Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468144	04/26/2024
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Review of personnel records, lack of documentation and interview with laboratory staff members determined that annual (and/or twice annually during the first year of employment) competency determinations were not performed for two of five personnel listed on the CMS 209 form which were reviewed. Findings follow: A) Review of personnel records revealed that no competency evaluations were presented for the laboratory staff member (# 3 on the CMS 209 form) who began employment in the laboratory on December 2022, no competency evaluations were presented for the laboratory staff member (# 5 on the CMS 209 form) who began employment in August 2022. B) Upon request the laboratory was unable to produce records of comptency assessment performed in 2023 on the staff members identified above. C) In an interview on 4/24/24 at 2:40 p.m. the laboratory staff member (# 1 on the CMS 209 form) stated that competency evaluations for the personnel identified above were not available. .
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: Observation, review of temperature records, lack of documentation and interview demonstrated that the laboratory failed to monitor the temperature on each day of operation in one of five rooms in which supplies with storage temperature requirements were stored. . Findings follow: A) During a tour of the laboratory on 4/24 /24 at 01:40 p.m.., the surveyor observed five separate rooms (Main laboratory, Covid Room, Microbiology, Respiratory Therapy, and supply storeroom) containing laboratory items with a temperature storage requirement. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the Covid Room. C) During a tour of the laboratory on 4/26/24 at 10:40 a.m. the surveyor observed 12 boxes of Gene X Pert Xpress Cov-2/RSV/Flu Plus reagents with a storage temperature requirement of 2 degrees Centigrade (C.) to 28 degrees C. in the Covid Room. D) Upon request, the laboratory could not present the temperature records for the storage room in which the supplies identified above were stored. E) In an interview on 4/26/24 at 10:40 a.m., the laboratory staff member (# 1 on form CMS 209) confirmed that temperature records for the Covid Room were not kept.
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: Observations made during a tour of the laboratory, demonstrated the laboratory had supplies available for use when they had exceeded their expiration date. Survey findings follow: A) During a tour of the laboratory at 11:00 a.m.on 4/26/24 the surveyor observed, two sodium citrate "blue top" blood collection tubes lot number 3111761 with expiration date of 2024-1-31, and one sodium citrate "blue top" blood collection tube lot number 3136119 with expiration date of 2024-2-29 available for use in a phlebotomy blood collection tray when they had exceeded their expiration date. B) In an interview on 4/26/24 at 11:05 a.m., the laboratory staff member (# 1 on the CMS 209 form) confirmed that the items identified above had exceeded the expiration date and 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: 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, determined the laboratory failed to use correct 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 entered an incorrect range for the acceptable range for Troponin (TR) assays due to a decimal point placement error resulting in the acceptable range reading ten times greater than the correct range and an effective SD used being +/- 20 SD instead of +/- 2SD. The SD used to define the acceptable range for level one TR (lot # 00067691) controls was 0.101 instead of the correct value of 0.0101. This error was reflected in all TR level assays from February through November 2023. D) In an interview, at 8:30 a.m. on 4 /26/24, employee #1 (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 incorrect SD to establish acceptable range for TR assays from February through November 2023.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Review of the laboratory's policy and procedure for "Testing Refrigerator Alarms", the continuous monitoring charts for the blood bank refrigerator and plasma storage freezer, records of the blood bank refrigerator and plasma storage freezer alarm checks, lack of documentation and interview demonstrated that the laboratory failed to perform periodic alarm checks for the blood bank blood storage refrigerator and plasma storage freezer for the calendar year 2023 Findings follow: A) Review of the laboratory's policy and procedure for "Testing Refrigerator Alarms" revealed "the

	alarm on each blood-storage refrigerator should be checked periodically to ensure it functions properly, quarterly alarm checks are appropriate". B) Review of the laboratory documentation for blood bank refrigerator alarm check revealed that no alarm check was documented in 2023 and review of the plasma storage freezer documentation for alarm checks revealed that one alarm check was documented in March 2023. C) Review of the continuous temperature monitoring charts for 2023 revealed that no documentation of alarm checks was present for the blood storage refrigerator or the plasma storage freezer . D) Upon request, the laboratory was unable to provide documentation of blood bank refrigerator or plasma freezer alarm checks performed other than the single instance in March 2023 E) In an interview on April 26 2024 at 10:40 a.m., the laboratory staff member (# 1 on the CMS 209 form,)stated that the laboratory had only performed one alarm check on the plasma freezer and no alarm checks on the blood storage refrigerator in 2023. .
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: . Review of personnel files for five testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, determined the laboratory director failed to authorize one of five testing personnel to perform testing without direct supervision. Survey findings include: A) During a review of personnel files for five testing personnel listed on form CMS-209 (Personnel #'s 2, 3, 5, 8, and 9) the surveyor determined employee number 3 (as listed on the form CMS-209), with a date of hire of 12/8/22, failed to have written authorization, from the laboratory director, to perform moderate complexity testing without direct supervision. B) In an interview, at 2:40 p.m.. on 4/24/24, laboratory employee #1 (as listed on the form CMS-209) confirmed the lack of written authorizations to test for employee # 3 (on form CMS 209).