Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0677527	01/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Comanche County Medical Center Company	10201 Highway 16 North, Comanche, TX	

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
D0000	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of facility and laboratory blood product policies, patient blood transfusion records/electronic notes, and confirmed in staff interview, the facility failed to promptly identify, investigate and report blood transfusion reactions to the laboratory for 1 of 10 patients randomly reviewed from September to December 2022. Findings included: 1. Review of the facility policy "Issuing Blood Products" revealed an attachment titled "Blood Products Administration Protocol", the attachment stated:

"Infusion ... During infusion patient will be monitored for signs and symptoms of reaction. If reaction noted, infusion will be stopped immediately, physician notified and Blood Transfusion Reaction Form and Transfusion Related Investigation Form will be initiated." The policy failed to state the laboratory needed to be notified. Review of the "BLOOD TRANSFUSION RECORD" form revealed: "** Watch for the following s/s of transfusion reaction anytime during or after the transfusion. If reaction is suspected, stop infusion, notify doctor and complete "Blood Transfusion Reaction Form and Transfusion Related Investigation form." Unless otherwise indicated, there were no adverse reactions during the transfusion. Signs and Symptoms of reaction: Temperature increased change of 2 degrees Fahrenheit from baseline vital signs for this unit. Gross hematuria/proteinemia (not present prior to transfusion) Pulse increase of 40bpm from Pre-Spiked V/S Systolic Blood pressure with decrease of 30% from baseline vital signs. Systolic Blood pressure increase of 30% from baseline vital signs AND clinical symptoms **(rales, itching, shortness of breath, altered mental status, etc)** Pain in the chest, abdomen, flank, or infusion site. Shaking of chills with/without fever. Respiratory distress, itching, or flushing of the skin. Nausea" The form failed to state the laboratory needed to be notified. 2. Review of the laboratory's policy titled "Transfusion Related Reaction Investigation" stated: "II. Reporting the Transfusion Reaction: All transfusion reactions should be reported to the BB and evaluated to the extent considered appropriate by the pathologist. Major adverse effects, e.g., hemolytic transfusion reactions and disease transmission, must be reported to the Bureau of Biologics, Food and Drug Administration. III. Preliminary steps: Whenever a transfusion reaction involving more than just hives is suspected, the transfusion should be immediately discontinued but the intravenous line kept open. Perform a clerical recheck between the patient and the component. Contract the Pathologist for instructions on patient care and Blood Bank to notify them of the transfusion reaction. IV. Signs and symptoms of acute and delayed adverse consequences of transfusion: Re-establish Baseline vital signs with EACH UNIT for Blood Pressure Condition: Fever Symptoms: Defined as 2 degrees F rise in patient's temperature Condition: Chills Symptoms: With or without rigors Condition: Respiratory Distress Symptoms: Including wheezing, coughing, dyspnea, and cyanosis Condition: Hypertension Symptoms: 30% Increase in Systolic BP Condition: Hypotension Symptoms: 30% Decrease in Systolic BP Condition: Pain Symptoms: Abdominal, chest flank, or back Condition: Skin Manifestations Symptoms: Urticaria, rash, flushing, pruritus, localized edema Condition: Hemoglobinemia Symptoms: The presence of free hemoglobin in the blood plasma Condition: Jaundice Symptoms: Yellowing of the skin and the white of the eyes is indication of red blood cell breakdown. Condition: Abnormal Bleeding Symptoms: Any new onset or unsuspected bleeding occurrence. Oozing blood at IV site. Condition: Oliguria Symptoms: Low urine output (less than 300-500 mL/day) Condition: Anuria Symptoms: Absence of urine output ... IX. Procedure: Nursing/Transfusionist Responsibility i. STOP the transfusion of blood. ii. KEEP the line open with saline. iii. Notify the CCMC Laboratory. Suspected transfusion related reactions must be immediately reported to the Laboratory. iv. Notify the patient's attending Physician for instructions for patient care. v. Obtain the complete a suspected transfusion related reaction investigation form from the laboratory." 