Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0466447	09/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Health Medical Center - Hot Spring County	1001 Schneider Drive, Malvern, AR	

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
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: Through a review of January, April, and August 2022 temperature and humidity records for the blood gas laboratory, and interviews with laboratory staff, it was determined the blood gas laboratory failed to document daily room temperature and humidity. Survey findings include: A. A review of blood gas laboratory records revealed the daily temperature and humidity is documented on a form called "Replacements report". Refrigerator and room temperatures as well as room humidity are documented on this report. Acceptable temperature for the refrigerator is 2 to 8 degrees Celsius, acceptable room temperature is 68 to 76 degrees Fahrenheit, and acceptable humidity is 30% to 85%. B. Through a review of Replacement reports for January 2022 it was determined the laboratory failed to document refrigerator temperature on six of thirty-one days, room temperature on seven of thirty one days, and room humidity on five of thirty-one days in January 2022. C. A review of August 2022 Replacement reports revealed the laboratory failed to document refrigerator temperature on two of thirty-one days and room humidity on two of thirty-one days. D. In an interview, at 9:34 a.m. on 9/22/2022, Employee #12 (as listed on form CMS-209)confirmed the blood gas laboratory temperatures and humidity were not documented on days the laboratory was in operation.

D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the laboratory policies and procedures, QC Summary Graphical Reports and QC Summary Reports for January, April, and August 2022, and through interviews with laboratory staff, it was determined the laboratory failed to monitor, over time, the accuracy of the hematology test results. Survey findings include: A. A review of the general policy and procedure manual revealed a quality control policy stating that quality control data will be reviewed at least monthly for shifts and trends. B. A review of the January 2022 QC Summary Graphical Reports and QC Summary Reports revealed the results for Monocytes were shifted below the mean all month (43 of 43 points) for Coulter 6C Level 2 control (lot # 133184070). The Coulter 6C Level 3 control (lot # 143194070) was below the mean all month (46 of 46 points). No corrective actions were documented. C. A review of the April 2022 QC Summary Graphical Reports and QC Summary Reports revealed the results for Monocytes were shifted below the mean all month (43 of 43 points) for Coulter 6C Level 2 control (lot # 143194230). No corrective actions were documented. D. A review of the August 2022 QC Summary Graphical Reports and QC Summary Reports revealed the results for Monocytes were shifted below the mean all month (52 of 52 points) for Coulter 6C Level 2 control (lot # 133184400). The Coulter 6C Level 3 control (lot # 143194400) was below the mean all month (48 of 48 points). No corrective actions were documented. E. In an interview, at 2:35 p.m. on 9/20/2022, laboratory employee #2 (as listed on the CMS-209 form) confirmed the shifts were present without documented corrective actions.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Through a review of hematology written policies, a review of coagulation quality control (QC) charts and Quality Assurance Program (QAP) reports, and interviews with laboratory staff, it was determined the laboratory failed to follow their policies for establishing acceptable ranges for coagulation QC. Survey findings include: A. The laboratory policy titled "Quality Control Program" states, "Two levels of controls will be tested every 8 hours for PT and PTT. New lot numbers of quality control material must be run in parallel to existing lot number prior to initiation of new lot. A minimum of 20 values should be obtained to establish mean and SD. The mean and SD are to be reviewed for the first 2 months by the supervisor to determine the need for adjustment...Coagulation QC range is determined by multiplying Mean by +/- 3 SD. Accept results if within +/- 3 SD. B. The January 2022 QAP report for PTT was reviewed. The laboratory lot to date standard deviation (SD) for Ci-Trol 1 (lot 564837A) was listed as 0.20 and the SD for Ci-Trol 3 (lot 55649A) was listed as 0.60. Using these calculated SD values for a +/- 3 SD range would give the lab a +/- 0.6 for Ci-Trol 1 and a +/- 1.8 for Ci-Trol 3. C. A review of January 2022 QC charts revealed the ranges used as +/- 3 SD in January were +3.6 and -4.4 for Ci-Trol 1 (more than 6 times the calculated range) and +/- 7.0 for Ci-Trol 3 (almost 4 times the calculated range). D. The April 2022 QAP report for PTT was reviewed. The laboratory lot to date standard deviation (SD) for Ci-Trol 1 (lot 564837A) was listed as 0.33 and the SD for Ci-Trol 3 (lot 55649A) was listed as 0.85. Using these calculated SD values for a +/- 3 SD range would give the lab a +/- 0.99 for Ci-Trol 1 and a +/- 2.55 for Ci-Trol 3. E. A review of April 2022 QC charts revealed the ranges used as +/- 3 SD in April were +3.6 and -4.4 for Ci-Trol 1 (more than 3.5 times the calculated range) and +/- 7.0 for Ci-Trol 3 (2.74 times the calculated range). F. QAP reports were not available for August to determine the current ranges. G. In an interview, at 10:15 a.m. on 9/21/22, employee #4 (as listed on the form CMS-209) confirmed the ranges were wider than the +/- 3SD required by the written policy and further stated that she couldn't explain where the values used as acceptable ranges originated.