Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0647560	(X3) Date Survey Completed 07/23/2024
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 Proficiency Testing Review survey was completed on 7/23/2024. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.803(a)(b)(c) Successful Participation
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to achieve satisfactory performance of 80% or greater for two consecutive proficiency testing (PT) events in 2024 (event 1 in 2024 and event 2 in 2024) for one of four regulated analytes tested in the subspecialty of endocrinology (triiodothyronine (T3)) and for two of four analytes tested in the subspecialty of toxicology (digoxin and phenytoin). T3 results were 60%

	for event 1 and 20% for event 2 of 2024 (refer to D2099). Digoxin results were 40% for event 1 and 0% for event 2 2024. Phyenytoin results were 60% for event 1 and 60% event 2 of 2024 (Refer to D2118).
D2099	ENDOCRINOLOGY CFR(s): 493.843(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to achieve satisfactory performance of 80% or greater for two consecutive proficiency testing (PT) events in 2024 (event 1 in 2024 and event 2 in 2024) for one of four analytes tested in the subspecialty of endocrinology (triiodothyronine (T3)). T3 results were 60% for event 1 and 20% for event 2 of 2024. Findings Include: 1. Review of the Casper Report 0155D (Individual laboratory Profile) indicated the following scores for triiodothyronine: Event 1 of 2024 = 60% and Event 2 of 2024 =20%. 2. Review of the American Proficiency Institute (API) Performance Summary 2024 Core- 2nd event confirmed the scores for triiodothyronine for event 1 of 2024 = 60% and event 2 of 2024 =20%. 3. In an interview on 7-23-24 at 12:52 PM, SP-01 (testing personnel) and SP-02 (testing personnel) confirmed the results. 4. Total annual test volume for Triiodothyronine is 39 patients.
D2118	TOXICOLOGY CFR(s): 493.845(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to achieve satisfactory performance of 80% or greater for two consecutive PT events in 2024 for two of four analytes in the specialty of Chemistry, subspecialty toxicology (digoxin and phenytoin). Digoxin results were 40% for event 1 and 0% for event 2 2024. Phyenytoin results were 60% for event 1 and 60% event 2 of 2024 (Refer to D2118). Findings Include: 1. Review of the Casper Report 0155D (Individual Laboratory Profile) indicated the following unsatisfactory scores: a) digoxin event 1 of 2024=40%, event 2 of 2024 = 0%, and b) phenytoin event 1 2024= 60%, event 2 of 2024=60%. 2. Review of the American Proficiency Institute (API) Performance Summary 2024 Core- 2nd event confirmed the digoxin results were 40% for event 1 and 0% for event 2 2024, and Phyenytoin results were 60% for event 1 and 60% event 2 of 2024 3. Interview on 7-23-2024 at 12:52 PM with SP-01 (testing personnel) and SP-02 (testing personnel) confirmed the scores were accurate for digoxin and phenytoin. 4. Total annual test volumes: Digoxin = 130 patients per year Phenytoin = 32 patients per year.