Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0647560	03/21/2025
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
D0000	A proficiency testing desk review survey was completed on 3/21/2025. The following condition-level deficiencies were found to be out of compliance: D2016- 42 C.F.R. 493.803 Condition: Successful participation (proficiency testing) D6000-42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 surveyor proficiency testing (PT) desk review of the laboratory PT records, the American Proficiency Institute(API) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and

	emails from the Technical Consultant (SP-2) on 03/21/205, the laboratory failed to achieve satisfactory performance in two out of three events (Event 2 of 2024 and Event 1 of 2025) resulting in unsuccessful participation in the subspecialty of Endocrinology for the analyte of thyroxine in 2024 and 2025. Refer to D2099.
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the American Proficiency Institute (API) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Technical Consultant (SP-1) on 3/21/2025, the laboratory failed to achieve satisfactory performance in two out of three events (event 2 in 2024 and event 1 in 2025) resulting in unsuccessful participation in the subspecialty of Endocrinology for the analyte of thyroxine in 2024 and 2025. Findings included: 1. Review of the "CASPER Report 0155D," run date 3/14/2025 indicated a score of 0% for event 2 2024, and 40% for event 1 2025 for thyroxine as reported by API. 2. Upon request for information on PT for 2024 and 2025 for thyroxine, via email on 3/21/2025 at 4:12 pm, SP-2 (Technical Consultant) provided a document "Performance Review and Corrective Action Documentation 2025 Chemistry - Core - 1st Event". 3. Review of "Performance Review and Corrective Action Documentation 2025 Chemistry - Core - 1st Event", signed by the SP-2 (Technical Consultant) on 3/21/2025, detailed the following for thyroxine: a.) 2024 2nd event was 0% b.) 2025 1st event was 40% 4. Review of the API Proficiency Testing Performance Evaluation report for "2024 Chemistry- Core- 2nd Event", final report date 2/26/2025, detailed the following for thyroxine: a.) Part 2 of 4, Page 1 of 1 "Performance Summary": 1.) Thyroxine was listed under the Endocrinology subspecialty section. 2.) Proficiency Event 2024 2 thyroxine had a score of 0%. b) Part 3 of 4, Page 3 of 4 "Chemistry (Endocrinology)": 1.) Five samples were submitted. 2.) Five out of five samples had an unacceptable reported result. 5. Review of the API Proficiency Testing Performance Evaluation report for "2025 Chemistry- Core- 1st Event", final report date 2/26/2025, detailed the following for thyroxine: a.) Part 2 of 4, Page 2 of 2 "Performance Summary": 1.) Thyroxine was listed under the Endocrinology subspecialty section. 2.) Proficiency Event 2024 2 thyroxine had a score of 0%. 3.) Proficiency Event 2025 1 thyroxine had a score of 40%. 4.) Long Term performance was "unsuccessful". b.) Part 3 of 4, Page 3 of 5 "Chemistry (Endocrinology)": 1.) Five samples were submitted. 2.) Three out of five samples had an unacceptable reported result.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by:

	Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the American Proficiency Institute (API) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Technical Consultant (SP-1) on 3/21/2025, the laboratory director failed to ensure that the laboratory successfully participated in two out of three events (event 2 in 2024 and event 1 in 2025) resulting in unsuccessful participation in the subspecialty of Endocrinology for the analyte of thyroxine in 2024 and 2025. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the American Proficiency Institute (API) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Technical Consultant (SP-1) on 3/21/2025, the laboratory director failed to ensure that the laboratory successfully participated in an Health and Human Services (HHS) approved testing program for the analyte thyroxine. Refer to D2098.