Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468144	07/08/2022
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
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 policy titled, "Quality Control Program", a review of the BioRad Liquichek Cardiac Markers Plus Control manufacturer's requirements, and a review of the Roche Diagnostics Cobas e 411 quality control (QC) documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to use statistical parameters to calculate criteria for acceptability of QC for one of two tests reviewed in which BioRad Liquichek Cardiac Markers Plus Control was the quality control material. Survey findings include: A. The "Quality Control Program" policy states, "Acceptable ranges will be established for these controls for all procedures. Control results will be evaluated as follows: Accept the results obtained if both control reads between +/- 2 SD (standard deviation) from the mean. Reject the run and troubleshoot the method involved if one or both controls are greater than +/- 2 SD from the mean or if procedural or electronic controls "fail". B. BioRad quality control instructions for use (as stated on their quality control website QCnet My e-Inserts)

	state, "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." C. Through a review of Roche Diagnostics Cobas e 411 quality control (QC) documentation, it was determined the laboratory used the package insert range as the acceptable range for N- Terminal Pro-Brain Natriuretic Peptide (NT-ProBNP). The manufacturer's package insert for BioRad Liquichek Cardiac Markers Plus Control LT states the NT-ProBNP quality control range for Level 1 (lot 67671) was 61.8 to 134 pg/ml. Quality control range listed for Level 3 (lot 67673) was 1911 to 4300. The ranges listed in use by the laboratory, for Level 1 and Level 3, on the Roche Diagnostics Cobas e 411 quality control (QC) documentation were the same ranges as on the package inserts. D. In an interview, at 9:53 on 7/7/2022, employee #2 (as listed on the form CMS-209) confirmed the laboratory policy states the laboratory will use a +/- 2 SD range for quality control and further confirmed the laboratory used the package insert ranges instead of calculating a +/- 2 SD range for NT-ProBNP.
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 five randomly selected personnel files for testing personnel in the blood gas laboratory, a review of the Cardiopulmonary Policy and Procedure Manual, lack of documentation, and interviews with blood gas laboratory personnel, it was determined the laboratory director failed to give four of five personnel reviewed, written authorization to perform blood gas testing. Survey findings include: A. Through a review of five randomly selected personnel files out of eleven blood gas lab testing personnel, it was determined that four of the five personnel files (personnel #13, #17, #19, and #20 as listed on the CMS-209) lacked documentation that the testing person was authorized to perform arterial blood gas testing. B. The Cardiopulmonary Policy and Procedure Manual included a policy titled, "Arterial Blood Gas Puncture Authorization". The policy included the name of personnel #13 but did not include the signature of the laboratory director. The policy did not include a date revised to indicate that it was revised prior to the last laboratory director signature of the policy and procedure manual. C. In an interview, at 10:00 on 7/8 /2022, the blood gas laboratory supervisor (listed as laboratory employee #10 on the CMS-209) confirmed that the only authorizations for personnel there were no written authorizations for personnel #17, #19, and #20 and that the authorization for employee #13 was not signed by the laboratory director.