Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445888	11/04/2024
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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of patient blood bank worksheet, blood bank policies, laboratory procedures, 2023/2024 Vitros 5600 calibration records, Sysmex CA-660 coagulation quality control (QC) records, coagulation patient reports, blood bank QC log, observation, blood bank patient crossmatch tags, nursing progress notes, physician progress notes, hospital policy and procedure manual, lack of documentation of communication with laboratory, corrective action documentation, hospital transfusion procedures, and interview, the laboratory failed to follow procedures for documentation on blood bank patient worksheets (Refer to D5401); the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range in 2023 and 2024 (Refer to D5439); the laboratory failed to ensure results of the QC materials met manufacturer's test system criteria for acceptability before reporting patient test results for 3 of 23 patient test results for D Dimer (Refer to D5481); the laboratory failed to ensure the acceptability of QC results prior to accepting patient results for 1 of 44 patient test results for partial thrombin time from August 1, 2024 to October 26, 2024 (Refer to D5545); the laboratory failed to document quality control for three days from January 1, 2024 to date October 29, 2024 (Refer to 5551A); the laboratory failed to follow defined laboratory procedures (Refer to D5551B); and the laboratory failed to ensure

	that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused (Refer to D5559).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of blood bank policies, review of patient blood bank worksheet, and interview with general supervisor (GS), the laboratory failed to follow procedures for documentation on blood bank patient worksheets. Findings: 1. Review of policy "History Check" states, "Document whether or not blood bank records for the patient are found. Perform a result inquiry that goes back at least 10 years." "Verify these three things if records are found: Patient type and Rh match the new results, unexpected antibodies identified, any past transfusion reactions." 2. Review of policy "Immediate Spin Crossmatch" does not state the length of time the crossmatch is acceptable before expiration. 3. Review of blood bank worksheet 0033 for patient with medical record number 96243 and BB Spec Accession number 39-24-232-0031 showed the following: blood type and antibody screen performed: 08/19/2024 at 1400 by SM crossmatch performed: date and time unavailable history for patient documented as "found" and "A pos". No documentation for historic antibodies. patient had historical anti-e antibody Unit number W181124090196002 was released to nursing for transfusion on 08/22/2024 at 1343. 4. Review of blood bank worksheets 0043 with BB Spec Accession number 39-24-283-0087 showed the following: blood type performed: no date and time available history: no documentation of history look back performed 5. Interview with the GS on October 29, 2024 at 10:30 AM confirmed the laboratory failed to follow procedures for documentation on blood bank patient worksheets.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable

	limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, 2023/2024 calibration records for the Vitros 5600 chemistry analyzer and interview with the general supervisor (GS) #1, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range in 2023 and 2024. Findings: 1. Review of laboratory procedure "Quality Control Vitros 5600" states "Accuracy across the reportable range is verified semiannually. Linearity materials are traceable. They verify the upper and lower reportable limits and contains at least 5 points." 2. Review of the Vitros 5600 chemistry analyzer calibration records for 2023 /2024 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: acetaminophen, albumin, alcohol, alkaline phosphatase, alanine aminotransferase, amylase, asparate aminotransferase, brain natriuretic peptide, blood urea nitrogen, calcium, cholesterol, creatine kinase, chloride, creatinine, c-reactive protein, carbon dioxide, iron, ferritin, folate, glucose, high density lipoprotein, hemoglobin A1C, potassium, lactic acid, lipase, magnesium, sodium, phosphorus, prostate specific antibody, unconjugated/conjugated bilirubin, total iron binding capacity, total protein, triglyceride, troponin, thyroid stimulating hormone, uric acid, vitamin D, vitamin B12, and vancomycin. 3. Interview with the GS #1 on October 30, 2024, at 1:30 PM confirmed the laboratory failed to perform calibration verification procedures at least once every six months.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Sysmex CA-660 coagulation analyzer quality control (QC) records, patient reports and interview with the general supervisor, the laboratory failed to ensure results of the QC materials met manufacturer's test system criteria for acceptability before reporting patient test results for 3 of 23 patient test results for D Dimer. Findings: 1. Review of QC records for D Dimer showed the acceptable range for Level One QC is 0.28-0.42 mg/L. 2. Review of QC records for D Dimer showed the laboratory did not have acceptable QC before reporting patients for the following: October 7, 2024 Level One results 0.21 mg/L and 0.23 mg/L October 26, 2024 Level One results 0.27 mg/L and 0.25 mg/L 3. Patients were resulted at the following times: Specimen accession number 39-24-281-0009 verified October 7, 2024 at 06:53 AM Specimen accession number 39-24-300-0013 verified October 26, 2024 at 1141 AM Specimen accession number 39-24-300-0038 verified October 26, 2024 at 9:21 PM. 4. Interview with the general supervisor October 29, 2024 at 11:00 AM confirmed the laboratory failed to ensure results of the QC materials met manufacturer's test system criteria for acceptability before reporting patient test results.

