Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521095	01/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Tri-State Clearwater Medical Clinic	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
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 a Proficiency Testing (PT) desk review of graded PT results from the American Association of Bioanalysts (AAB) and an interview with the laboratory manager on 1/19/2023, the laboratory failed to successfully participate in PT for the analyte creatinine for one event in 2020 and two (2) consecutive testing events in 2021 and 2022. See D2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(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 a Proficiency Testing (PT) desk review of graded PT results from the American Association of Bioanalysts (AAB) and an interview with the laboratory manager on 1/19/2023, the laboratory failed to achieve an overall score of satisfactory performance for two (2) consecutive testing events for the analyte creatinine in 2022. The findings include: 1. A PT desk review of graded PT results from AAB identified that the laboratory failed to achieve satisfactory results for the following analyte: Analyte Year Event Score Creatinine 2020 3 20% Creatinine 2021 1 0% Creatinine 2021 2 20% Creatinine 2022 2 20% Creatinine 2022 3 20% 2. A rolling review of the laboratory's graded PT results from AAB identified the subsequent occurrence of unsuccessful PT participation for the analyte creatinine in 2020 event three (20%), and in 2021 for events one (0%) and two (20%) for which the laboratory submitted an allegation of compliance (AOC) on 11/26/2021 which resulted in the reinstatement of testing of the analyte creatinine on 6/15/2021. 3. A PT desk review performed on 1/24 /2023 identified the additional subsequent occurrence of unsuccessful PT participation for the analyte creatinine in 2022 for event two (20%) and event three (20%). 4. An interview with the Clinic manager on 1/19/2023 at 2:08 pm confirmed the PT failures in 2020, 2021 and 2022 for creatinine.
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), the subsequent occurrence of unsuccessful participation for the analyte creatinine (event three in 2020, events one and two in 2021), the corresponding allegation of compliance (AOC) and evidence of compliance (EOC) which provided the basis for reinstatement of testing on 6/15/2022 for the analyte creatinine, the laboratory director failed to ensure the plan of remedial action, training, or technical assistance was successful from previous proficiency testing failures and sanction for the analyte creatinine to ensure that the laboratory maintained successful participation for the analyte creatinine for two (2) consecutive proficiency testing events in 2022. See D6019
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 limitation on testing for the analyte creatinine for the subsequent occurrence of unsuccessful participation dated 11/1/2021, the laboratory director failed to ensure that the laboratory maintained successful participation for the analyte creatinine. The findings include: 1. A rolling review of the laboratory's graded PT results from AAB identified that the laboratory director failed to ensure that the laboratory maintained successful participation for the analyte creatinine for event three in 2020, events one and two in 2021 and events two and three in 2022. 2. The laboratory submitted an allegation of compliance (AOC) for the subsequent unsuccessful PT participation for creatinine (event three in 2020 and events one and two in 2021) on 11/30/2021 which was accepted on 11/30/2021 and resulted in the reinstatement of testing of the analyte creatinine on 6/15/2021. 3. A PT desk review on 1/24/2023 revealed the additional subsequent occurrence of unsuccessful PT participation for the analyte creatinine in 2022 for event two (20%) and event three (20%) which 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 in 2022. 4. An interview with the laboratory manager on 1/19/2023 at 2:08 pm confirmed the failure to achieve a satisfactory score for the analyte creatinine for event three in 2020, events one and two in 2021 and events two and three in 2022.