Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 15D0647560	**(X3) Date Survey Completed** 08/05/2024
Name of Provider or Supplier Twin Rivers Medical Laboratory, Inc	**Street Address, City, State** 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**
D0000	A recertification survey was completed on 8/5/2024. It was determined that the following condition-level deficiencies existed: 42 C.F.R. 493.1250 Condition: Analytic systems
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, lack of documentation, record review and interview, the laboratory failed to meet the following analytic system requirements: the laboratory failed to ensure the open and expiration dates were labeled for the three of three complete blood count (CBC) controls in use (refer to D5415); the laboratory failed to follow manufacturer's instructions for using calibration material with at least the frequency recommended by the manufacturer for five of 34 assays (triglycerides, alkaline phosphate, calcium, free thyroxine (FT4) and digoxin) tested in the specialty of chemistry using the Roche Cobas 601 serial # 1619-02 (refer toD5437); and the laboratory failed to include two levels of quality control (QC) material for each day of patient testing for one of one analyte (prothrombin time) tested on the Seimens Coagulations Analyzer CA 600 serial# 12253 (refer to D5447).
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, and interview, the laboratory failed to ensure the open and expiration dates were labeled for the three of three complete blood count (CBC) controls in use. Findings include: 1. During a tour of the laboratory on 7-23-2024 at 11:20 AM, the following was observed: a) An Abbott Cell Dyne Complete Blood Count analyzer was in use. b) A container in the laboratory refrigerator held three levels of Complete Blood Cell (CBC) quality control (QC) material. The QC material had a laboratory manufactured barcode label on top of each control vial. 2. In an interview on 7-23-2024 at 11:20 AM, SP-03 (testing personnel) verified no open or expiration dates were on the quality controls vials labeled Low, Normal, High. 3. During continuation of the laboratory tour on 7-23-2024 at 12:15 PM, SP-01 (testing personnel) and SP-03 (testing personnel) removed the laboratory manufactured barcode label off the quality control vials to reveal the Biotecneic quality control material lot number kk119 had an expiration date of 7-5-2024. 4. Total annual test volume for CBC is 11798.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on observation, lack of documentation, record review, and interview, the laboratory failed to follow manufacturer's instructions for using calibration materials with at least the frequency recommended by the manufacturer for five of 34 assays (triglycerides, alkaline phosphate, calcium, free thyroxine (FT4) and digoxin) tested in the specialty of chemistry using the Roche Cobas 601 serial # 1619-02. Findings include: 1. During laboratory tour on 7-23-2024 at 10:38 am, a Roche Cobas 601 serial #1619-02 was in use for patient testing in the specialty of chemistry including: triglycerides, alkaline phosphate, calcium, free thyroxine, and digoxin. 2. Upon request for manufacture package inserts for triglycerides, alkaline phosphatase, and calcium, on 7-23-2024 at 10:38 am, SP-02 (testing personnel) could not provide package inserts for the reagents or calibration materials. SP-02 further confirmed they did not have any calibration materials in the laboratory for triglycerides, alkaline phosphatase, or calcium. 3. The package inserts for the Cobas required the following: a. "Elecsys FT4 III" reference number 07976836190 required the analyte FT4 to be

	calibrated at least every 30 days. b. "Elecsys Digoxn" reference number 11820796190 required the analyte digoxin to be calibrated at least every 30 days. 4. A calibration report printed from the Roche Cobas 601 dated 11-20-2023 for the analyte FT4 and dated 1-05-2024 for the analyte digoxin indicated these were the last calibration dates for each analyte. 5. In an interview on 7-23-23 at 2:53 pm, SP-01 (testing personnel) confirmed the last calibration dates for FT4 were 11-20-2023 and 1-05-2024 for digoxin. 6. Patient (PT)#1 had free thyroxine (FT4) tested on of 1-15-2024 at 7:46 am with a result of 1.7ng/dl without a calibration being performed every 30 days. 7. PT#2 had digoxin tested on 7-23-24 at 3:03 PM confirmed the laboratory performed patient testing on 2-21-2024 for the analyte digoxin without a calibration being performed every 30 days. 8. Total annual test volume for FT4 is 1,586 and digoxin is 130.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to include two levels of quality control (QC) material for each day of patient testing for one of one analyte (prothrombin time) tested on the Seimens Coagulations Analyzer CA 600 serial# 12253. Findings Include: 1. On 7-23-2024 at 10:38 AM, a Seimens Coagulation analyzer CA 600 serial # 12253 was in use for the testing on patient samples for Prothrombin time (PT). 2. In an interview on 7-23-2024 at 2:32 PM, SP-03 (testing personnel) stated "we only run one level of quality control daily". 3. Review of the quality control for the date of 7-08-2024 revealed only one level of quality control material was run. 4. Review of policy titled "Quality Control Activities", with no review date by the current laboratory director, reads..."B. Procedure for Daily Quality Control Decisions using Two Level Program..." The policy does not define the "Two Level Program". 5. Review of the "Daily Control Report" "Name: "COAG GC-02" run on 7/8/2024 confirmed only 1 level of Quality Control was performed. 6. Total annual test volume for prothrombin is 1,939.