

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0056438	(X3) Date Survey Completed 07/13/2021
Name of Provider or Supplier Lost Rivers Medical Center	Street Address, City, State 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of proficiency testing (PT) records from Wisconsin State Laboratory of Hygiene (WSLH), the CASPER 96D report and an interview with the laboratory manager on 7/13/2021, the laboratory failed to enroll in proficiency testing for the analyte rheumatoid factor. The findings include: 1. A review of proficiency testing records from WSLH and the CASPER 96D identified that the laboratory failed to enroll and participate in PT for the analyte rheumatoid factor for 2019, 2020 and 2021. 2. An interview with the Laboratory manager on 7/13/2021 at 10:05 am confirmed that the laboratory failed to enroll and participate in PT for the analyte rheumatoid factor for 2019, 2020 and 2021. 3. The laboratory reports performing 253 rheumatoid factor tests annually.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p>

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records from Wisconsin State Laboratory of Hygiene (WSLH) and an interview with the laboratory manager on 7/13/2021, the laboratory failed to ensure that the laboratory director or designee sign the PT attestation statements. The findings include: 1. A review of PT records from WSLH identified that the laboratory director or their delegated designee failed to attest to the routine integration of the PT samples in to the routine workload for all PT shipments for events 2 and 3 in 2020. 2. An interview with the laboratory manager on 7/13/2021 at 9:58 am confirmed that the laboratory failed to sign the attestations for all PT testing for events 2 and 3 in 2020. 3. The laboratory reports performing 200,000 moderate and high complexity tests annually.