

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2127117	(X3) Date Survey Completed 04/14/2026
Name of Provider or Supplier Carter Bloodcare At John Peter Smith (Jps)	Street Address, City, State 1500 S Main Street, 3rd Floor Blood Bank, Fort Worth, 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	A validation survey was conducted on 4/14/2026 and standard level deficiencies were cited.
D3025	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of blood administration procedure, interview with the blood management coordinator, review of the laboratory's procedure, and transfusion records, the facility failed to ensure one of one procedure defined specific criteria for identifying and reporting a suspected transfusion reaction. Findings included: 1. Review of the "PC 502 Adult Blood Administration Procedure" (Effective Date: 08/23 /2023) page 3 stated, "III. Suspected Transfusion Reaction: A. The patient is observed for and instructed to notify the nurse immediately of any sign of a transfusion reaction. Symptoms may include but are not limited to: 1. Fever (1C/2F arise) 2. Chills 3. Muscle aches, pain 4. Headache 5. Chest or back pain 6. Heat at site of infusion or along vein 7. Nausea 8. Urticaria, hives, skin reaction 9. Hematuria 10. Dyspnea 11. Hypo- or hypertension 12. Jaundice" The procedure did not include defined criteria for hypotension and hypertension, and dyspnea. 2. During an interview on 4/14/2026 at 2:13 pm, the blood management coordinator was asked to describe criteria for transfusion reactions. The coordinator stated agitation, discomfort, restlessness, fluid overload, patient's respiration rate increase, and oxygen saturation decrease. The coordinator stated they had been working on defining criteria and acknowledged their procedure lacked criteria to ensure identification of</p>

transfusion reactions. 3. Review of the laboratory's "Initial Transfusion Reaction Investigation" (SOP #: RT2013.00; Version: 08; Effective Date: 10/10/2025) included signs and symptoms of a TRALI transfusion reaction, "Dyspnea, Fever, Bilateral pulmonary infiltrates." The laboratory did not have transfusion reaction criteria defined and the additional signs and symptoms the facility procedure included. Refer to D5559. 4. According to transfusion records from 2025, the facility had transfused about 13,000 blood products and there were 25 reported transfusion reactions (0.19%). The transfusion reactions were febrile or allergic (rise in body temperature or urticaria, hives, skin reaction).

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 the laboratory's procedure, the facility's procedure, and transfusion records, the laboratory failed to ensure one of one procedure was consistent with the facility procedure for identifying transfusion reactions. Findings included: 1. Review of the laboratory's "Initial Transfusion Reaction Investigation" (SOP #: RT2013.00; Version: 08; Effective Date: 10/10/2025) included signs and symptoms of a Transfusion-Related Acute Lung Injury transfusion reaction, "Dyspnea, Fever, Bilateral pulmonary infiltrates." The laboratory did not have defined criteria for fever and dyspnea and failed to include the additional signs and symptoms stated in the facility procedure (1. Fever (1C/2F arise) 2. Chills 3. Muscle aches, pain 4. Headache 5. Chest or back pain 6. Heat at site of infusion or along vein 7. Nausea 8. Urticaria, hives, skin reaction 9. Hematuria... 11. Hypo- or hypertension 12. Jaundice). 2. Review of the facility's "PC 502 Adult Blood Administration Procedure" (Effective Date: 08/23/2023) page 3 stated, "III. Suspected Transfusion Reaction: A. The patient is observed for and instructed to notify the nurse immediately of any sign of a transfusion reaction. Symptoms may include but are not limited to: 1. Fever (1C/2F arise) 2. Chills 3. Muscle aches, pain 4. Headache 5. Chest or back pain 6. Heat at site of infusion or along vein 7. Nausea 8. Urticaria, hives, skin reaction 9. Hematuria 10. Dyspnea 11. Hypo- or hypertension 12. Jaundice" The procedure did not include defined criteria for hypotension and hypertension, and dyspnea. The laboratory did not ensure sign and symptoms of transfusion reactions were defined for prompt identification, reporting, and investigation of a transfusion reaction. 3. According to transfusion records from 2025, the facility had transfused about 13,000 blood products and there were 25 reported transfusion reactions (0.19%). The transfusion reactions were febrile or allergic (rise in body temperature or urticaria, hives, skin reaction).