3. A random review of blood transfusion patient records and electronic nursing notes (September through December 2023) revealed the following 1 of 10 patients transfused in which the facility did not follow its own policy to ensure transfusion reactions were promptly identified, investigated and documented for all blood products: a. Patient Account: V00000661961 Unit #W141422254872 (second transfused unit) Type: Red Blood Cells Transfusion initiated: 12/09/2022 at 15:45 hours Transfusion ended: 12/09/2022 at 18:00 hours Vital signs documented at baseline 15:37 hours: BLOOD PRESSURE: 187/75

	TEMPERATURE: 97.1 F PULSE RATE: 57 RESPIRATORY RATE: 20 OXYGEN SATURATION: 95 Vital signs documented at end of transfusion 18:10 hours: BLOOD PRESSURE: 170/90 TEMPERATURE: 97.2 F PULSE RATE: 65 RESPIRATORY RATE: 22 OXYGEN SATURATION: 94 Comments: None A review of the electronic nursing note at 12/09/2022 18:40 hours (created 12/09/2022 21:27 hours) revealed: "This nurse entered room for shift change evaluation. Pt lying in bed watching tv. Respirations even, shallow and slightly labored with use of accessory muscles noted. Crackles noted BLL. Pt verbalizes feeling "short of breath" but denies distress. SpO2=92% on room air." Unit #W141422365272 (third transfused unit) Type: Red Blood Cells Transfusion initiated: 12/9/2022 at 20:25 hours Transfusion ended: 12/10/2022 at 00:15 hours Vital signs documented at baseline 19: 40 hours: BLOOD PRESSURE: 170/65 TEMPERATURE: 97.3 F PULSE RATE: 65 RESPIRATORY RATE: 16 OXYGEN SATURATION: 95 Vital signs documented at end of transfusion 00:15 hours: BLOOD PRESSURE: 179/69 TEMPERATURE: 97.3 F PULSE RATE: 61 RESPIRATORY RATE: 22 OXYGEN SATURATION: 94 Comments: "Complete" A review of the electronic nursing note at 12/10/2022 00:25 hours (created 12/10/2022 00:26 hours) revealed: "Dr. [XX] notified that pt verbalizes complaint of shortness of breath after completion of third unit PRBC and that patient has abdominal accessory muscle use with RR=22, SpO2=94% on room air. Orders received for one-time dose Lasix 40mg IV, discontinue NS @ 100ml/hr and O2 2L NC for comfort. No further orders received at this time." After the second and third transfusion of blood products the patient stated feeling short of breath. The nurse documented "crackles" (rales) in the electronic note after the second transfusion was complete. Per facility and laboratory policies, respiratory distress including dyspnea (shortness of breath) and rales (crackles) were signs/symptoms of a possible transfusion reaction. The facility failed to follow its own policy for transfusion reaction identification. 4. During an interview on 01/26/2023 at 9:45 am, the laboratory General Supervisor after review of the above findings and confirmed the facility failed to ensure transfusion reactions were promptly identified, investigated, documented. Word Key: s/s: signs and symptoms V/S: vital signs BB: blood bank BP: blood pressure Pt: patient BLL: bilateral lower lobes SpO2: oxygen saturation
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 laboratory policy, patient manual differential forms, final patient reports, and confirmed in staff interview, the laboratory failed to follow its own written policy for reporting atypical lymphocytes for 5 of 28 patients randomly reviewed from January 2023. Findings included: 1. Review of the laboratory's policy titled "Manual Differentials" revealed: "Counting Differential ... 2. Atypical Lymphocytes ... b. Up to 5% atypical lymphocytes are considered normal and do not need to be commented on. (5% of the total WBCs, not 5% of the total Lymphs.) Quantitate the number of atypical lymphs with descriptive terms: i. Occasional (occ) = >5-30%)[sic] ii. Moderate (mod)= >30 to 60% iii. Many= >60%" 2. A random review of patient manual differential forms and patient final reports from January 2023 revealed the following patients' atypical lymphocytes were reported as a whole

