Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468144	02/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Five Rivers Medical Center	2801 Medical Center Drive, Pocahontas, 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
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 policies and procedures for Arterial Blood Gas testing and through interviews with staff, it was determined the blood gas procedures had not been approved, signed, and dated by the current laboratory director. Findings include: A. A review of written policies and procedures revealed the laboratory director did not sign procedure manual for Cardiopulmonary or the individual procedures for Critical Values in Blood Gases, the Arterial Blood Gas Analysis Procedure, or the Policy for Daily Review of Blood Gas and Quality Control Reports. B. In an interview at 1:20 on 2/21/2018, laboratory employee #9 confirmed the laboratory director had not signed the blood gas policies and procedures.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through review of Emergency Requests for Uncrossmatched Blood for 2017, and interview it was determined that the request for release of uncrossmatched blood in

	two of two units released on an uncrossmatched basis in 2017 were not signed by the requesting physician as required at 21 CFR 606.160(b)(3)(v). Findings follow: A. Review of Emergency Requests for Uncrossmatched Blood for the calendar year 2017 revealed that two units of uncrossmatched blood products (Units #W2055 17 244738 and W2049 17 275974) were released for patient #1199224 on 7/10/2017 and that requests were not signed or counter signed by the requesting physician but were only signed by nursing personnel. B. In an interview on 2/21/2018 at 10:47 a.m., laboratory employee #2 (as listed on the CMS 209 form) confirmed that the request for emergency release of uncrossmatched blood forms had been signed by nursing staff and not by the physician.
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 a review of the quality control policy, chemistry quality control results for July 2017, November 2017, and January 2018, lack of documentation, patient test records, and interviews with laboratory personnel, it was determined the laboratory failed to take and document corrective actions when quality control results were outside of the laboratory's established criteria for acceptability in one of three months reviewed. Survey findings include: A. The laboratory quality control policy titled "Quality Control Program" states the acceptable range for quality control is +/- 2 Standard Deviations (SD) from the mean. B. A review of November 2017 quality control results for Troponin T Level 1 revealed an acceptable 2 SD range of .051 to . 091 and quality control results outside of the acceptable range on 11/10/2017 (.094 and repeated .095), 11/11/2017 (.093), and 11/12/2017 (.106 and repeated .097) Five of fourty-one control runs in November were outside of acceptable range with no corrective actions documented. C. Patient test records for Troponin T revealed four patients tested on 11/10/2017, seven patients tested on 11/11/2017 and three patients tested on 11/12/2017. Quality control for Troponin T was unacceptable on these days of testing. D. In an interview at 1:20 on 2/21/2018, laboratory employee #2 confirmed the lack of documented corrective actions for the quality control failures.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the Cardiopulmonary Competency Evaluations for 2017 as well as interviews with staff, it was determined the Technical Consultant failed to evaluate

	the competency of testing personnel for 2017 using the required competency assessment components in six of six 2017 competency assessments reviewed as evidence by: 1. A review of the Cardiopulmonary Competency Evaluations for 2017 revealed the Competency Evaluations consisted of a list of duties that had been signed by the Cardiopulmonary Supervisor and the Laboratory Director. The form didn't state that the employee was competent or indicate the methods used to determine competency. Elements missing from the competency assessment include: a. Assessment of problem solving skills b. Direct observation of routine patient test performance, including patient preparation. c. Monitoring the recording and reporting of test results. d. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. In an interview at 1:20 on 2 /21/2018, laboratory employee #9 confirmed the lack of documentation, stating that she had changed the competency evaluation forms in 2017 and didn't realize they were missing information.