

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0441828	(X3) Date Survey Completed 09/13/2022
Name of Provider or Supplier Madison Medical Center	Street Address, City, State 611 West Main, Fredericktown, MO	
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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on review of 2021 and 2022 immunohematology proficiency testing (PT) results reported to the CLIA database by the PT provider and phone interview with the technical supervisor, the laboratory failed to successfully participate in PT. See D-tag 2181; unsatisfactory performance in two out of three consecutive compatibility PT challenges.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e)

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 immunohematology proficiency testing (PT) results for 2021, 2022 and phone interview with the technical supervisor, the laboratory failed to achieve satisfactory performance for compatibility testing in two out of three consecutive PT events. Findings: 1. Review of the immunohematology PT results for the third event of 2021 revealed the laboratory obtained an unacceptable score of 0 percent for compatibility testing. 2. Review of the immunohematology PT results for the second event of 2022 revealed the laboratory obtained an unacceptable score of 80 percent for compatibility testing. 3. Phone interview with the technical supervisor on September 12, 2022 at 1:17 PM confirmed the laboratory failed to achieve satisfactory performance for compatibility testing in two out of three consecutive PT events.