	number and not in descriptive terms as stated in the laboratory's policy: Patient Sample No: 095488 Date: 01/03/2023 Manual differential form: 2 atypical lymphocytes Patient final report: 2 reactive lymphocytes Patient Sample No: 096868 Date: 01/10/2023 Manual differential form: 8 atypical lymphocytes Patient final report: 8 reactive lymphocytes Patient Sample No: 096937 Date: 01/11/2023 Manual differential form: 1 atypical lymphocyte Patient final report: 1 reactive lymphocyte Patient Sample No: 098765 Date: 01/24/2023 Manual differential form: 5 atypical lymphocytes Patient final report: 5 reactive lymphocytes Patient Sample No: 099007 Date: 01/25/2023 Manual differential form: 5 atypical lymphocytes Patient final report: 5 reactive lymphocytes The laboratory failed to follow its own written policy for reporting atypical lymphocytes as descriptive terms. Note: atypical lymphocyte and reactive lymphocyte are synonymous terms 3. During an interview on 01/26/2023 at 2:40 pm, the Technical Consultant-2, after review of the records, confirmed the above findings. Word key: Lymphs: lymphocyte
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory policy and confirmed in interview, the laboratory failed to perform calibration verification at least every 6 months for the Nova StatStrip lactate analyzer in 2022. The findings include: 1. Review of the laboratory's quality assurance plan revealed: "VI. Laboratory Equipment and Instrumentation ... 2. Calibration and/or verification must be performed at least as frequently as recommended by the manufacturer or at least every six months and when any of the following occur ..." 2. During an interview on 01/27/2023 at 09:48 a.m. with the Laboratory Manager, the surveyor requested documentation of calibration verification for the Nova StatStrip. None was provided. This confirmed the above findings.
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 laboratory and facility blood product policies, patient blood transfusion records/electronic notes, and confirmed in staff interview, the laboratory failed to promptly identify, investigate and report blood transfusion reactions to the laboratory for 1 of 10 patients randomly reviewed from September to December 2022. Findings included: 1. Review of the laboratory's policy titled "Transfusion Related Reaction Investigation" stated: "II. Reporting the Transfusion Reaction: All transfusion reactions should be reported to the BB and evaluated to the extent considered appropriate by the pathologist. Major adverse effects, e.g., hemolytic transfusion reactions and disease transmission, must be reported to the Bureau of Biologics, Food and Drug Administration. III. Preliminary steps: Whenever a transfusion reaction involving more than just hives is suspected, the transfusion should be immediately discontinued but the intravenous line kept open. Perform a clerical recheck between the patient and the component. Contract the Pathologist for instructions on patient care and Blood Bank to notify them of the transfusion reaction. IV. Signs and symptoms of acute and delayed adverse consequences of transfusion: Re-establish Baseline vital signs with EACH UNIT for Blood Pressure Condition: Fever Symptoms: Defined as 2 degrees F rise in patient's temperature Condition: Chills Symptoms: With or without rigors Condition: Respiratory Distress Symptoms: Including wheezing, coughing, dyspnea, and cyanosis Condition: Hypertension Symptoms: 30% Increase in Systolic BP Condition: Hypotension Symptoms: 30% Decrease in Systolic BP Condition: Pain Symptoms: Abdominal, chest flank, or back Condition: Skin Manifestations Symptoms: Urticaria, rash, flushing, pruritus, localized edema Condition: Hemoglobinemia Symptoms: The presence of free hemoglobin in the blood plasma Condition: Jaundice Symptoms: Yellowing of the skin and the white of the eyes is indication of red blood cell breakdown. Condition: Abnormal Bleeding Symptoms: Any new onset or unsuspected bleeding occurrence. Oozing blood at IV site. Condition: Oliguria Symptoms: Low urine output (less than 300-500 mL/day) Condition: Anuria Symptoms: Absence of urine output ... IX. Procedure: Nursing/Transfusionist Responsibility i. STOP the transfusion of blood. ii. KEEP the line open with saline. iii. Notify the CCMC Laboratory. Suspected transfusion related reactions must be immediately reported to the Laboratory. iv. Notify the patient's attending Physician for instructions for patient care. v. Obtain the complete a suspected transfusion related reaction investigation form from the laboratory." 