Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0466447	09/03/2020
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 observation, lack of documentation and interview it was determined the laboratory failed to monitor room temperature in one of two rooms in which supplies with storage temperature requirement were stored. Findings include: A) During a tour of the laboratory on 09/1/2020 at 9:25 a.m., 400 BD Red Top Vacutainer Tubes, 600 Green Top Vacutainer Tubes, 100 Blue Top Vacutainer Tubes, 100 Pink Top Vacutainer Tubes, and 600 BD Lavender Top Vacutainer Tubes,were observed stored in a phlebotomy room separate from the laboratory. The Vacutainer Tubes have a manufacturer's storage temperature requirement of 4 to 25 degrees Celsius. B) Upon request, the laboratory was unable to provide records of room temperature in the separate storage room. C) In an interview on 9/1/2020 at approximately 10:53 a.m., the laboratory staff member, identified as number one on the CMS 209 form, stated that the laboratory did not monitor the room temperature in the phlebotomy room.
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 Levey - Jennings reports for nineteen tests performed on the Architect Chemistry Analyzer, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document all control procedures performed. A. In an interview with laboratory employee #1 (as listed on the form CMS-209) she stated that the laboratory used unassayed quality control and that the laboratory must set their own acceptable ranges. B. A review of the Levey - Jennings reports for Troponin I Level 3 (lot 67600) revealed the standard deviation (SD) range used by the laboratory did not match the calculated cumulative SD used in November 2019. The SD used for the acceptable range was 3.21. The calculated cumulative SD based on 218 points was 1.18. C. A review of the Levey - Jennings reports for CSF Glucose Level 1 (lot 56400) revealed the SD range used by the laboratory did not match the calculated cumulative SD used in November 2019. The SD used for the acceptable range was 3.00. The calculated cumulative SD based on 364 points was 1.25. D. A review of the Levey - Jennings reports for Acetaminophen Level 1 (lot 31870) revealed the SD range used by the laboratory did not match the calculated cumulative SD used in November 2019. The SD used for the acceptable range was 3.00. The calculated cumulative SD based on 465 points was 1.24. E. A review of the Levey - Jennings reports for Acetaminophen Level 2 (lot 31870) revealed the SD range used by the laboratory did not match the calculated cumulative SD used in November 2019. The SD used for the acceptable range was 2.00. The calculated cumulative SD based on 465 points was .50. F. A review of the Levey - Jennings reports for Triglyceride Level 2 (lot 31870) revealed the SD range used by the laboratory did not match the calculated cumulative SD used in November 2019. The SD used for the acceptable range was 7.00. The calculated cumulative SD based on 468 points was 3.98. G. A review of the Levey - Jennings reports for Ammonia Level 1 (lot 54310) revealed the SD range used by the laboratory did not match the calculated cumulative SD used in March 2020. The SD used for the acceptable range was 5.00. The calculated cumulative SD based on 91 points was 2.35. H. A review of the Levey - Jennings reports for Ammonia Level 3 (lot 54310) revealed the SD range used by the laboratory did not match the calculated cumulative SD used in March 2020. The SD used for the acceptable range was 25.00. The calculated cumulative SD based on 91 points was 3.7. I. A review of the Levey - Jennings reports for CSF Glucose Level 1 (lot 56430) revealed the SD range used by the laboratory did not match the calculated cumulative SD used in March 2020. The SD used for the acceptable range was 3.00. The calculated cumulative SD based on 86 points was 1.28. J. A review of the Levey - Jennings reports for Cholesterol Level 1 (lot 569200) revealed the SD range used by the laboratory did not match the calculated cumulative SD used in March 2020. The SD used for the acceptable range was 9.00. The calculated cumulative SD based on 94 points was 2.38. K. During a review of the long-term standard deviation documentation it was determined the documents did not include calculations of the SDs L. In an interview at 9:22 on 9/2/2020 laboratory employee #1 (as listed on the form CMS-209) confirmed the laboratory had no

	documentation of calculation of the SDs in use for the quality controls on the Architect chemistry analyzer.
