Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2117481	07/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Health Medical Center Conway	1555 Exchange Avenue, Conway, 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
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: . Through a review of Quality Assessment Plan for Proficiency's testing, Proficiency Testing (PT) records for 2018, American Proficiency Institute (API) performance review logs, lack of documentation as well as interviews with staff, it was determined the Laboratory failed to prevent the recurrence of problems in the General Laboratory Systems. As evidenced by: A. The laboratory performs Activated Clotting Times (ACT) on the HEMOCHRON Analyzer. B. A review of the Laboratory's Quality Assessment Plan for Proficiency Testing revealed: "All results will be checked for accuracy. Any wrong or unacceptable result will be investigated to determine the cause of the failed result to reduce the likelihood of a recurrence of the problem in future surveys. Documentation of this process will take place on the Proficiency testing error report/corrective action form. C. A review of PT records for 2018 revealed the laboratory failed ACT in the first event of 2018 with a score of 0% and in the second event of 2018 with a score of 50%. D. A review of the API performance review and corrective action documentation for the first failed proficiency testing event of 2018 revealed: 1. "Findings: Samples were not mixed long enough. 2. Corrective Action: Annual competencies for Post-Anesthesia Care Unit (PACU) were completed last week." E. A review of the API performance review and corrective action documentation for the second failed proficiency testing event of 2018 revealed: "Continue to monitor and provide additional education to nursing staff." F. On 7/30 /2019 at 1250, the surveyor requested documentation of additional training for nursing staff. None was provided. G. The Laboratory's Quality Assessment Plan did not

	prevent recurrence of problems in the second testing event of 2018. H. In an interview on 7/30/2019 at 1250, the technical consultant (as listed on form CMS 209) confirmed the laboratory failed to prevent the recurrence of problems in the General Laboratory 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: Through observation, review of the manufacturer's package insert and interview it was determined that the laboratory stored three of three boxes of Thermo Scientific Anaerobic Indicator under incorrect temperature conditions. Findings follow: A) During a tour of the laboratory on 7/31/19 at approximately 01:00 PM three of three boxes of Thermo Scientific Anaerobic Indicators (Lot # 1810138, expiration date 2020/10) were observed stored at ambient room temperature. B) Review of the manufacturer's package insert for Thermo Scientific Anaerobic Indicator revealed a required storage temperature requirement of 2 degrees C. to 8 degrees C. C) In an interview on 7/31/19 at approximately 02:10 PM the laboratory staff member, identified as number three on the CMS 209 form, confirmed that the Thermo Scientific Anaerobic Indicators were stored at room temperature and they should be stored at refrigerated temperatures.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Through a review of the Chemistry Policy and Procedure Manual, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document function checks of laboratory timers semiannually as required by their written policy. Survey findings include: A. The Chemistry policy #CHE.1100.2 states that timer accuracy checks will be conducted semiannually. B. The surveyor requested documentation of timer accuracy being checked semiannually for three laboratory timers (serial numbers 170690434, 170690439, and 170690417) but none was provided. C. In an interview at 3:25 pm on 7/31/2019, laboratory employee #3 (as

	listed on the form CMS-209) confirmed there was no documented timer accuracy checks for three of three timers and also no documented date that the timers were put in service.
