

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0445888	(X3) Date Survey Completed 02/08/2021
Name of Provider or Supplier Hermann Area District Hospital	Street Address, City, State 509 West 18th Street, Hermann, 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	<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 review of immunohematology compatibility testing proficiency testing (PT) results for 2020 reported to the CLIA database by the PT provider and phone interview with the laboratory manager, the laboratory failed to successfully participate in PT. See tag D2173; failure to attain an overall event score of 100 percent for compatibility testing. See tag D2181; unsatisfactory performance in two out of three consecutive testing events for the analyte; compatibility testing.</p>
D2173	<p>COMPATIBILITY TESTING CFR(s): 493.863(a)</p>

Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Based on review of immunohematology compatibility testing proficiency testing (PT) results and phone interview with the laboratory manager, the laboratory failed to attain an overall testing performance score of 100 percent for the first and third testing events for 2020. Findings: 1. Review of compatibility PT results for 2020 showed the laboratory obtained a score of 80 percent in the first testing event and 0 percent in the third testing event. 2. Phone interview with the laboratory manager on February 8, 2021 at 08:30 AM confirmed the laboratory failed to attain a testing performance score of 100 percent for compatibility testing in the first and third testing events of 2020.

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 and phone interview with the laboratory manager, the laboratory failed to achieve satisfactory performance for compatibility testing in two out of three testing events for 2020. Findings: 1. Review of the immunohematology PT results for the first testing event of 2020 revealed the laboratory obtained an unsatisfactory score of 80 percent for compatibility testing. 2. Review of the immunohematology PT results for the third testing event of 2020 revealed the laboratory obtained an unsatisfactory score of 0 percent for compatibility testing. 3. Phone interview with the laboratory manager on February 8, 2021 at 08:30 AM confirmed the laboratory failed to achieve satisfactory performance for compatibility testing in two out of three consecutive events in 2020.