Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521095	07/26/2018
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to retain calibration records from the Cobas Integra 400 Plus chemistry analyzer for all 23 chemistry analytes. Findings: 1. A calibration record review for the Cobas Integra 400 revealed the laboratory failed to retain the chemistry calibration print-outs from the dates requested for December 2017. 2. An interview on July 26, 2018 at 10:45 AM, with the laboratory manager, confirmed the laboratory failed to retain the chemistry calibration instrument print-outs from 2017 because the lab only keeps the most current calibration records onboard the instrument computer.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory director failed to ensure two phlebotomists receive appropriate training and demonstrate they can perform testing on the Sysmex pocH-100i complete blood count (CBC) analyzer prior to testing patient samples since the last survey on February 18, 2016. Findings: 1. A record review revealed two phlebotomists failed to have documentation of training prior to testing patient CBC samples since 2016. 2. An interview on July 26, 2018 at 10:05 AM, with the laboratory manager, confirmed the laboratory director failed to ensure the phlebotomists receive appropriate training and demonstrate they can reliably perform CBC tests for patient samples.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on competency assessment records and an interview with the laboratory manager, the laboratory director who is the technical consultant failed to have a qualified individual perform competency assessments for 3 out of 5 testing personnel performing complete blood counts (CBCs), chemistry, endocrinology, and microscopic examinations since the last accreditation survey on February 18, 2016. The technical consultant also failed to assess the competency for 2 out of 5 phlebotomists performing CBCs since 2016. Findings: 1. A review of personnel records revealed the laboratory director failed to have a qualified individual perform competency assessments on the 5 testing personnel listed on the CMS-209 Personnel Report form. 2. An interview on July 26, 2018 at 8:15 AM, with the laboratory manager, confirmed the laboratory director failed to have a qualified individual perform competency assessments since 2016.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on competency assessment records and an interview with the laboratory manager, the laboratory director who is the technical consultant failed to perform direct observations of patient test performance including handling and processing of samples since the last survey on February 18, 2016. Findings: 1. A review of the Competency Based Assessment forms for the laboratory manager and the medical technologists revealed the forms failed to include the direct observation of routine patient test performance since 2016. 2. An interview on July 26, 2018 at 8:15 AM, with the laboratory manager, confirmed the laboratory assessment forms in use failed to include the direct observation of test performance.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on competency assessment records and an interview with the laboratory manager, the laboratory director who is the technical consultant failed to perform direct observations of instrument maintenance performance including function checks since the last survey on February 18, 2016. Findings: 1. A review of the Competency Based Assessment forms for the laboratory manager and the medical technologists revealed the forms failed to include the direct observation of instrument maintenance performance including function checks since 2016. 2. An interview on July 26, 2018 at 8:15 AM, with the laboratory manager, confirmed the laboratory assessment forms in use failed to include the direct observation of instrument maintenance and function checks.