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 chemistry Levey-Jennings Reports for January, March, and June of 2019, laboratory test volumes provided by the laboratory, as well as interviews with laboratory staff, it was determined the laboratory failed to set quality control QC) ranges that will detect immediate errors. Survey findings include: A. The surveyor reviewed Levey-Jennings graphs and QC Summary Reports from the two Architect Chemistry Analyzers for January, March, and June 2019. 1. For Architect #1 the surveyor reviewed nineteen Chemistry tests (Acetaminophen, Alkaline Phosphatase, Alanine aninotransferase (ALT), Amylase, Total Bilirubin, Calcium, Creatine Phosphokinase (CPK), Glucose, Lactate dehydrogenase (LDH), Carbon Dioxide (CO2), Triglyceride, Uric Acid, High Density Lipoprotein (HDL), Urea, Ammonia, Beta Hydroxybutyric Acid, Ethyl Alcohol (ETOH), CSF Protein, and Brain Natriuretic Peptide (BNP). Ten of the nineteen Chemistry tests had at least one control with the standard deviation (SD) in use as acceptable range significantly wider than the true calculated SD. Tests performed on Architect #1 with SD in use significantly wider than the actual calculated SD are as follows: Acetaminophen Level 2 control calculated SD was 2.1 but the SD in use was 9.0; Alkaline Phosphatase Level 1 control calculated SD was 3.4 but the SD in use was 11.0 and Level 2 control calculated SD was 12.7 and SD in use was 43; ALT Level 2 control calculated SD was 3.2 but the SD in use was 9.0; Amylase Level 1 control calculated SD was 2.2 but the SD in use was 8.0 and Level 2 control calculated SD was 15.0 and SD in use was 44; CPK Level 1 control calculated SD was 3.7 but the SD in use was 16.0 and Level 2 control calculated SD was 14.7 and SD in use was 50; Glucose Level 1 control calculated SD was 1.6 but the SD in use was 8.0 and Level 2 control calculated SD was 5.6 and SD in use was 28; LDH Level 1 control calculated SD was 5.4 but the SD in use was 14.0 and Level 2 control calculated SD was 11.8 and SD in use was 38; Triglyceride Level 2 control calculated SD was 4.5 and SD in use was 18; ETOH Level 3 control calculated SD was 6.6 and SD in use was 23.7; and Ammonia Level 3 control calculated SD was 5.2 and SD in use was 23.2. 2. For Architect #2 the surveyor reviewed twenty-one Chemistry tests (Acetaminophen, Alkaline Phosphatase, ALT, Amylase, Total Bilirubin, Calcium, CPK, Glucose, LDH, CO2, Triglyceride, Uric Acid, HDL, Urea, Ammonia, Potassium, ETOH, CSF Protein, TSH, PTH, and BNP. Eleven of the twenty-one Chemistry tests had at least one control with the standard deviation (SD) in use as acceptable range significantly wider

	than the true calculated SD. Tests performed on Architect #2 with SD in use significantly wider than the actual calculated SD are as follows: Acetaminophen Level 2 control calculated SD was 3.6 but the SD in use was 8.7; Alkaline Phosphatase Level 1 control calculated SD was 3.2 but the SD in use was 10.5 and Level 2 control calculated SD was 5.96 and SD in use was 43; ALT Level 2 control calculated SD was 1.9 but the SD in use was 9.0; Amylase Level 1 control calculated SD was 2.6 but the SD in use was 8.0 and Level 2 control calculated SD was 10.8 and SD in use was 44; CPK Level 1 control calculated SD was 4.1 but the SD in use was 16.0 and Level 2 control calculated SD was 6.7 and SD in use was 50; CSF Protein Level 2 control calculated SD was 3.9 and SD in use was 9.0; Glucose Level 1 control calculated SD was 1.6 but the SD in use was 8.0 and Level 2 control calculated SD was 3.8 and SD in use was 28; LDH Level 2 control calculated SD was 9.1 and SD in use was 38; Triglyceride Level 2 control calculated SD was 2.5 and SD in use was 18; ETOH Level 3 control calculated SD was 10.1 and SD in use was 23.7; and Ammonia Level 3 control calculated SD was 6.1 and SD in use was 23.2. B. In an interview at 12:15 pm on 7/30/2019, employee #3 (as listed on the form CMS-209) stated that the laboratory had originally used 10% of the mean as the 1 SD instead of calculating a true 1 SD. She further confirmed that the ranges were plus or minus 20% (when using 2 SD as the range) and that they were too wide. She confirmed that the SD should have been calculated after enough data was obtained. C. Through a review of test volumes provided by the laboratory, failure to have QC acceptable ranges set based on the calculated SD has the potential to affect all testing performed on the following analytes: Acetaminophen (140 tests annually); Alkaline Phosphatase (7531 tests annually); ALT (7534 tests annually); Amylase (102 tests annually); CPK (1590 tests annually); CSF Protein (52 tests annually); Glucose (21,738 tests annually); LDH (628 tests annually); Triglyceride (424 tests annually); ETOH (239 tests annually); and Ammonia (144 tests annually).
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the Individualized Quality Control Plan (IQCP) for the Hemochron Jr. Activated Clotting Time (ACT) instrument, and interview with laboratory staff, it was determined the laboratory IQCP for ACT testing did not include required components. Survey findings follow: A) During a review of the IQCP for ACT testing it was determined the IQCP quality control plan (QCP) was missing one of the two required components. The QCP did not specify what external control material will be utilized in the QCP. C) In an interview at approximately 02:00 PM on 7/30/19 the laboratory staff member identified as number 2 on the CMS 209 form confirmed the IQCP did not specify the external control material used for ACT testing .

