

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2149975	(X3) Date Survey Completed 11/15/2023
Name of Provider or Supplier Biomat Usa Inc	Street Address, City, State 201 1st Street W, Humble, 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 announced validation survey was performed on November 15, 2023. The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the review of the laboratory's quality control records from January 2023 to September 2023, the laboratory's submitted CMS 116 application, and confirmed in an interview, the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for four of four Reichert digital refractometers in use for the test of total protein for nine of nine months reviewed. The findings were: 1. Review of the laboratory's records revealed the laboratory had four Reichert digital refractometers in use. SN: 11655-0418 Equipment#: E17837 Alias: D40 SN: 11654-0418 Equipment#: E17838 Alias: D41 SN: 11730-0518 Equipment#: E17842 Alias: D44 SN: 11634-0318 Equipment#: E17843 Alias: D45 2. Surveyor's direct observation on 11/15/23 at 11:50</p>

am in the quality control storage area revealed the laboratory used KOVA Refractrol low and Normal controls. KOVA Refractrol Low Control Lot#: K305931 Ranges: 3.2-4.7 KOVA Refractrol Normal Control Lot#: K306166 Ranges: 7.3-8.1 3. Review of the laboratory's quality control records from January 2023 to September 2023 revealed the laboratory did not have a method in place to monitor quality control values over time to detect shifts and trends for four of four Reichert digital refractometers in use for the test of total protein for nine of nine months reviewed. January 2023 February 2023 March 2023 April 2023 May 2023 June 2023 July 20223 August 2023 September 2023 4. Review the laboratory submitted CMS 116 application, signed by the LD on 11/07/2023 revealed the annual volume was 44950. 5. An interview with the center manager and quality systems manager on 11/15/2023 at 12:10 pm in a conference room confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Service LD=Laboratory Director

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have high school U.S. equivalency documentation to qualify one of 18 testing personnel (TP) who performed moderate complexity testing on Reichert digital refractometers. (Refer to 6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have U.S. equivalency documentation of high school diploma to qualify one of 18 TP who performed moderate complexity testing on Reichert digital refractometers. The findings were: 1. Review of the laboratory's submitted CMS 209, Laboratory Personnel Report, signed by the LD on 11/07/23 revealed the laboratory identified 18 TP who performed moderate complexity testing on Reichert digital refractometers. 2.

Review of the laboratory's TP educational credential records revealed the laboratory failed to have U.S. equivalency documentation of high school diploma to qualify one of 18 TP who performed moderate complexity testing on Reichert digital refractometers. TP#16 Hired Date: 3/24/2022 3. An interview with the center manager and quality systems manager on 11/15/2023 at 12:20 pm in a conference room confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services U.S.=United States TP=Testing personnel LD=Laboratory Director