

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0309608	<b>(X3) Date Survey Completed</b>  04/27/2026
<b>Name of Provider or Supplier</b>  Memorial Health Care System	<b>Street Address, City, State</b>  2051 Hamill Rd, Hixson, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Intakes: TN00077593 Based on a review of the laboratory procedure manual, review of patient records, and staff interviews, the laboratory failed to follow the policy for blood bank post-transfusion reaction work-up in February 2025. The findings include: 1. A review of the laboratory's "Suspected Transfusion Reactions" procedure revealed the following: -If TRALI is suspected: collect two lavender top tubes. Store whole blood from these two EDTA tubes at room temperature. Store other specimens in the refrigerator. -Compare pre-transfusion specimen and post-transfusion specimen for: - Color of serum/plasma for hemolysis and icterus. Grade as negative, slight, moderate or gross. -Perform direct antiglobulin test (DAT) using polyspecific anti-human globulin reagent. If positive, perform differential DAT's to determine whether IgG or complement is coating the red cells. -Repeat ABO testing on both pre- and post-transfusion specimens. 2. A review of the Suspected Transfusion Reaction Investigation worksheet for patient medical record, 05733439, from 02.25.2025 revealed no documentation that the laboratory completed the post-transfusion reaction specimen work-up, which included specimen collection, appearance, DAT, and ABO /Rh. 3. An interview on 04.27.2026 at 10:30 a.m. with the blood bank supervisor, she stated the blood bank did not complete a post-transfusion reaction work-up because the patient's physician wanted the patient's samples sent to the reference laboratory for TRALI work-up. She also stated that looking back, the blood bank should have performed the post-transfusion reaction work-up. Subsequent interview on 04.27.2026 at 12:50 p.m. with the Laboratory Manager, Blood Bank Supervisor, Quality</p>

Assurance Manager, Vice President of Operations, Chief Operations Officer, Chief Nurse, Patient Safety Officer, and Marketing Director, confirmed the laboratory failed to follow its policy and to complete a post-transfusion reaction work-up on patient 05733439 on 02.25.2025. Word Key: TRALI = Transfusion Related Acute Lung Injury EDTA = Ethylenediaminetetraacetic acid IgG = Immunoglobulin G ABO = ABO blood group system, which categorizes blood into four main types: A, B, AB, and O Rh = Rhesus factor