

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0521095	<b>(X3) Date Survey Completed</b>  11/01/2021
<b>Name of Provider or Supplier</b>  Tri-State Clearwater Medical Clinic	<b>Street Address, City, State</b>  1522 17th St, Lewiston, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<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: Based on a Proficiency Testing (PT) desk review of graded PT results from the American Association of Bioanalysts (AAB) and an interview with the clinic manager on 11/1/2021, the laboratory failed to successfully participate in PT for the subspecialty of routine chemistry for the analyte creatinine for three (3) of three (3) consecutive testing events. See D2096</p>
<b>D2096</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

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 a Proficiency Testing (PT) desk review of graded PT results from the American Association of Bioanalysts (AAB) and an interview with the Clinic manager on 11/1/2021, the laboratory failed to achieve an overall testing event score of satisfactory performance for three (3) consecutive testing events for the subspecialty of routine chemistry for the analyte creatinine. The findings include: 1. A PT desk review of graded PT results from AAB revealed the laboratory failed to achieve satisfactory results for the subspecialty of routine chemistry for the following analyte: Analyte Year Event Score Creatinine 2020 3 20% Creatinine 2021 1 0% Creatinine 2021 2 20% 2. An interview with the Clinic manager on 11/1/2021 at 2:33 pm confirmed the PT failures.

**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 a Proficiency Testing (PT) desk review of graded PT results from the American Association of Bioanalysts (AAB) and the previous CMS-2567 for unsuccessfully participation dated 6/3/2021 and its corresponding Allegation of Compliance (AOC)/ Evidence of compliance (EOC) dated 6/9/2021, the laboratory director failed to ensure the plan of remedial action, training, or technical assistance was successful from previous proficiency testing failure for the analyte creatinine and failed to ensure that the laboratory maintained successful participation for the analyte creatinine for three (3) of three (3) consecutive proficiency testing events. (D6019) The laboratory director failed to ensure that the laboratory submit PT results for creatinine for 2021 event one (1). (D6017)

**D6017**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a Proficiency Testing (PT) desk review of graded PT results from the American Association of Bioanalysts (AAB) and an interview with the Clinic manager on 11/1/2021, the laboratory director failed to ensure that the laboratory submitted PT results for analytes in the subspecialty of routine chemistry for 2021

event one (1) . The findings include: 1. A PT desk review of graded PT results from AAB revealed the laboratory failed to submit PT results for 19 analytes in the subspecialty of routine chemistry, including creatinine for 2021 event one (1). 2. An interview with the Clinic manager on 11/1/2021 at 2:33 pm confirmed the failure to submit PT results.

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on a Proficiency Testing (PT) desk review of graded PT results from the American Association of Bioanalysts (AAB) and the previous CMS-2567 for unsuccessful participation and its corresponding Allegation of Compliance (AOC)/ Evidence of Compliance (EOC), the laboratory director failed to ensure that the laboratory maintained successful participation for the analyte creatinine. The findings include: 1. A PT desk review of graded PT results from AAB revealed the laboratory director failed to ensure that the laboratory maintained successful participation for the analyte creatinine for three (3) of three (3) consecutive proficiency testing events. 2. A review of the previous CMS-2567 for unsuccessful participation dated 6/3/2021 and the corresponding AOC/EOC dated 6/9/2021 identified that laboratory director failed to ensure that the plan of remedial action, training, or technical assistance was successful from the previous proficiency testing failures for the analyte creatinine. 3. An interview with the Clinic manager on 11/1/2021 at 2:33 pm confirmed the failure to achieve a satisfactory score for the analyte creatinine for three (3) of three (3) consecutive PT events.