Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0049978	09/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Health Medical Center Heber Springs	1800 Bypass Road, Heber Springs, 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
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, as well as interview with staff, it was determined the laboratory had BD Vacutainer Green Top (Lithium Heparin) blood collection tubes available for use when they had exceeded their expiration date. As evidenced by: A. During a tour of the laboratory on 09/13/2018 at 11:30, the Surveyor observed 50 of 50 BD Vacutainer Green top blood collection tubes (lot # 5203602) located in a upper shelf within the laboratory with an expiration date of 08/31/2018. The tubes were available for use when they had exceeded their expiration. B. In an interview on 09/13/2018 at 10:30, testing personnel #3 (as listed on form CMS-209) confirmed the expiration dates and the vacutainer collection tubes were available for use.
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 Streck Erythrocyte Sedimentation Rate (ESR) Chex package inserts, ESR quality control, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to establish the criteria for acceptability of ESR control. As evidenced by: A. Streck Auto Plus analyzer is utilized by the laboratory to perform ESR assay. A review of package insert for ESR-CHEX for automated Sedimentation Rate states: "The assay values are derived from replicate analysis on both automated and manual methods. Upon receipt of a new control lot, it is recommended that an individual laboratory establish its own mean and limits. However, the control means established by the laboratory should fall within the Expected range specified for the control." B. In a review of ESR quality control data, it was determined the mean and acceptable range in three of three months (January, April and August 2018) reviewed matched the expected range as listed on the ESR-Chex package insert. Level I control range (1-17) and Level II control range (65-101). C. The surveyor requested documentation of established ranges for ESR quality controls. None was provided. D. In an interview on 08/13/2018 at 10:00, laboratory employee #3 (as listed on CMS-209) confirmed that the laboratory has not established their own mean and range for ESR quality controls. The laboratory uses the manufactures ranges for the ESR control.