

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2154093	(X3) Date Survey Completed 12/22/2020
Name of Provider or Supplier Biomat Usa, Inc	Street Address, City, State 5341 E Thompson Road, Indianapolis, IN	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on document review and interview (email confirmation), the laboratory failed to successfully participate in the Accutest, Inc. Proficiency Testing (PT) program for Total Protein, for one of one analyte, in the subspecialty of Routine Chemistry. The laboratory has two consecutive unsatisfactory testing Events (Events 2 and 3, 2020) for both Total Protein and Routine Chemistry. (Refer to D2096.)</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on document review and interview (email confirmation), the laboratory failed to achieve a PT score of 80% or higher for Total Protein and Routine Chemistry during two consecutive PT events (Events 2 and 3, 2020), resulting in unsatisfactory performance. Findings include: 1. Review of "CASPER Report 0155D" indicated the laboratory received unsatisfactory scores: a) for Total Protein: 1) Event 2, 2020 = 0% 2) Event 3, 2020 = 60% b) for the subspecialty of Routine Chemistry: 1) Event 2, 2020 = 0% 2) Event 3, 2020 = 60% 2. Review of proficiency testing scores from Accutest, Inc., indicated the above failing scores for events two and three in 2020. 3. In interview on 12/18/20 at 2:00 pm, SP-1 (One World Accuracy Support Representative/Accutest), confirmed (via email), the unsatisfactory scores from Accutest, Inc. (Proficiency Testing Provider) for the above listed analyte, Total Protein and the subspecialty Routine Chemistry.