Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236863	03/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Braxton County Memorial Hospital	100 Hoylman Drive, Gassaway, WV	

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 routine, on site, recertification survey was conducted at Braxton County Memorial Hospital on March 15 and March 16, 2022. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to achieve a satisfactory performance score for Compatibility Testing in 1 of 3 Immunohematology proficiency testing events of 2021. Findings: 1. Review of American Proficiency Institute (API) PT records revealed an unsatisfactory performance of 80% for the analyte #0895 Compatibility Testing in the 3rd PT event of 2021. 2. An interview with the general supervisor, on 3/15/22 at approximately 11:00 AM, confirmed the findings.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) 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. This STANDARD is not met as evidenced by: Based on review of written policies and procedures (P&P), lack of documentation ,

	and interview the facility failed to: 1) Define the specific criteria parameters to be observed and monitored to identify a possible transfusion reaction in 2 of 2 P&P reviewed 2) Establish a uniform process for the laboratory to perform the investigation of transfusion reactions in 2 of 2 P&P reviewed Findings: 1) A. Review of facility P&P "Blood Administration" revealed a chart containing a column for vital signs to be monitored for each blood or blood product administered, referring to "Blood Administration Step #18" for RBCs, RBCs frozen and washed, WBCs, Plateletpheresis, FFP, and Platelets. "Blood Administration Step #18" states the required time intervals for monitoring the BP and Temperature of the recipient. No definition of the criteria for abnormal vital signs or specific changes in temperature or blood pressure that could identify a possible transfusion reaction could be located. B. Review of the facility "Transfusion Reaction Report" worksheet contains an area to document the recipient Temperature, BP, and Pulse. No definition of the criteria for abnormal vital signs or specific changes in temperature, blood pressure, or pulse that could identify a possible transfusion reaction could be located. 2) A. Review of laboratory P&P "Transfusion Reaction Investigation" and the "Transfusion Reaction Report" worksheet identified discrepancies in the step by step procedures regarding the specific tests that must be completed, the timeframe to complete the transfusion reaction investigation testing, and the documentation of the testing. i. P&P Step 4 instructs to check centrifuged samples for hemolysis and icterus. The worksheet has no area to document the presence or absence of icterus. ii. P&P Step 5 instructs to perform pre- and post- transfusion DATs using both gel and tube methods. The worksheet has no area to document the results of the gel DAT testing. iii. P&P Step 6 instructs to perform Bacteriologic Testing on the blood bag or segments if the bag is not available. The worksheet has no instructions for when to perform Bacteriologic testing in the process. iv. P&P states that a ABO/Rh, crossmatch, and antibody screen on the pre- and post- transfusion specimens (Steps 7 thru 10) are performed if "there is hemolysis, DAT is positive, or a transfusion reaction other than an allergic reaction is suspected." The worksheet states that the ABO/Rh, crossmatch, and antibody screen (Steps 4-6) be performed on a routine basis if there is no hemolysis, DAT is negative, and the suspected transfusion reaction is other than an allergic reaction. An interview with the general supervisor, 3/15/22 at approximately 11:35 AM, confirmed all the findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, policies and procedures (P&P), and interview the laboratory failed to document the competency assessment concerning the secondary Immunohematology testing method for 7 of 7 testing personnel (TP) in 2020 and 8 of 8 TP in 2021. Findings: 1. Review of 2020 TP competency assessment documents revealed no evaluation of the secondary tube test methodology for Immunohematology for all 7 TP. 2. Review of 2021 TP competency assessment documents revealed no evaluation of the secondary tube test methodology for Immunohematology for all 8 TP. 3. Review of P&P identified a procedure for the tube

	testing method for Immunohematology. 4. An interview with the general supervisor, on 3/15/22 at approximately 8:40 AM, confirmed the lack of documentation for all TP competency with the tube testing method in 2020 and 2021.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on record review, policies and procedures (P&P), lack of documentation, and interview the laboratory failed to establish (3) the criteria for when to perform a manual differential from fluid cell counts (CSF) and (8) failed to establish a procedure for the recognition and resolution of out of range quality control (QC) results in 2 of 4 departments. Findings: (3)A. Review of P&P identified "Policy: Cerebrospinal Fluid" which states the step by step process of CSF analysis- gross examination, cell count, differential count, gram stain/culture, and cytological analysis. No specific criteria for when a differential count should be performed from the manual WBC count could be located. B. Review of Body Fluid Cell Count Worksheet from 11/25/21 thru date of survey identified the following 5 patient CSF analyses: 11/25/21: 160 WBCs counted, differential performed 12/9/21: 87 WBCs counted, differential performed 12/11/21: 970 WBCs counted, differential performed no date documented on worksheet: 40 WBCs counted, differential performed (count in patient chart and not documented on worksheet) 3/4/22: 6.25 WBCs counted, no differential performed C. An interview with the technical supervisor, 3/16/22 at approximately 10:45 AM, confirmed the findings. (8)A. Review of QC records in Chemistry and Microbiology identified the release of patient test results when QC was out of range. Refer to D5481. B. No P&P for the identification and the corrective actions to perform for resolution of out of range quality control results could be located for Chemistry and Microbiology testing. C. An interview with the general supervisor, on 3/16/22 at approximately 8:15 AM, confirmed that no P&P existed for the handling of out of range QC results.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, record review, and interview the laboratory failed to perform and document the calibration of 4 of 9 pipettes utilized for patient testing for adequate and consistent delivery. Findings: 1. A tour of the laboratory identified 4 pipettes with no documentation of calibration: ID Tipmaster A20305131, MLA 10uL, Finnpipette F2 Fixed 3ml, and MLA 500uL. 2. Review of maintenance and function check records revealed no calibration for the 4 pipettes in 2021. 3. An interview with the general supervisor, on 3/15/2022 at approximately 2:45 PM, confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of policies and procedures (P&P), record review, and interview the laboratory failed to ensure the results of quality control (QC) met the criteria of acceptability before reporting patient results for 4 of 26 days of patient testing in Chemistry and 1 of 16 days of patient testing in Microbiology. Findings: 1. No P&P for the corrective actions to resolve out of range QC for Chemistry and Microbiology could be located. Refer to D5403. 2. Chemistry QC records reviewed 2/17/22 thru 3/14 /22 for the analyte ECO2 identified 4 days a data point of QC was greater than the 2 SD acceptable range on the analyzer: 2/20/22 level 2 QC out of range on both Alinity analyzers for ECO2, no corrective action 2/27/22 level 2 QC out of range on Alinity 2 for ECO2, no corrective action 2/28/22 level 2 QC out of range on Alinity 2 for ECO2, no corrective action 3/14/22 level 2 QC out of range on Alinity 1 for ECO2, no corrective action 3. Microbiology QC records reviewed 3/1/22 thru 3/16/22 for the Microscan GP and GN panels identified a failed run of the GN panel 3/15/22 with no corrective action until 3/16/22. Two patient panel results were released 3/15/22. 4. An interview with the technical supervisor, on 3/16/22 at approximately 11:00 AM, confirmed the findings.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 policies and procedures (P&P), lack of documentation, and interview the laboratory failed to (c) establish the acceptable storage conditions required for 1 of 3 blood and blood products in Immunohematology. Findings: 1. Review of Immunohematology P&P revealed the lack of an established, acceptable temperature range for the storage of platelets in the laboratory. 2. An interview with the general supervisor, on 3/16/22 at approximately 9:35 AM, confirmed that no acceptable temperature range for the storage of platelets could be located.