Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0647560	09/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Twin Rivers Medical Laboratory, Inc	902 W Broadway, Logansport, IN	

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: Based on observation, document review and interview, the laboratory failed to ensure the clean solution for the ISE (Ion Selective Electrode) used for the maintenance procedures for three of three analytes (sodium, potassium and chloride) tested on the Roche Cobas501/601 serial number 1619-02 had not exceeded its expiration date from 1-31-24 to 9-3-2024. Findings included: 1. During a lab tour on 9-3-2024 at 12: 00 pm, the following was observed: a) A Cobas Roche 501/601 serial # 1619-02 was in use for patient testing. b) A box of ISE (Ion Selective Electrode) cleaning solution used in the daily maintenance procedure for sodium, potassium and chloride was in the laboratory refrigerator with a date of 5-31-24. The bottle did not state if it was an open date or expiration date. c) Review of the original box listed an expiration date of 1-31-2024. The open bottle had an expiration date of 1-31-2024. 2. "ISE Cleaning /Elecsys SYS Clean" package insert, REF 11298500, removed from the open box of ISE Cleaning solution read, "The solution is stable to the stated expiration date when stored at 2-8 degrees Celsius". 3. During an interview on 9-3-2024 at 12:00 pm, SP-03 (testing Personnel) stated "the cleaning solution is used daily to clean the pipe". 4. Total annual test volume for Sodium, Potassium and chloride is 40,374
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--

	(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the laboratory failed to follow their policy on performing quality control after calibration is completed to verify accuracy of the calibration for three of 32 analytes (analytes sodium, potassium and chloride) tested on the Cobas Roche 501/601analyzer and three of three patients (PT #1-PT#3) reviewed. Findings Include: 1. During a laboratory tour on 9-3-2024 at 12: 00 pm, a Cobas Roche 501/601 Chemistry analyzer serial number 1619-02 was in use for patient testing, including the analytes sodium, potassium and chloride. 2. In an interview on 9-3-2024 at 12:00 pm, SP-01 (testing personnel) stated that "the analytes sodium, potassium and chloride are calibrated daily." 3. Review of calibration reports for sodium, potassium and chloride indicated a calibration occurred on 8-27-2024 at 16:37 pm. 4. A review of patient (Pt) medical records indicated three patient (pt) samples were run on the Cobas Roche 501/601 serial # 169-02 on 8-28-2024 between 06:31 am and 06:38 am for the analytes of sodium (Na), potassium (K+) and chloride (cl). Pt Time Na K+ cl #1 06:31 am 140.0 4.2 101.7 #2 06:32 am 142.0 4.8 107.6 #3 06:38 am 141.0 3.9 99.8 3. Review of quality control records indicated quality control materials were run on 8-28-2024 at 08:46 am. 4. Policy dated on 8-16-2024 titled: Employee training sheet: Calibration Procedure for the Roche Cobas 6000 requires: "4.1 Running Quality Controls: After calibration run quality control samples to verify the accuracy of the calibration". 5. Total annual test volume is 40,347