Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0056438	12/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lost Rivers Medical Center	551 Highland Dr, Arco, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation and an interview with the laboratory manager, the laboratory failed to follow the procedure to ensure positive patient identification for blood samples collected in the laboratory as observed on the day of inspection. Findings: 1. An observation of patient blood samples collected on December 11, 2018 revealed 3 blood collection tubes labeled with only the patient's name. 2. An interview on December 11, 2018 at 1:05 P.M., with the laboratory manager, confirmed laboratory personnel failed to follow the procedure for blood collection of patient samples to ensure integrity and positive patient identification.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records from the American Association of Bioanalysts (AAB) and an interview with the laboratory manager, the laboratory failed to verify the accuracy of chemistry analytes not scored for all three events in

	2018. Findings: 1. A review of AAB PT documents revealed the laboratory failed to evaluate results not scored by AAB for the blood gas analytes pH, pCO2, and pO2, as well as total triiodothyronine (TT3) for all three events in 2018. 2. An interview on December 11, 2018 at 9:15 A.M., with the laboratory manager, confirmed chemistry results that were not scored by AAB were not evaluated and verified for accuracy.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records from the American Association of Bioanalysts (AAB) and an interview with the laboratory manager, the laboratory failed to verify the accuracy of chemistry analytes scored an artificial 100% for all three events in 2018. Findings: 1. A review of AAB PT documents revealed the laboratory failed to evaluate all artificial scores received from AAB for the blood gas analytes pH, pCO2, and pO2, as well as insulin, total triiodothyronine (TT3), and low-density lipoproteins (LDL) for all three events in 2018. 2. An interview on December 11, 2018 at 9:15 A.M., with the laboratory manager, confirmed artificial scores of 100% received from AAB for the chemistry analytes were not evaluated and verified for accuracy.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records from the American Association of Bioanalysts (AAB) and an interview with the laboratory manager, the laboratory failed to verify the accuracy at least twice a year for the chemistry analytes either scored with an artificial 100% or not graded during all three events in 2018. Findings: 1. A review of AAB PT documents revealed the laboratory failed to evaluate and verify the accuracy for artificial 100% scores and results not graded by AAB for insulin, troponin, and low-density lipoproteins (LDL) during all three events in 2018. 2. An interview on December 11, 2018 at 9:55 A.M., with the laboratory manager, confirmed results not graded and artificial scores of 100% received from AAB for the chemistry analytes were not verified for accuracy at least twice a year.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records from the American Association of Bioanalysts (AAB) and an interview with the laboratory manager, the laboratory failed to document the evaluation of unsatisfactory PT results for troponin in event 2 and insulin in event 3 of 2018. Findings: 1. A document review of PT results from AAB revealed the laboratory failed to document the evaluation and corrective actions taken for unsatisfactory troponin and insulin tests performed in events 2 and 3 of 2018. 2. An interview on December 11, 2018 at 9:55 A.M., with the laboratory manager, confirmed the laboratory failed to document the evaluation and corrective actions of unsatisfactory PT results received on troponin and insulin for 2018.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review from the American Association of Bioanalysts (AAB) and an interview with the laboratory manager, the laboratory failed to establish and follow a written policy to monitor, correct, and document problems with proficiency testing and patient blood collection procedures since the last survey on July 18, 2017. Findings: 1. A review of the procedure manual revealed the laboratory personnel failed to follow the written procedure for labeling patient blood specimen tubes. 2. A review of proficiency testing (PT) records from the American Association of Bioanalysts (AAB) revealed the laboratory failed to review, evaluate, and document corrective actions for unsatisfactory PT results and failed to evaluate test scores with artificial scores or not graded. 3. An interview on December 11, 2018 at 4:35 P.M., with the laboratory manager, confirmed the laboratory failed to monitor, assess, and document problems with PT and labeling patient blood specimens.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record reviews and an interview with the laboratory manager, the laboratory director failed to ensure all proficiency testing scores are reviewed by the appropriate personnel to evaluate and identify problems with proficiency testing from the time reviewed between 2017 event 3 through 2018 event 3. Findings: 1. A review of documents from the American Association of Bioanalysts (AAB) revealed the laboratory director failed to evaluate and identify problems in the laboratory's performance of testing in the specialty of chemistry. 2. An interview on

	December 11, 2018 at 4:45 PM, with the laboratory manager, confirmed the laboratory director failed to evaluate and identify problems that would require corrective actions and verification of accuracy in the laboratory's performance of PT.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 personnel record review and an interview with the laboratory manager, the laboratory director failed to ensure the laboratory testing personnel receive appropriate training and education for the complexity of tests performed in the laboratory since the last survey on July 18, 2018. Findings: 1. A review of 1 out of 7 testing personnel records revealed the laboratory failed to develop a training program for the types of testing performed in the laboratory since the last survey. 2. An interview on December 11, 2018 at 10:05 A.M., with the laboratory manager, confirmed the laboratory director failed to ensure the laboratory developed a training program to ensure the testing personnel receive proper training and education.