2. Review of the facility policy "Issuing Blood Products" revealed an attachment titled "Blood Products Administration Protocol", the attachment stated: "Infusion ... During infusion patient will be monitored for signs and symptoms of reaction. If reaction noted, infusion will be stopped immediately, physician notified and Blood Transfusion Reaction Form and Transfusion Related Investigation Form will be initiated." The policy failed to state the laboratory needed to be notified. Review of the "BLOOD TRANSFUSION RECORD" form revealed: "** Watch for the following s/s of transfusion reaction anytime during or after the transfusion. If reaction is suspected, stop infusion, notify doctor and complete "Blood Transfusion Reaction Form and Transfusion Related Investigation form." Unless otherwise indicated, there were no adverse reactions during the transfusion. Signs and Symptoms of reaction: Temperature increased change of 2 degrees Fahrenheit from baseline vital signs for this unit. Gross hematuria/proteinemia (not present prior to transfusion) Pulse increase of 40bpm from Pre-Spiked V/S Systolic Blood pressure with decrease of 30% from baseline vital signs. Systolic Blood pressure increase of 30% from baseline vital signs AND clinical symptoms **(rales, itching, shortness of

	breath, altered mental status, etc)** Pain in the chest, abdomen, flank, or infusion site. Shaking of chills with/without fever. Respiratory distress, itching, or flushing of the skin. Nausea" The form failed to state the laboratory needed to be notified. 3. A random review of blood transfusion patient records and electronic nursing notes (September through December 2023) revealed the following 1 of 10 patients transfused in which the facility did not follow its own policy to ensure transfusion reactions were promptly identified, investigated and documented for all blood products: a. Patient Account: V00000661961 Unit #W141422254872 (second transfused unit) Type: Red Blood Cells Transfusion initiated: 12/09/2022 at 15:45 hours Transfusion ended: 12/09/2022 at 18:00 hours Vital signs documented at baseline 15:37 hours: BLOOD PRESSURE: 187/75 TEMPERATURE: 97.1 F PULSE RATE: 57 RESPIRATORY RATE: 20 OXYGEN SATURATION: 95 Vital signs documented at end of transfusion 18:10 hours: BLOOD PRESSURE: 170/90 TEMPERATURE: 97.2 F PULSE RATE: 65 RESPIRATORY RATE: 22 OXYGEN SATURATION: 94 Comments: None A review of the electronic nursing note at 12/09 /2022 18:40 hours (created 12/09/2022 21:27 hours) revealed: "This nurse entered room for shift change evaluation. Pt lying in bed watching tv. Respirations even, shallow and slightly labored with use of accessory muscles noted. Crackles noted BLL. Pt verbalizes feeling "short of breath" but denies distress. SpO2=92% on room air." Unit #W141422365272 (third transfused unit) Type: Red Blood Cells Transfusion initiated: 12/9/2022 at 20:25 hours Transfusion ended: 12/10/2022 at 00: 15 hours Vital signs documented at baseline 19:40 hours: BLOOD PRESSURE: 170 /65 TEMPERATURE: 97.3 F PULSE RATE: 65 RESPIRATORY RATE: 16 OXYGEN SATURATION: 95 Vital signs documented at end of transfusion 00:15 hours: BLOOD PRESSURE: 179/69 TEMPERATURE: 97.3 F PULSE RATE: 61 RESPIRATORY RATE: 22 OXYGEN SATURATION: 94 Comments: "Complete" A review of the electronic nursing note at 12/10/2022 00:25 hours (created 12/10/2022 00:26 hours) revealed: "Dr. [XX] notified that pt verbalizes complaint of shortness of breath after completion of third unit PRBC and that patient has abdominal accessory muscle use with RR=22, SpO2=94% on room air. Orders received for one-time dose Lasix 40mg IV, discontinue NS @ 100ml/hr and O2 2L NC for comfort. No further orders received at this time." After the second and third transfusion of blood products the patient stated feeling short of breath. The nurse documented "crackles" (rales) in the electronic note after the second transfusion was complete. Per laboratory and facility policies, respiratory distress including dyspnea (shortness of breath) and rales (crackles) were signs/symptoms of a possible transfusion reaction. The facility failed to follow its own policy for transfusion reaction identification. 4. During an interview on 01/26/2023 at 9:45 am, the laboratory General Supervisor after review of the above findings and confirmed the laboratory failed to ensure transfusion reactions were promptly identified, investigated, documented. Word Key: s/s: signs and symptoms V /S: vital signs BB: blood bank BP: blood pressure Pt: patient BLL: bilateral lower lobes SpO2: oxygen saturation