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 the laboratory policy and procedure manual, a review of Chemistry quality control (QC) records for January, March, and June 2019, and through interviews with laboratory staff, it was determined the laboratory failed to establish an acceptable 2 SD range for control materials. Survey findings follow: A. The General Laboratory Policy and Procedure Manual Policy includes policy # GEN. 1027.CW which states, "A well defined, specific quality control program is available in each department of the laboratory.", and further states, "Department-specific Quality Control Plans can be found in each individual department's procedure manual." B. During a review of the Chemistry Policy and Procedure manual the surveyor determined there were no written policies and procedures for establishing the acceptable range for chemistry QC material. C. In an interview at 12:15 pm on 7/30 /2019, employee #3 (as listed on the form CMS-209) stated that there was no written policy for establishing acceptable ranges for quality control material. D. A review of the QC Summary Report dated 7/30/2019 revealed the ranges in use were too wide to identify immediate errors in eleven of twenty-one Chemistry tests reviewed as cited at D5441. 35659 Through review of quality control records, control manufacturer ' s product inserts, and interview with laboratory staff, it was determined that the laboratory did not establish their own statistical parameters (target and range) of Activated Clotting Time (ACT) control materials used for quality control in two of two Hemochron Jr. ACT instruments used in both Catheritization units . Findings follow: A) Review of the Package insert for Accriva Liquid ACT controls reveal that " Accriva recommends that each laboratory establish its own expected range of response based on the mean plus-minus 2 standard deviations of at least 20 repeated test results" . B) Review of quality control (QC) records for November 2018, March 2019 and June 2019 included means and ranges that matched those provided in the Accriva inserts and there was no documentation that the laboratory established it's own acceptable ranges. C) In an interview on 7/30/19 at approximately 02:00 PM, the laboratory staff member identified as number two on the CMS 209 form, confirmed that values supplied on Accriva package inserts are scanned into the Hemochron Jr. ACT instrument and are used to define performance specifications for ACT assays for both ACT instruments in both Catheritization units.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through review of the laboratory's policy and procedure for quality control, quality control records for March 2019, Sysmex CA 600 instrument result tapes and interview it was determined that the laboratory failed to evaluate patient results back until the last successful quality control results in the event of quality control failure on one of 31 days of patient testing for Prothrombin Times (PT) in March 2019 affecting two of three patients. Findings follow: A. Review of the laboratory policy and procedure for coagulation quality control revealed that controls for PT are performed every eight hours and the controls must be within established acceptable range before patient testing can be performed and results reported. B. Review of the instrument print tapes for PT testing for March 21, 2019 revealed that QC3 lot # 548495 with an acceptable range of 43.2 sec. to 48.2 sec. was resulted as: * 45.6 sec. at 01:53 AM, (Result acceptable) * 48.3 sec with a notation "out" at 08:07 AM, * 48.5 sec with a notation "reran out" at 08:15 AM, * 48.3 sec with a notation "new QC out" at 08:37 AM. * 47.2 sec at 08:57 with a notation "new innovin" AM (Result acceptable) C. Review of instrument print tapes for PT testing revealed that the last successful quality control results were performed at 01:53 AM on 3/21/19 and that three patient PT tests, identified as numbers 1 through 3 on a separate patient identification list, were performed between 01:53 AM on 3/21/19 and 08:57 AM on 3/21/19 and there was no instance of successful quality control between those dates and times. D. Review of the instrument print tapes for PT testing revealed that PT testing was performed on 8/21 /19 after sucessful QC on the patient identified as number 1 on the separate patient identification list. E. Upon request, the laboratory was unable to provide documentation that the results of PT tests run and reported between 01:53 AM and 08: 57 AM on 3/21/19 on patients identified as numbers 2 and 3 on the separate patient identification list had been evaluated. F. In an interview on 7/31/19 at approximately 11:15 AM, the laboratory staff member, identified as number 2 on the CMS 209 report, confirmed that quality control had failed on 3/21/19 at the times identified above, the corrective action of preparing new innovin was a substantial change in the testing system and the two patient results reported since the last successful quality control had not been evaluated.