Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1081650	01/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Biomat Usa, Inc	13473 Perris Blvd, Moreno Valley, 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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, instrument comparison records, laboratory policies, procedures, and interview with laboratory personnel, for 10 out of 10 total protein patients records reviewed from January 14, 2017 to October 20, 2018, it was determined that the laboratory failed to test proficiency testing samples the same number of times that it routinely tests patient samples. The findings included: a. The laboratory was enrolled in the Accutest proficiency testing program (lab identification number CA1216) for Total Protein. b. The laboratory has multiple Reichert refractometers in use with the following serial numbers: 0650-1113, 02533-1207, 02532-1207, 02845-0608, and 06507-1113. c. Review of laboratory procedure entitled, "Refractometer Validation", implementation date 2/22/2016, stated "Sample drawn from the leftover Proficiency Test vial will be evaluated in-house via the method recommended by the Proficiency Test company-comparison to published results." The laboratory failed to adhere to the CLIA regulation 493.801 (b) (2): The laboratory must test samples the same number of times that it routinely tests patient samples. d. Review of Refractometer Comparison Form Records and Accutest worksheet for proficiency testing showed the test dates for total protein to be the same for the proficiency testing sample and multiple refractometers used in the laboratory. e. The laboratory affirmed 1/23/19 12:30 PM (survey date) that proficiency testing samples were not tested the same number of times that it routinely tests patient samples.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a)

	Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on interviews with the staff on January 23, 2019, and review of Accutest proficiency testing records from the 1st testing event of 2017 through the 3rd testing event of 2018, for one out of six proficiency testing events reviewed, the laboratory failed to attain a score of at least 80 percent in the specialty of Routine Chemistry. The findings included: a. The laboratory is enrolled in the Accutest proficiency testing program (lab identification number CA1216) for Total Protein. b. Laboratory proficiency testing records showed the laboratory attained a score of 0% for total protein testing during the 1st proficiency testing event of 2017. c. A testing person affirmed on January 23, 2019, the unsatisfactory score of 0% obtained by the laboratory for total testing during the 1st proficiency testing event of 2017. d. Based on the annual test volume reported, the laboratory performed and reported approximately 30,000 total protein tests for the specialty of Routine Chemistry.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director of moderate complexity testing failed to ensure quality testing was monitored and evaluated for the overall quality of the analytical systems and to correctly identify problems for testing performed. (See D5403)
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.

	(12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: The procedure manual must include the following when applicable to the test procedure: (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. The Findings include: See 5783
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policies/procedures, quality control records, for 10 out of 10 randomly selected patients records reviewed from January 14, 2017 to October 20, 2018 and an interview with the laboratory personnel for 10 out of 10 total protein patients records reviewed from January 14, 2017 to October 20, 2018, it was determined that the laboratory's failed to include corrective action steps to be taken when the quality control failed the laboratory's acceptability criteria. The findings included: a. On January 23, 2019 at approximately 12:30 pm (survey date) for 04/13 /2017, 06/21/2017, 07/24/2017, 10/31/2017, 12/05/2017, 12/13/2018 the total protein quality control testing performed on the Reichert refractometer instrument that no documentation of corrective action was noted when the quality control failed to meet the reference criteria. Smpl# Date performed result Control 30 04/13/17 7.9 Normal 3 06/21/17 7.9 Normal 4 06/22/17 7.9 Normal 5 06/23/17 7.9 Normal 19 07/24/17 4.7 Low 4 12/05/17 7.8 Normal 26 10/31/17 7.9 Normal 28 12/13/18 7.8 Normal b. The laboratory policy "Total Protein Control/Refractometer Reichert stated: under "4. STATISTICAL ANALYSIS: "An acceptable range will be established using the formula: Range = mean +/- 2SD. Results will be plotted in control charts and data will be comprehensively analyzed." c. Quality control records (Daily Control Report Reichert Digital Refractometer-Statistical analysis Worksheet)) showed that patients results were reported when the quality control results exceeded 2SD (See D5403), and the QC results exhibited shifts and trends. d. The laboratory affirmed 1/23/19 12:30 pm (survey date) that quality control results had exceeded the established reference range and no corrective actions was documented and patient testing results were reported, the quality and accuracy those the patient results could not be affirmed. e. Per the Laboratory Testing Declaration (01/23/2019), approximately 28,000 total protein specimens were tested annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the total protein quality control (QC) record review, 10 out of 10 randomly selected patients records reviewed from January 14, 2017 to October 20, 2018 and an interview with the laboratory personnel, the laboratory failed the written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. The findings included: a. On 01/23/2019 (survey date), it was found that the laboratory was not documenting corrective action(s) for trending and shifting of their quality control (QC) from 07/25/2017 to 07/21/2017, 12/15/2017 to 12/12/2017, 10/13 /2018 to 10/24/2018. The laboratory performed two (2) levels of controls daily (in-use). During this period the quality controls for all parameters for the total protein testing periodically had trended and shifted to the upper limits of the reference range and yet no corrective actions were noted on the QC data reports. No corrective actions were documented for quality control trending and shifting failures or when quality controls were outside of reference criteria (see 5783). b. On 01/23/2019 the laboratory personnel confirmed that no documentation was recorded for ongoing quality control mechanism to monitor, assess, and correct problems when identified. c. The laboratory testing declaration (01/23/2019) estimated an annual total protein patient testing volume of 28,000.
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 proficiency testing records, instrument comparison records, laboratory policies, procedures, and interview with laboratory personnel and technical consultant, for 10 out of 10 randomly selected patients total protein testing records reviewed from January 14, 2017 to October 20, 2018, it was determined that the laboratory failed to ensure that proficiency testing samples are tested as required under subpart H. The findings included. See D2010.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the

	specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the lack of quality control(QC) records, a random sampling of 10 out of 10 total protein patients records reviewed from January 14, 2017 to October 20, 2018, performance specification records, and interview with a technical consultant, that the laboratory failed to establish a quality control program appropriate for testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that those levels were maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. (See D5783, D5791)