Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0313254	11/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Haywood County Community Hospital, Inc	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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of the Ortho Transfusion Services test log, laboratory observation, and staff interview, the laboratory failed to ensure the specimen integrity and identification of patient samples was maintained throughout the testing process in transfusion medicine testing for patient number 512663, tested on 11/03/25. The findings include: 1. A review of the Ortho Transfusion Services test log revealed compatibility testing performed for patient number 512663 on 11/03/25 for unit numbers W0408 25 117335, W0408 25 105606, and W0408 25 117341. 2. Observation of gel test cards on 11/13/25 at 12:10 p.m., revealed a card that was labeled with unit numbers W0408 25 117335, W0408 25 105606, and W0408 25 117341. The gel test card was not labeled with the patient's name, identifier, or date of testing. 3. Testing Person Four stated the gel cards with the unit number stickers attached were for the compatibility testing for patient 512663 and confirmed the survey findings during an interview on 11/13/25 at 12:15 p.m.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5)

	Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of the laboratory's specimen collection policy for Transfusion Medicine samples, and staff interviews, two of three persons interviewed failed to state the correct labeling process for samples collected for Transfusion Medicine testing. The findings include: 1. A review of the laboratory procedure titled "Blood Bank Specimen Identification" revealed that the Tempenex armband is put on at the time of collection for specimens collected for Transfusion Medicine Testing. 2. Staff interviews revealed the following: Testing person two stated the armband is put on the patient after the testing is completed during interview on 11/12/25 at 9:55 a.m. Phlebotomist number one stated the armband is put on the patient after testing during interview on 11/12/25 at 10:50 a.m. 3. The Regional Laboratory Supervisor/Technical Consultant confirmed the survey findings during interview on 11/13/25 at 5:00 p.m.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: CITATION ONE: Based on a review of the laboratory's wet prep procedure and staff interviews, the laboratory failed to follow the policy for the correct amount of saline to add to the wet prep specimen when received in the laboratory. The findings include: 1. A review of the wet prep procedure revealed that after the specimen is received in the laboratory that 0.5 mL of saline is added to the tube. 2. Testing person number four failed to state the amount specified in the procedure during an interview on 11/13/25 at 9:00 a.m. 3. The Regional Laboratory Director/Technical Consultant Two confirmed the survey findings during an interview on 11/13/25 at 5:35 p.m. mL=milliliter CITATION TWO: Based on a review of the laboratory procedure manual, a review of laboratory records and staff interview, the laboratory failed to perform calibration verification every six months as required by procedure for analytes performed on the Beckman Coulter AU700 chemistry instrument in 2024 and 2025 (two of four were not performed when due). The findings include: 1. A review of the laboratory's procedure for Calibration Verification (PolicyStat ID 16406177) revealed that calibration verifications were to be performed every six months for all analytes performed on the Beckman Coulter AU700 Chemistry instrument. 2. A review of the laboratory's calibration verification records revealed that the laboratory failed to perform calibration verifications every six months, as outlined in the laboratory's Calibration Verification (PolicyStat ID 16406177) procedure. The calibration verification that was due in January 2024 was not performed until February 2024. The calibration verification that was due in August of 2025 were not completed until October of 2025. 3. Testing person four confirmed the survey findings during an interview on 11/13/25 at 3:35 p.m.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

	(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: CITATION ONE: Based on a review of laboratory procedures and staff interviews, the laboratory procedure for Wet Prep failed to include the requirements for sample preservation and transport, criteria for specimen acceptability and rejection, and the magnification used for performing the microscopic examination. The findings include: 1. A review of the laboratory's Wet Prep (PolicyStat ID 15890893) procedure revealed that the procedure lacked requirements for sample preservation and transport, criteria for specimen acceptability and rejection, and the microscope magnification to use for examination. 2. The Regional Laboratory Supervisor/Technical Consultant Two stated during an interview on 11/12/25 at 2:00 p.m. that acceptability and rejection criteria were included in the Unacceptable Specimen Criteria Procedure (PolicyStat ID 19270277). 3. A review of the Unacceptable Specimen Criteria Procedure revealed that the procedure did not include Wet Prep specimens. 4. The Regional Laboratory Director/Technical Consultant Two confirmed the survey finding during an interview on 11/13/2025 at 5:35 p.m. CITATION TWO: Based on laboratory observation, staff interview, and a review of the laboratory procedure manual, the laboratory procedure for the Beckman Coulter DxH 690T included references to sample types (body fluids) that were not tested. 1. Laboratory observation on 11/12/25 at 8:30 a.m. revealed the Beckman Coulter DxH 690T used for performing patient testing for Complete Blood Count (CBC) with automated White Cell Differential (CBC w/Diff), and reticulocyte count. During observation, the Regional Laboratory Supervisor stated that the laboratory did not perform body fluid cell counts. 2. A review of the laboratory procedure manual revealed that the procedure included references to body fluid cell counts which were not performed. 3. The Regional Laboratory Director confirmed the survey findings during interview on 11/13/25 at 5:00 p.m.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems

quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on laboratory observation, a review of the laboratory procedure manual, a review of the log used to record Transfusion Medicine test results, a lack of documentation, and staff interview, the laboratory failed to identify errors in documentation on the transfusion medicine test record and perform corrective action to prevent future occurrences for eight of eight test records with errors identified by the surveyor in 2025. The findings include: 1. Laboratory observation on 11/12/25 at 8:15 a.m. revealed the Ortho Gel System used for performing patient testing for transfusion medicine testing (ABO, Rhesus Factor (Rh), Antibody Screen, and Compatibility Testing). 2. A review of the procedure titled "Quality Assurance Plan - Laboratory Services" revealed the following statement: The quality management plan provides for the continuous monitoring and evaluation of patient care activities within the Clinical Laboratory. This monitoring includes pre-analytic, analytic, and post-analytic phases of testing." "Since laboratory errors may have adverse clinical consequences, it is necessary to search actively for mistakes and investigate their causes." "The laboratory surveillance checklist is a guide to ensure all areas of the laboratory are checked. Corrective action logs are used to pinpoint and process errors, trends, or potential re-evaluation of an employee's training/competency or testing work flow. A summary is completed monthly for the laboratory medical director to review for further action." 3. A review of the Ortho Transfusion Services Test log revealed the following documentation errors: Patient number 510344 with a test date of 02/12/25: Unit number W0404 24 106654 released for transfusion on 02/12/25 with no documented compatibility testing on the line for the unit number. Testing Person five completed the test record. The General Supervisor reviewed the record on 02/12 /25. Patient number 509685 with test date of 02/12/25: The unit retype had recorded anti-D results of 4+. The Rh interpretation was recorded as A for unit numbers W0408 24 107320 and W0408 24 107327. The General Supervisor completed the test record. The General Supervisor reviewed the test record on 02/13/25. Patient number 501649 with a test date of 02/24/25: No testing was recorded under the reverse typing in the column for A1 and B. The testing person was not recorded. The General Supervisor reviewed the document on 02/24/25. Patient number 509684 with a test date of 02/25 /25: The testing person was not recorded. The General Supervisor reviewed the test record. Patient number 504467 with a test date of 04/07/25: The compatibility testing was not recorded on the line for the unit number. Testing Person Two completed the test record. The General Supervisor reviewed the record on 04/07/25. Patient ID number 506760 with a test date of 06/19/25: The test method (CAT vs. Tube) for the antibody screen or Rh was not indicated on the test log. The crossmatch interpretation was not recorded. Testing Person Five completed the test record. The General Supervisor reviewed the record on 06/30/25. Patient number 503268 with a test date of 10/9/25: The ABO and Rh of unit numbers W0408 25 101713 and W0408 25 202311 was not recorded on the log. Testing Person Two completed the record. Testing Person two reviewed the record on 10/18/25. Patient number 509180, test date of 10/20/25: The crossmatch reaction was recorded in the wrong column. Testing Person Two completed the record. Testing Person Five reviewed the test record. Patient number 512663 with a test date of 11/03/25: The test record had reactions recorded for reverse typing in the column for a reagent that was not used by the laboratory (A2 cells). 4. There was no documentation that the laboratory identified the documentation errors or performed corrective action. The laboratory did not document retraining of personnel or implement procedure changes to prevent recurrence. 5. The

	Regional Laboratory Supervisor confirmed the survey findings during an interview on 11/13/25 at 5:00 p.m. Word Key: CAT=Column Agglutination Test vs=versus