

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0658932	(X3) Date Survey Completed 05/01/2019
Name of Provider or Supplier Marshall County Healthcare Center	Street Address, City, State 413 9th Street, Britton, SD	
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 proficiency testing (PT) record review and interview with the laboratory supervisor, the laboratory failed to achieve successful participation for the compatibility test method. Unsatisfactory results had been received in two of three College of American Pathologists PT events (J-C 2018 and J-A 2019 Transfusion Medicine [Comp] events) resulting in unsuccessful PT participation. Refer to D2181.</p>
D2181	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p>

Failure to achieve an overall testing event score of satisfactory for 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 review of CASPER Reports and interview with the laboratory supervisor, the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the compatibility test method in two out of three events College of American Pathologists (CAP) events (J-C 2018 and J-A 2019 Transfusion Medicine [Comp] events). 1. Review of the laboratory's CASPER Reports 153D and 155D revealed the CAP PT scores for the compatibility test method were less than the 100% required to pass the compatibility test per CLIA requirements found at CFR 493.861(a): a. J-C 2018 Transfusion Medicine (Comp) compatibility score = 67% (J-19S was graded as unacceptable). b. J-A 2019 Transfusion Medicine (Comp) compatibility score = 67% (J-04S was graded as unacceptable). Interview with the laboratory supervisor on 4/29 /19 confirmed the failure. She stated she had investigated the unsatisfactory results. In the first event sample J-19S had a positive antibody screen result. Laboratory staff did not perform the IgG phase of compatibility testing which was required when a specimen had a positive antibody screen. Laboratory staff performed only an immediate spin compatibility test and that result was reported as compatible. In the second event, the laboratory staff reported the cell suspension had been too heavy which led to a false positive result. The laboratory staff involved had received additional training.