

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0647560	(X3) Date Survey Completed 08/30/2023
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 desk review survey was completed on 8/30/2023. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.803(a)(b)(c) Successful Participation 42 CFR 493.1411 Laboratory Director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Repeat deficiency. Based on record review and staff interview, the laboratory failed to successfully participate in American Association of Bioanalysts (AAB), proficiency testing (PT) for three out of five consecutive events (1 and 3 in 2022 and 2 in 2023) in the subspecialty Bacteriology, for the analyte, Urine Culture (Refer to D2028).</p>

<p>D2028</p>	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Repeat deficiency. Based on record review and staff interview, the laboratory failed to successfully participate in proficiency testing (PT) by achieving a score of 80% or higher for three out of five consecutive events (1 and 3 in 2022 and 2 in 2023) in the subspecialty Bacteriology, for the analyte, Urine Culture. Findings include: 1) Review of Oscar Report 155D (Individual Laboratory Profile) indicated the following unsatisfactory scores for Bacteriology and the analyte Urine Culture: Event 1 (2022) = 0%, Event 3 (2022) = 67%, and Event 2 (2023) = 20%. 2) Review of proficiency testing scores from American Association of Bioanalysts (AAB) Medical Laboratory Evaluation "CMS Cumulative Scores- Regulated Analytes" dated 10/18/2022 and "Nch22Q3 Score NCH23M1 Score Nch23M2 Score" no date, confirmed the above Bacteriology scores for Urine Culture: Event 1 (2022) = 0%, Event 3 (2022) = 67%, and Event 2 (2023) = 20% 3) On 12/21/2022 at 1:13 pm, SP#1 (Technical Supervisor), confirmed the scores for Event 1/2022 (0%) and Event 3/2022 (67%) for Bacteriology and the analyte, Urine Culture. 4) On 8/21/2023 at 4:23 pm, SP#1 (Technical Supervisor), confirmed the scores for Event 2/2023 (20%) for Bacteriology and the analyte, Urine Culture.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure the laboratory successfully participated in the American Association of Bioanalysts (AAB) proficiency testing (PT) program in the subspecialty of Bacteriology. The laboratory had unsatisfactory overall PT event testing scores (less than 80%) for three out of five consecutive events (1 and 3 in 2022 and 2 in 2023) in the subspecialty Bacteriology, for the analyte, Urine Culture (Refer to D6089).</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure the laboratory successfully participated in the American Association of Bioanalysts (AAB) proficiency testing (PT) program in the subspecialty of Bacteriology. The</p>

laboratory had unsatisfactory overall PT event testing scores (less than 80%) for three out of five consecutive events (1 and 3 in 2022 and 2 in 2023) in the subspecialty Bacteriology, for the analyte, Urine Culture Findings included: 1) Review of Oscar Report 155D (Individual Laboratory Profile) indicated the following unsatisfactory scores for Bacteriology and the analyte Urine Culture: Event 1 (2022) = 0%, Event 3 (2022) = 67%, and Event 2 (2023) = 20%. 2) Review of proficiency testing scores from American Association of Bioanalysts (AAB), confirmed the above Bacteriology scores for Urine Culture: Event 1 (2022) = 0%, Event 3 (2022) = 67%, and Event 2 (2023) = 20% 3) On 12/21/2022 at 1:13 pm, SP#1 (Technical Supervisor), confirmed the scores for Event 1/2022 (0%) and Event 3/2022 (67%) for Bacteriology and the analyte, Urine Culture. 4) On 8/21/2023 at 4:23 pm, SP#1 (Technical Supervisor), confirmed the scores for Event 2/2023 (20%) for Bacteriology and the analyte, Urine Culture.