/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Biomat Usa, Inc	355 E 3rd St, Calexico, CA	

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
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 the laboratory's proficiency testing (PT) results reports, and interview with the center supervisor, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent is unsatisfactory performance. The findings included: a. The laboratory performed serum total Protein by using Reichert TS-DSP Refractometer. b. The laboratory enrolled it proficiency testing with Accurtest PT provider to verify the proficiency testing performance annually. c. The laboratory attained a score of 0 % for serum total Protein an overall testing in the 1st 2017 PT event which was unsatisfactory performance. d. The laboratory performed serum total Protein in approximately 8,333 patient samples monthly. e. The laboratory affirmed (11/20/18 @ 14:05) that the laboratory failed to attain an overall testing event score of at least 80 percent which was unsatisfactory performance
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 proficiency testing (PT) results reports, and interview with the center supervisor, it was determined that the laboratory failed to perform and document calibration verification procedures, at least once every 6 months 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. The findings included: a. The laboratory performed serum total Protein by using Reichert TS-DSP Refractometer. b. The laboratory uses distill water to do calibration in daily use. c. The laboratory failed to perform and document calibration verification at least once every 6 months 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.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) results reports, and interview with the center supervisor, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2088
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) results reports, and interview with the center supervisor, it was determined that the laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided. The findings included: See D-5439