

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0313254	(X3) Date Survey Completed 12/18/2024
Name of Provider or Supplier Haywood County Community Hospital, Inc	Street Address, City, State 2545 North Washington Ave, Brownsville, TN	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, lack of procedure, and staff interview, the laboratory failed to establish alert / critical values for transfusion medicine testing. The findings include: 1. Observation of the laboratory on 11/21/24 at 8:30 a.m. revealed the Ortho MTS Gel System and cards that had been validated for use for patient testing for ABO type, Rh factor, Antibody Screen, and Compatibility testing. 2. A review of the transfusion medicine procedure manual revealed no policy/procedure for alert / critical test results. 3. The general supervisor confirmed the survey findings during an interview on 11/21/24 at 1:30 p.m.</p>