D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on interview, review of the Sysmex CA-660 coagulation analyzer quality control (QC) records, patient reports and interview with the general supervisor, the laboratory failed to ensure the acceptability of QC results prior to reporting patient results for 1 of 44 patient test results for partial thrombin time (PTT) from August 1, 2024 to October 26, 2024. Findings: 1. Interview with the general supervisor stated, "due to humidity being out of specification for the Coag analyzer, all QC is to be run with each patient for Protime, PTT, and D Dimer. The humidity has been out since October 1st. QC is only good for 15 minutes." 2. Review of patient results and QC records for PTT showed the laboratory ran a patient for PTT at 9:33 PM on October 21, 2024 with the last QC run at 4:57 PM on October 21, 2024. 3. Interview with the general supervisor October 29, 2024 at 11:00 AM confirmed the laboratory failed to ensure the acceptability of QC results prior to accepting patient results .
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on interview, review of blood bank quality control (QC) log, and interview with the general supervisor (GS) #1, the laboratory failed to document quality control (QC) for three days from January 1, 2024 to date October 29, 2024. Findings: 1. Interview with the general supervisor #1 on October 29, 2024 at 9:45 AM, the GS #1 stated that "they perform blood bank QC daily." 2. Review of the blood bank QC log states "Daily QC." 3. Review of blood bank QC logs showed no documented QC on January 26, 2024, June 6, 2024 and June 13, 2024. 4. Interview with the GS #1 on October 29, 2024 at 10:00 AM, confirmed the laboratory failed to document quality control for three days in 2024. Surveyor: Brake, Kimberly B. Based on observation, blood bank procedures, and interview with the testing personnel and general supervisor, the laboratory failed to follow defined laboratory procedures. Findings: 1. Observation of refrigerator showed MTS IgG and ABD monoclonal and reverse blood bank cards are stored in the refrigerator at 2-8 Celsius. 2. Procedure for MTS IgG blood bank cards states, "bring samples and reagents to room temperature (18-25C)."

	3. Procedure for MTS ABD monoclonal and reverse blood bank cards states, "bring samples and reagents to room temperature (18-25C)." 4. Interview with testing personnel #3 stated, "we use the ABD cards right out of the refrigerator and the IgG cards are incubated for 15 minutes prior to using." 5. Interview with the general supervisor on October 29, 2024 at 10:00 AM confirmed the laboratory failed to follow defined laboratory procedures. 47802
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of blood bank patient crossmatch tags, Nursing Progress Notes, Physician Progress Notes, hospital policy and procedure manual, lack of documentation of communication with laboratory, corrective action documentation, hospital transfusion procedures and interview with the laboratory director (LD), the laboratory failed to ensure that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. Findings: 1. Review of blood bank patient crossmatch tags showed patient MRN 103574 had the transfusion of unit# W18242006088 A stopped at 2:35 PM on March 21, 2024. 2. Review of Nursing Progress Note showed patient MRN 103574 "complained of feeling short of breath and shivering while receiving 2nd unit of PRBC. NP ordered transfusion to be stopped and IV Lasix to be given." 3. Review of Physician Progress Note showed patient MRN 103574 "03/21/2024 2:41 PM was notified by nursing staff that patient has new complaints of shortness of breath and is slightly hypoxia. Transfusion of 2nd unit was nearly completed. Ordered to stop transfusion and obtain a chest x-ray to evaluate prior noted pleural effusion. Nursing reports all other vital signs including temp, heart rate and blood pressure were within normal limits. 03/21/2024 at 4:00 PM patient also noted with low grade fevers". 4. Review of hospital policy and procedure manual showed policy "Blood Administration: Transfusion of Blood Products" states "Observation of adverse effects during administration with appropriate actions if such effects should occur will be documented in the patient EHR (i.e., immediately stopping of administration, notification of provider and the Laboratory." 5. Lack of documentation of communication with the laboratory showed hospital staff failed to notify the laboratory of the possible transfusion reaction. 6. Review of correction action documentation showed 12 of 39 nursing staff attended the transfusion reaction training following the incident on March 21, 2024. 7. Review of the hospital's transfusion procedures showed that the hospital and laboratory failed to review and update the hospital transfusion procedures to match the updated laboratory procedure. 8. Interview with the laboratory director on October 29, 2024, at 1:00 PM confirmed

	the laboratory failed to ensure that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on interview, review of Vitros 5600 chemistry quality control (QC) for 3 of 39 analytes and interview with the technical supervisor (TS), the TS failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained. Findings: 1. Interview with the general supervisor stated the laboratory adjusts chemistry QC to peer ranges and standard deviations. 2. Review of Vitros 5600 chemistry analyzer QC results for alkaline phosphatase, total bilirubin and hemoglobin A1c from September 2024 to date October 29, 2024 showed the TS established a standard deviation (SD) for chemistry controls that was larger than the peer standard deviations. 3. Review of QC showed the following SD discrepancies: total bilirubin level 1 QC peer SD .067, laboratory SD .095 total bilirubin level 3 QC peer SD .325, laboratory SD .5 alkaline phosphatase level 1 QC peer SD 1.72, laboratory SD 3 alkaline phosphatase level 3 QC peer SD 10.80, laboratory SD 14 hemoglobin A1c level 1 QC peer SD .146, laboratory SD .3 hemoglobin A1c level 3 QC peer SD .382, laboratory SD .5 4. Interview with the TS on October 30, 2024 at 12:15 PM confirmed the TS failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained.