Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445888	11/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hermann Area District Hospital	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
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT), immunohematology quality control (QC), initial training, quality control and quality assessment program, and interviews, the laboratory director (LD) failed to provide overall management and direction of the laboratory. The LD failed to ensure PT testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (Refer to D6091); the LD failed to ensure immunohematology QC programs and quality assessment programs are maintained to assure the quality of laboratory services and to identify failures in quality as they occur (Refer to D6093); the LD failed to ensure acceptable levels of analytic performance in immunohematology for 43 days (Refer to D6095); and LD failed to ensure initial training was performed on one new testing personnel (TP) prior to testing patient specimens (Refer to D6102).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by:

	Based on review of 2024 and 2025 proficiency testing (PT) records and interview with the general supervisor (GS), the laboratory director failed to ensure PT testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for three of five PT events in 2024 and 2025. Findings: 1. Review of 2024 PT records revealed American Proficiency Institute (API) Immunohematology 3rd Event showed no documentation of review by appropriate staff. 2. Review of 2025 PT records revealed API Immunohematology 1st Event and 2nd Event showed no documentation of review by appropriate staff. 3. Interview with GS on November 12, 2025 at 2:00 PM confirmed the laboratory director failed to ensure PT testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action in 2024 and 2025.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of immunohematology quality control (QC), review of the quality assessment (QA) program and interview with the general supervisor (GS), the laboratory director failed to ensure immunohematology QC programs and QA programs are maintained to assure the quality of laboratory services and to identify failures in quality as they occur. Findings: 1. Review of immunohematology QC from April 2025 to date November 12, 2025 showed no review by qualified personnel for immunohematology QC to identify failures in quality as they occur. 2. Interview on November 12, 2025 with testing personnel #3 stated they manually put the patients immunohematology results in the laboratory information system (LIS). 3. Review of immunohematology showed no QA addressing the manual immunohematology results entered into the LIS to identify failures in quality as they occur. 4. Interview with the GS on November 12, 2025 at 2:00 PM confirmed the laboratory director failed to ensure immunohematology QC and QA programs are maintained to assure the quality of laboratory services and to identify failures in quality as they occur.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of immunohematology quality control (QC) from January 2024 to date November 12, 2025, and interview with the general supervisor (GS) #1, the laboratory director failed to ensure acceptable levels of analytic performance in immunohematology for 43 of 687 days. Findings: 1. Review of immunohematology QC showed no documentation of QC: January 24, 2024 to January 29, 2024 May 26, 2024 to May 31, 2024 March 1, 2025 to March 31, 2025 2. Interview with the GS on November 12, 2025 at 2:00 PM confirmed the laboratory director failed to ensure acceptable levels of analytic performance 43 days.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of competencies, and interview with the general supervisor (GS), the laboratory director failed to ensure initial training was performed on one of two new testing personnel (TP) prior to testing patient specimens. Findings: 1. Review of competencies showed no initial training in February 2025 for TP #5. 2. Interview with GS on November 12, 2025 at 1:00 PM confirmed the laboratory director failed to ensure initial training was performed on TP #5 prior to testing patient specimens.