

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0451291	<b>(X3) Date Survey Completed</b>  10/26/2022
<b>Name of Provider or Supplier</b>  William Newton Hospital	<b>Street Address, City, State</b>  1300 E 5th Ave, Winfield, KS	
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>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the procedure manual and interview, the laboratory failed to establish and follow written procedures for specimen labeling. Findings: 1. Review of the procedure manual for "Activated Clotting Time (Kaolin), CG4 and Creatinine Abbott i-STAT" revealed under "Specimen Labeling: the following statement: "Unless the specimen is analyzed immediately after collection and then discarded, the specimen container must be labeled with the following information: Patient name /DOB Patient ID number 2. Regulation 493.1242 (a)(3) does not contain circumstance which allows for samples to be analyzed without patient name or unique identifier labeling. 3. Interview with the GS #1 on 10/26/22 at 2:20 p.m. confirmed, the laboratory failed to establish and follow written procedures for specimen labeling.</p>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a lack of available documentation and confirmed during interview with General Supervisor #5 (GS) #5 the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use. Findings: 1. Upon review of the laboratory procedures, the current Laboratory Director (LD) did not approve, sign, and date the laboratory procedure/policy for: 41 of 51 immunohematology procedures in the laboratory at time of survey. 2. The following procedures were not signed by the current LD: a. Blood Transfusion Ordering Policy b. Blood Bank Quality Indicators (QI) Plan. (Blood Utilization Review) c. Blood Storage Alarm d. Blood Storage Alarm Activation Test (quarterly pm) e. Emergency Order Procedures (from Blood Supplier) f. Type and Screen - Hold Tube Policy and Procedure / Flow Chart for Blood Bank work g. Tachometer and Timer Checks for Serologic Centrifuge h. Microtyping System Equipment Maintenance i. Daily Inventory and Blood Storage Checks j. Nursing Service: Blood Transfusion procedure k. Nursing Service: Blood Warmer Protocol l. Nursing Service: Blood Components administration instructions m. Nursing Service: Blood Reactions n. Nursing Service: Autoinfusion System o. Outpatient Transfusion p. Autologous and Directed Blood Donations q. American Red Cross Blood Service Agreement r. Renal Transplant Center (Policy statement and Agreement) s. Derivatives - Factor Concentrates t. Lookback Policy and Procedure u. Biological Products Deviations (Errors and Accidents) v. Receipt of Reagents and Supplies w. Transferring and Stock Rotation of Red Blood Cell Units x. Patient Sample Labeling for Pretransfusion Testing Flow Chart for Blood Bank work y. Blood Bank Tags, Labels, and Paper z. Emergency Release OR Incompatible/Special Circumstance aa. Policy for Blood Availability due to Serological Complications bb. Blood Product Issue cc. Grading Tube Reactions dd. Identification of Passively Acquired Anti-D due to Rh Immune Globulin ee. ARC Reference Lab ff. Memo for Antibody Identification gg. Direct Antiglobulin Test (Direct Coombs or DAT) hh. Receipt and Final Disposition of Blood or Tissue ii. Cryoprecipitate jj. Transfusion Reactions kk. Therapeutic Phlebotomy ll. Tube Methods for Antibody Screens and Crossmatch (alternative to gel) mm. Prewarmed Testing nn. Massive Transfusion Protocol oo. Blood Bank Procedure for LIS Downtime 3. Interview with the GS #5 10/26/22 at 9:30 a.m. confirmed, the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use.