Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236863	12/12/2019
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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the written laboratory policies and procedures, laboratory quality assessment (QA) records, and an interview with technical supervisor 1 (TS1), the laboratory failed to establish a written policy or procedure for Quality Assessment (QA) of the general laboratory systems. Findings: 1. No written policy or procedure for QA of the general laboratory systems could be located. This includes the monitoring and assessment of confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing evaluation. 2. A review of laboratory 2018 and 2019 QA records identified the laboratory is performing QA monitoring of general laboratory systems documented on monthly and quarterly QA forms. 3. An interview with TS1, on 12/12/19 at approximately 12:45 PM, confirmed there is no written policy or procedure for the QA of general laboratory systems.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

	This STANDARD is not met as evidenced by: Based on a review of the written laboratory policies and procedures, laboratory quality assessment (QA) records, and an interview with technical supervisor 1 (TS1), the laboratory failed to establish a written policy or procedure for the quality assessment (QA) of the preanalytic systems. Findings: 1. No written policy or procedure could be located for QA of the preanalytic system, which includes the following: test request and specimen submission, handling, and referral. 2. A review of QA records for 2018 and 2019 identified the laboratory is performing QA monitoring of the preanalytic systems documented on monthly and quarterly QA forms. 3. An interview with TS1, on 12/12/19 at approximately 12:45 PM, confirmed there is no written policy or procedure for the QA of the preanalytic system.
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 a tour of the laboratory, a review of laboratory temperature and humidity documentation logs, and an interview with technical supervisor 1 (TS1), the laboratory failed to monitor and document the (2) temperature and (3) humidity for reliable test system operation and proper storage of reagents utilizing a NIST certified calibrated thermometer and hydrometer. Findings: 1. A review of the temperature and humidity log for the laboratory identifies acceptable temperature and humidity ranges for the laboratory and provides a form for the documentation of the daily temperature and humidity monitoring. a. Humidity 75 to 85 percent b. Room Temperature 0 to 75 degrees Fahrenheit 2. A review of the laboratory temperature and humidity logs showed the daily documentation of laboratory temperature and humidity conditions. The temperature range established for the laboratory environment was identified as 0 to 75 degrees Fahrenheit. The lower end of the monitored ,acceptable temperature range should not exceed the requirements for storage temperatures of reagents. The laboratory reagent storage area contained Microscan GI Panel Film Array (storage reference range 15 to 25 degrees Celcius), MicroScan Blood Culture ID Panel (storage reference range 2 to 25 degrees Celcius), and Beckman Coulter DXH reagent (storage reference range 2 to 40 degrees Celcius). 3. An examination of the thermometer/hydrometer revealed the laboratory was utilizing a SP (SN#51096858) thermometer/hydrometer and the NIST certified calibration had expired 5/2/2017. No documentation of a current calibration or traceability validation could be located. 4. An interview with TS1, on 12/12/19 at approximately 1:00 PM, confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the written laboratory policies and procedures, laboratory quality assessment (QA) records, and an interview with technical supervisor 1 (TS1), the laboratory failed to establish a written policy or procedure for Quality Assessment (QA) of the analytic systems. Findings: 1. No written policy or procedure could be located for QA of the analytic systems, which includes the following: procedure manual, test systems/equipment/supplies, establishment and verification of performance specifications, maintenance and function checks, calibration and calibration verification procedures, control procedures, comparison of test results, corrective actions, and test records. 2. A review of laboratory 2018 and 2019 QA records identified the laboratory is performing QA monitoring of the analytic systems documented on monthly and quarterly QA forms. 3. An interview with TS1, on 12/12 /19 at approximately 12:45 PM, confirmed there is no written policy or procedure for the QA of the laboratory analytic systems.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of the written laboratory policies and procedures, laboratory quality assessment (QA) records, and an interview with technical supervisor 1 (TS1), the laboratory failed to establish a written policy or procedure for Quality Assessment (QA) of the laboratory postanalytic systems. Findings: 1. No written policy or procedure for QA of the postanalytic systems could be located, which includes test reports. 2. A review of laboratory 2018 and 2019 QA records identified the laboratory is performing QA monitoring of the laboratory postanalytic systems documented on monthly and quarterly QA forms. 3. An interview with TS1, on 12/12/19 at approximately 12:45 PM, confirmed there is no written policy or procedure for the QA of the laboratory postanalytic systems.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of testing personnel competency records, testing personnel qualifications, and an interview with Technical Supervisor 1 (TS1), the laboratory

	failed (8) to have the competency of the testing personnel in Immunohematology assessed by a qualified individual. Findings: 1. A review of testing personnel competency records for 2018 and 2019, identified that the required annual Immunohematology competency for all 9 of the laboratory testing personnel in Immunohematology was documented and assessed in 2018 by TS1. 2. A review of laboratory personnel qualifications revealed that TS1 did not meet the requirements to be technical supervisor of Immunohematology according to CLIA personnel regulations at CFR 493.1449 (q). 3. An interview with TS1, on 12/12/19 at approximately 8:20 AM, confirmed the findings.