Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 04D0466006	**(X3) Date Survey Completed** 12/20/2019
Name of Provider or Supplier Baptist Health Medical Center Arkadelphia	**Street Address, City, State** 3050 Twin Rivers Dr, Arkadelphia, 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**
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: . Through a review of the Proficiency Testing records for 2019, Survey Exception Reports, lack of documentation, and interviews with staff, it was determined the laboratory failed to prevent the recurrence of problems in the General Laboratory Systems. Survey findings follow: A. A review of the Proficiency testing records for 2019 revealed the laboratory's Chemistry proficiency testing results: for the 2nd and 3rd event of 2019 (two of two testing events of 2019) the laboratory scored 50% for the analyte Direct Neonatal Bilirubin. B. A review of the Survey Exception Report for the 2nd Chemistry Proficiency Testing event revealed: "Investigation for clerical errors-none found. Reviewed Quality Control last 2 months for shifts. None noted. Will monitor next event: samples most likely too old for adequate retesting." C. A review of the Survey Exception report for the 3rd Chemistry Proficiency testing event revealed: "Investigated for clerical errors. None found. Reviewed Quality Control and Calibrations. Will run these samples on the day of arrival to see if specimen stability is the issue." D. The corrective actions taken by the laboratory in the 2nd Chemistry Proficiency testing event of 2019 failed to prevent the recurrence of problems identified in the 3rd Chemistry Proficiency testing event of 2019. E. In an interview on 12/20/19 at 10:30, laboratory personnel #2 (as listed on form CMS 209) confirmed the action taken failed to prevent the recurrence of failures in two of two Proficiency testing events of 2019.

D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Through lack of documentation and an interview with laboratory staff, it was determined the laboratory failed to provide written instructions for referral of specimens from outside facilities. Survey findings include: A. During a review of laboratory General Policies and Procedures it was determined there were no policies for a client services manual of written instructions for submission of samples from facilities outside of the laboratory. B. During an interview at 1:47 p.m. on 12/18/2019 laboratory employees #2 and #3 (as listed on the form CMS-209) stated that there were two nursing homes that sent samples to the laboratory for testing and confirmed the laboratory did not provide written instructions for referral of specimens from the two outside facilities.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Through a review of the Laboratory General Policy and Procedure Manual, a review of patient critical value documentation, and interviews with laboratory staff, it was determined the laboratory director failed to approve sign and date changes in the critical value policy. Survey findings include: A. During a review of the Critical Value Verification and Reporting policy it was determined that the policy was dated and signed by the laboratory director on 5/7/2014. B. The procedure includes a step that states, "Re-analyze the specimen (if possible)". This step has a handwritten undated not that states, "not required" which is initialed by laboratory employee #3 (as listed on the form CMS-209. The handwritten change does not include the laboratory directors signature or date of the change. C. A review of 80 critical values documented in November 2019 determined that the laboratory was following the unapproved change in the critical value policy in that 3 of 80 critical values reviewed had documentation of repeat testing. D. In an interview at 10:55 on 12/18/2019, laboratory employee #3 (as listed on the form CMS-209) confirmed the laboratory director had not approved, in writing, the change in the critical value verification policy.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Through review of the manufacturer's Sysmex CA 1500 coagulation instrument user manual, CLSI document C28-A2 , laboratory records for determining normal patient mean used to calculate the International Normal Ratio (INR) for Prothrombin Time (PT) assays, lack of documentation, and interview it was determined that the laboratory failed to establish normal reference mean for PT assays according to instructions provided by the instrument manufacturer. Findings follow: A) The manufacturer's instrument manual for the Sysmex CA 1500 coagulation instrument and the Dade Innovin PT reagent package inserts state that the normal patient mean should be established according to requirements specified in the CLSI document C28-A2. B) The CLSI document C28-A2 requires the normal reference mean to be the geometric mean value. C) Review of the 20 samples used to establish the normal reference mean for Innovin Lot # 549715 revealed that the calculated mean was the arithmetic mean. D) Upon request, the laboratory was unable to provide the geometric mean for the 20 samples used to calculate the normal reference mean for Innovin Lot # 549715. E) In an interview on 12/18/19 at approximately 12:30 PM, the laboratory staff, identified as number six on the CMS 209 form, stated that the normal reference mean for Innovin Lot # 540715 was the arithmetic mean and not the geometric mean as specified in the CLSI document C28-A2.
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 review of the laboratory policy and procedure " Prothrombin Time - Innovin" with the effective date of 9/23/19, the "CA-1500 Preventive Maintenance Checklist", observation, lack of documentation and interview it was determined that the laboratory failed to document the expiration date and time of one of one vials of innovin currently in use on the Sysmex CA 1500 coagulation analyzer. Findings follow: A) Review of the laboratory policy and procedure "Prothrombin Time - Innovin" with the effective date of 9/23/19 revealed that the stability of the Innovin was for 24 hours after reconstitution when the Innovin was on board the Sysmex CA 1500 coagulation analyzer. B) During a tour of the laboratory on 12/18/19 at approximately 01:00 PM, one of one vials of Innovin, Lot # 549715 expiration date 2020/08/10, was observed on board and in use on the Sysmex CA 1500 coagulation instrument with no date and time of placing it on board noted on the vial. C) Upon request, the laboratory could not produce documentation of the date and time the vial of Innovin was reconstituted and placed on board the Sysmex CA 1500 instrument and no way to determine it is within the 24 hour expiration. D) In an interview on 12 /18/19 at approximately 01:00 PM, the laboratory staff, identified as number three on the CMS 209 form, stated that changing Innovin is part of the duties of third shift

