

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0056438	(X3) Date Survey Completed 11/30/2022
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the prothrombin time (PT) documents, the Dade Innovin Reagent package insert, a direct observation and an interview with the laboratory manager on 11/30/2022, the laboratory failed to verify the normal patient PT mean and use the correct international sensitivity index (ISI) for patient International Normalized Ratio (INR) calculations. The findings include: 1. A review of PT reagent documents identified that the laboratory failed to perform a normal patient PT mean study for the current Innovin lot number 564616. 2. A review of the Dade Innovin package insert for lot 564616 identified an ISI of 1.04. 3. A direct observation of the ISI in Sysmex CA600, the laboratory coagulation analyzer, identified an ISI of 1.07. The laboratory failed to use the correct ISI to calculate the INR for patient reporting. 4. An interview with the laboratory manger on 11/30/2022 at 11:49 am confirmed that the laboratory was using the incorrect ISI and normal mean to calculate patient INRs since the new lot of reagents were put in use on 8/25/2022. 5. The laboratory reports performing 240 PT/INR tests annually.</p>