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: Through review of Hospital Transfusion Records, the Laboratory Policy and Procedure "Reporting a Suspected Transfusion Reaction", System Nursing Policy Number 500.007 "Bood Transfusion/Red Cell and Non-Red Cell Products,"Blood Product Agreement between Baptist Health d/b/a/ Baptist Health Medical Center - Hot Springs County and Wellpath", patient electrronic medical records, lack of documentation and interview it was determined that the laboratory failed to assess the adequacy of procedures for investigating possible transfusion reactions and policies and procedures for blood transfusion recipient/Crossmatched Blood Product identification. Findings follow: I: The laboratory failed to evaluate the adequacy of the policy and procedure for identifying and investigating possible transfusion reactions. I A) Review of hospital statistics revealed that 238 units of red blood cells were transfused in the calendar year of 2019 and 122 units were transfused January through July of 2020. I B) In an interview on 9/2/20 at approximately 10:30 AM, the laboratory staff member identified as number four on the separate employee identification worksheet stated there had been no suspected transfusion reactions reported in 2019 and to date in 2020. I C) The Laboratory Policy and Procedure "Reporting a Suspected Transfusion Reaction" defines symptoms that may indicate a transfusion reactions include "fever with or without chills, defined as 1 degree C. or 2 degrees F." and "changes in blood pressure, usually acute, either hypertension or hypotension" and if acute hemolytic transfusion reaction, anaphylaxis, TRALI, sepsis or other serious problems are suspected a post-reaction blood sample should be drawn and a "Transfusion Reaction Investigation Form" should be completed and sent to the lab with the post-reaction specimen". I D) Nursing Policy Number 500.007 "Blood Transfusion/Red Cell and Non-Red Cell Products" states "observe patient closely for signs of a reaction which might include Sudden chilling or fever (>1.5 Degrees F above baseline, and "blood pressure changes" and "if a hemolytic reaction or other reaction is considered, the transfusion must be discontinued and the Blood Bank should immediately be notified". I E) In an interview on 9/2/20 at approximately 01: 20 PM, the hospital staff member identified as number five on the separate personnel identification sheet stated that nursing service defined a change in blood pressure to be an increase or decrease of 20 in either systolic or diastolic blood pressure measurement. I F) Review of twenty random blood administration records for calendar year 2020 revealed: * on 1/31/20 patient 657630 received unit W0919 19 385125 of leukocyte reduced packed red blood cells (LDRC) with a pre-administration blood pressure (BP) measurement of 143/58 and a 15 minute BP measurement of 116/49 which is a decrease of greater than 20 in systolic BP, * on 1/20 /20 patient 209405 received unit W0910 19 405912 of LDRC with a pre-administration BP of 167/56 and a 15 minute BP measurement of 198/62 which is an increase > 20 in systolic BP, * on 7/8/20 patient 89487340 received unit W0919 19 279926 of LDRC with a pre-administration BP of 124/76 and a 15 minute BP of 152

	/88 which is an increase > 20 in systolic BP and a pre-administration temperature of 97.5 degrees F. and a one hour temperature of 99.6 degrees F. which is an increase > 2.0 degrees F., * on 6/26/20 patient 2077100 received unit W0910 19 223005 of LDRC with a pre-administration BP of 94/48 and a 15 minute BP of 119/72 which is an increase > 20 in systolic BP. I G) In an interview on 9/3/20 at approximately 09:00 AM the laboratory staff member identified as number two on the separate "Employee Identification Worksheet" stated that the laboratory did not perform audits evaluating the efficacy of the transfusion reaction reporting policy. II: The laboratory failed to evaluate contract compliance regarding blood transfusion recipient/Crossmatched Blood Product identification. II A) The System Nursing Policy Number 500.007 " Blood Transfusion/Red Cell and Non-Red Cell Products states on page number 4, paragraph b. Check the transfusion slip AND the donor blood bag at the patient's bedside (one licensed nurse reviews the transfusion slip and the other licensed nurse reviews the blood bag at the same time). II B) The "Blood Product Agreement between Baptist Health d/b/a/ Baptist Health Medical Center - Hot Springs County and Wellpath",states on page 2, paragraph B. "Duties of Wellpath" subparagraph (v) Follow American Association of Blood Banks (AABB) guidelines for recipient identification and administration". II C) Review of ten blood administration records of transfusions performed by Wellpath reveal three transfusions failed to document the identity of the verifier and three transfusions failed to identify the transfusionist and the verifier. II D) In an interview on 9/3/20 at approximately 10:30 AM the laboratory staff member identified as number two on the separate "Employee Identification Worksheet" verified that contract compliance regarding identification of transfusion recipients/Crossmatched Blood Products were not followed and the laboratory had no quality assurance audit process for evaluating contract compliance in this regard.