	personnel and is noted as a check mark on the "CA-1500 Maintenance Checklist" under a heading of "Check/Prepare Reagents" but the time that Innovin was reconstituted and placed on board the instrument is not documented.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory and interviews with laboratory staff, it was determined laboratory supplies were available for use when they had exceeded their expiration. Survey findings follow: A. During a tour of the laboratory, at 2:00 p.m. on 12/19/2019, the surveyor observed the following expired blood collection tubes available for use: 11 each of BD Vacutainers (lot # 9004632 expiration 10/31/19) were observed on a phlebotomy tray used for collection of patient blood samples and one each of Cytocool Rapid Freezing Aerosol (lot #1206 expiration 1/25/2004) was observed on top of the Cryostat used for frozen section histopathology. B. In an interview, at 2:05 on 12/19/2019, laboratory employee #2 (as listed on the form CMS-209) confirmed the supplies were available for use beyond their expiration date. 35659 Through review of manufacturer's package inserts, observation and interview it was deetermined that the laboratory had two of two vials of manual cell count control material available for use after its expiration date. Findings follow: A) Review of the manufacturer's package insert revealed that Cell-Chex manual cell count controls maintained stability for thirty days after opening. B) In a tour of the laboratory on 12/19/19 at approximately 11:00 AM, two of two vials of Cell-Chex manual cell count control , Lot numbers 92100412 and 92100413 with a date of opening of 10/3/19 (expired on 11/2/19) were observed in the laboratory refrigerator. C) In an interview on 12/19/19 at approximately 11:00 AM, the laboratory staff identified as number three on the CMS 209 form confirmed that the Cell-Chex controls were beyond their date of stability and were available for use.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Through a review of temperature records for 2019, lack of documentation, and interviews with staff, it was determined the laboratory failed to document corrective actions taken when Microbiology Incubator temperatures were outside of the laboratory's acceptable criteria. Survey findings follow: A. A review of temperature logs for 2019 revealed the Microbiology Incubator temperature acceptable range 34 to 37 degrees Celsius. B. A review of the temperature logs for May - December 2019 (7 of 7 months) revealed in October 2019 (4 of 31 days) the incubator temperature was documented at 38 degrees Celsius on the following days; 10/5/19, 10/6/19, 10/9/19 and on 10/11/19. There was no documentation of corrective actions taken on days

	when the incubator was outside of the laboratory's acceptable temperature range. C. In an interview at 13:00 on 12/19/2019, laboratory personnel #2 (as listed on the form CMS-209) confirmed the lack of documented corrective actions for incubator temperatures outside acceptable criteria.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of personnel records, and interview with laboratory staff, it was determined the laboratory director failed to give written authorization for three of sixteen testing personnel identified on the CMS 2009 form to perform moderately complex laboratory tests. Survey findings follow: A. A review of personnel records, revealed there was no signed authorization to perform moderately complex arterial blood gas analysis for testing personnel identified as numbers eleven, twelve and fifteen on the form CMS-209. B. Upon request, the laboratory could not provide a signed authorization to perform Complete Blood Count testing for the testing personnel identified as numbers eleven, twelve and fifteen on the CMS 209 form. C. In an interview on 12/18/19 at approximately 11:45 AM, the laboratory staff, identified as number ten on the CMS 209 form, confirmed that the laboratory failed to have a signed authorization to perform moderately complex arterial blood gas analysis for the testing personnel identified as numbers eleven, twelve and fifteen on the CMS 209 form and the personnel routinely perform arterial blood gas analysis.