Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236863	03/27/2024
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 recertification survey was conducted at Braxton County Memorial Hospital, March 26 through March 27, 2024. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to achieve a satisfactory score for analytes #0325 PO2 Blood Gas and #0335 PCO2 Blood Gas in the 2nd American Proficiency Institute (API) routine chemistry testing event of 2023. Findings: 1. Review of API proficiency testing (PT) records revealed the following scores for 2023 2nd event: 60% PO2 Blood Gas 60% PCO2 Blood Gas 2. An interview with the testing personnel, 3/26/24 at 10:00 AM, confirmed 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: Review of policies and procedures (P&P), lack of documentation, and interview the laboratory failed to assess the competency of testing personnel (TP) for DAT

	Immunohematology testing in 2023. Findings: 1. Review of P&P revealed a process for assessing TP competency for all test methodologies at prescribed intervals. 2. No documentation of the competency assessment for DAT testing in Immunohematology for 8 of 8 Immunohematology TP could be located. 3. An interview with the general supervisor, 3/26/24 at 9:30 AM, confirmed no competency assessment for DAT had been performed for the 8 TP involved with Immunohematology testing in 2023.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, lack of documentation, and interview the laboratory failed to establish and monitor the environmental conditions required for the storage of the GEM Premier 5000 blood gas analyzer reagent packs. Findings: 1. A tour of the storage area for the reagent packs, 3/27/24 at 12:30 PM, identified no established environmental conditions. 2. GEM Premier 5000 reagent packs were observed to have a storage temperature range of 15-25 degrees Celsius on the boxes. No documentation of the monitoring of the storage temperature for the reagent packs could be located for 2023. 3. An interview with the testing personnel, 3/27/24 at 12:30 PM, confirmed no environmental monitoring of the storage area occurred.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on observation, record review, and interview the laboratory failed to ensure the calibration results for 2 of 10 analytes met the acceptability criteria before reporting patient results from the Alinity chemistry analyzer. Findings: 1. During a tour of the laboratory, 3/27/24 at 10:00 AM, the Alinity chemistry analyzer was observed as having current calibrations for analytes direct dilirubin (Bili D) and total bilirubin (Bili Total). 2. Review of reagent management logs for Chemistry identified reagent lot 24909FD01 put into use on the analyzer 11/8/23. 3. Review of the analyzer

	programmed calibration data identified the following calibration factors for lot 24909FD01 expiry 12/31/24: Bili D 0.84 cal 1, 7.86 cal 2 Bili Total 1.42 cal 1, 14.53 cal 2 4. Review of the product insert for lot 24909FD01 identified the following calibration factors: Bili D 0.78 cal 1, 8.5 cal 2 Bili Total 1.30 cal 1, 15.47 cal 2 5. An interview with the technical consultant, 3/27/24 at 10:15 AM, confirmed the calibration factors programmed on the analyzer were not the correct calibration factors for the lot of reagent in use for Bili D and Bili Total testing.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on policies and procedures (P&P), record review, and interview the laboratory failed to have established criteria for the evaluation of the comparisons of test results between the two Alinity chemistry analyzers, two hematology analyzers (Coulter DxH 600 and AcT diff), two GEM Premier 5000 blood gas analyzers, and the two methodologies used in Immunohematology testing (Echo and manual tube testing). Findings: 1. Review of P&P identified a "Semiannual Correlation of Instruments" stating: a. "The DxH and AcT analyzers are compared twice a year. Anytime a comparison does not match, the samples are reviewed and the study is repeated with fresh or additional samples." No specific acceptability criteria for the evaluation of the comparison between the results of the DxH and AcT analyzers could be located. b. "The lab will semi-annually compare between the two Alinity analyzers. Anytime a comparison does not match, the samples are reviewed and the study is repeated with fresh or additional samples." No specific acceptability criteria for the evaluation of the comparison of the Alinity results could be located. c. No process for the performance and evaluation of comparison between the Echo automated method and the manual tube testing utilized in Immunohematology testing could be located. d. No process for the performance and evaluation of comparison between the two GEM Premier 5000 blood gas analyzers could be located. 2. Review of 2022 and 2023 records revealed comparisons were being performed between the hematology, chemistry, and blood gas analyzers and between the Immunohematology testing methods. No evaluation of the results could be located. 3. An exit interview with the technical consultant, 3/27/24 at 4:45 PM, confirmed the findings.