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records, and confirmed in interview, the laboratory's policies for instrument comparisons between the Ortho Vitros chemistry analyzers and between the Sysmex XN hematology analyzers failed to include written criteria for acceptable differences in test values in 2022. The findings include: 1. Review of the laboratory policy titled "VITROS Instrument-to-Instrument Correlations" revealed: "V. Procedure Five verification samples are supplied with the Chemistry Core Event and will be performed on the "VITROS 3400 analyzer. Results are compared and are marked Acceptable or Unacceptable by API.." 2. Review of the laboratory policy titled "Sysmex XN Instrument-to-Instrument Correlations" revealed: "V. Procedure Five verification samples are supplied with the Hematology/Coagulation and will be performed on the XN 330 analyzer. Results are compared and are marked Acceptable or Unacceptable by API ..." 3. Review of 2022 API PT records revealed the laboratory participated in API's Verification Program for the Vitros 3400 and the Sysmex XN-330, but there was no documentation of evaluating the relationship of test results from Vitros 7600 to Vitros 3400 or Sysmex XN-550 to Sysmex XN-330. 4. During an interview on 01/26/2023 at 09:51 a.m., the Laboratory Manager confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient manual differential forms, patient final reports, and confirmed in staff interview the laboratory failed to ensure 1 of 28 patients' manual differential results were transcribed accurately to the final test report (January 2023). Findings included: 1. Review of the laboratory's policy titled "Manual Differentials" stated: "Manual differential- The first 100 leukocytes on a blood smear are identified and counted by a technologist using the manual counter, keyboard or mechanical counter, the leukocytes are differentiated, and the cell types are reported as relative percentage values." 2. A random review of manual differential forms from January 2023 revealed the following patient manual differential results documented: Patient MRN: M000012231 Date: 01/16/2023 Differential report form: Neut: 8 Lymph: 81 Mono: 1 Meta: 10 A review of the patient's final report revealed the manual differential report was resulted as: Neut Pct Manuaul: 8 Lymph Pct Manual: 81 Reactive Lymphs: 10 Mono Pct Manual: 1 The final report test results did not reflect results on the manual differential form. The laboratory failed to ensure test results were transcribed accurately when entered into the patient chart. 3. During an interview on 01/26/2023 at 1:13 pm, the Technical Consultant-2, after review of the records, confirmed the above findings. Word key: Neut: neutrophil Lymph(s): lymphocyte Mono: monocyte Meta: metamyelocyte Pct: percent

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS-209) form, laboratory policy, personnel records, and confirmed in interview, the technical consultant failed to perform annual personnel competency assessment for 3 of 13 testing persons (TP-11, TP-12, TP-13) who perform moderate complexity testing in 2022. Findings included: 1. Review of CMS 209 form revealed moderate complexity blood gas analysis procedures were performed by TP-11, TP-12, and TP-13. 2. Review of the laboratory's policy for technical consultant job description stated: "9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation." 3. Review of personnel records revealed annual competency assessment were performed in 2022 as follows: TP-11 annual competency was performed on 1/06/2022 for blood gas analysis by a former employee who was NOT qualified as the technical consultant. TP-12 annual competency was performed on 1/14/2022 for blood gas analysis by TP-11 who was NOT qualified as the technical consultant. TP-13 annual competency was performed on 1/20/2022 for blood gas analysis by a former employee who was NOT qualified as the technical consultant. The technical consultant failed to perform annual competency assessments for TP-11, TP-12, and TP-13. 4. During an interview on 01/25/2023 at 11:10 am, the Technical Consultant-2 confirmed the above findings.