Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0467719	07/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mississippi County Hospital System	1520 North Division Street, Blytheville, 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 Gem Premier 3500 Blood Gas analyzer user manual, manufacturer's instruction, observations made during a tour, lack of documentation, as well as interviews with staff, it was determined the Respiratory laboratory failed to document temperature ranges and humidity conditions that are essential for the proper storage of reagents and the operation of the Gem Premier 3500 analyzer. As evidenced by: A. A review of the user manual (Section 11.3 "Specifications") for the Gem Premier 3500 Blood Gas analyzer revealed the Ambient Environmental and storage requirements for the analyzer operations: Relative Humidity 5% to 90%; External Ambient Temperatures 15 to 35 degrees Celsius: Gem Premier 300 Pak cartridges 15 to 25 degrees Celsius. B. A review of the manufacturer's instructions of GEM CVP 1 (Calibration Valuation Product) (Lot # 1834 expiration date 03/2019) and CVP 2 (lot #2834 expiration date 03/2019) revealed the storage and stability requirements: " Unopened ampoules are stable until the expiration date shown on the label when stored at 2-8 degrees Celsius, or up to 12 months at room temperature (20-28 degrees Celsius)." C. A review of the manufacturer's instructions for BIORAD Liquichek Blood Gas Quality Control (lot #28710 expiration date 07/31/2020) revealed the storage and stability requirements: " This product will be stable until the expiration date when stored unopened at 18 to 25 degrees Celsius." D. During a tour

	of the Respiratory laboratory on 7/25/2018 at 1300, the following was observed stored and in use at room temperature: Gem Premier 3500 Blood Gas Analyzer, 4 of 4 boxes of Critical Care Quality Control 7 (storage requirements 15-25 degrees Celsius); 3 of 3 boxes of Gem CVP 1 (storage requirements 20-28 degrees Celsius); 3 boxes of Gem CVP 2 (storage requirements 20-28 degrees Celsius); 1 of 1 box of Level 1 Liquichek Controls (storage requirements 18-25 degrees Celsius); 2 of 2 boxes of Level 2 Liquichek Controls (storage requirements 18-25 degrees Celsius) and 2 of 2 boxes of Gem Premier 3500 cartridges (storage requirements 15-25 degrees Celsius). The quality controls and reagents did not contain an opened date. E. The surveyor requested documentation of temperature requirements and humidity conditions. None was provided. F. In an interview on 7/25/2018 at 1330, laboratory employee #14 (as listed on form CMS 209) confirmed the Respiratory laboratory has no documentation of temperature or humidity conditions.
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 through interviews with staff, it was determined the laboratory had culture media available for use when it had exceeded it's expiration date. Survey findings follow: A. During a tour of the laboratory, at 1:25 p.m. on 7/25/2018, the surveyor observed two of six blood agar slants (lot #8011991 expiration 7/5/18) in the microbiology refrigerator, available for use, when they had exceeded their expiration dates. B. In an interview, at the time of the laboratory tour, laboratory employee #14 (as listed on the form CMS-209) confirmed the blood agar slants were available for use after they had exceeded their expiration.
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 laboratory policy and procedure for quality control, quality control reports for July 2017, Novemebr 2017, and March 2018, Sysmex CA-500 Problem log, patient result reports, lack of documentation and interview it was determined that the laboratory failed to evaluate patient results since the last acceptable test run when results of quality control for prothrombin times failed to meet the laboratory's established criteria for acceptability on one of one occasions of quality control failure affecting 3 patients in November 2017. Findings follow: 1. Review of the laboratory's

	policy and procedure for quality control revealed that the policy states that control tolerance limits ranges are "calculated based on plus or minus 2.0 to plus or minus 3.0 standard deviations from the mean control value" and specifies corrective action to be taken when tolerance limits are exceeded. 2. Review of the quality control report for November 24, 2017 revealed that the abnormal prothrombin time control (lot number 54849 with an acceptable range of 42.8 to 48.4) was reported as 49.9 at 14:54, 50.7 at 15:18, 49.1 at 15:39, and 46.1 at 15:59. 3. Review of the Sysmex CA-500 Problem log for the coagulation instrument revealed the entry on November 24, 2017 was "Problem : PT 3 high" and "Resolution: repeat still out, new QC still out, made new Innovin, new CaCL - QC OK". Because it required a complete change of reagents to obtain an acceptable quality control result indicates a flaw in the test system which had the potential to affect prior patient results. 4. Review of the quality control report revealed that the last acceptable prothrombin time quality control was performed at 06: 52 on November 24, 2017. 5. Review of the patient result report for November 24, 2017 revealed that prothrombin time tests were performed and resulted on three patients (identified as numbers 1 through 3 on a patient identification list) at 08:27, 11: 06, and 12:22 respectively . 6. Upon request, the laboratory was unable to provide documentation that patient prothrombin time results performed on November 24, 2017 identified above had been evaluated. 7. In an interview on 7/25/17 at approximately 1030, the technical supervisor identified as number 14 on the CMS 209 report confirmed that quality control for prothrombin time failed to meet the laboratory's criteria for acceptability on November 24, 2017 between the hours of 14: 54 and 15:59, that the resolution cited on the Sysmex CA-500 Problem Log indicated a problem with the test system and the patient prothrombin time results since the last successful quality control run had not been evaluated.