

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0652478	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Roosevelt Medical Center	Street Address, City, State 818 2nd Avenue East, Culbertson, MT	
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
D0000	Based on an on-site recertification survey conducted on 8/8/18, a deficiency was cited for Roosevelt Medical Center in Culbertson, MT.
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 observation, record review, and interview, the laboratory failed to follow manufacturer instructions for establishing the mean of the prothrombin time (PT) normal range with each new lot number of RecombiPlasTin 2G reagent for two of two lot numbers used between 7/21/16 to 8/8/18. The findings include: 1. On 8/8/18 at 7:30 a.m., an Instrumentation Laboratory ACL Elite coagulation analyzer was observed in the laboratory. 2. On 8/8/18 at 7:30 a.m., staff member A stated PTs were performed on the ACL Elite analyzer. 3. On 8/8/18 at 11:30 a.m., a mean of the PT normal range of 11.5 seconds was observed on the ACL Elite analyzer. Data from the calculation of the 11.5 seconds mean was not located. 4. On 8/8/18 at 11:30 a.m., the current bottle of RecombiPlasTin 2G reagent in use had an observed lot number of N1166512. 5. On 8/8/18 at 11:30 a.m., staff member A stated the mean was last established in 2013. 6. A review on 8/8/18 at 12:00 p.m. of the HemosIL RecombiPlasTin 2G manufacturer instructions included instructions to "establish the mean of the PT normal range with each new lot" of RecombiPlasTin 2G. 7. A review on 8/8/18 at 12:00 p.m. of the HemosIL RecombiPlasTin 2G manufacturer instructions included a handwritten note that the current lot in use (N1166512) was started in use on 4/17/17. 8. A review on 8/8/18 at 12:00 p.m. of the ACL Elite Operator's Manual included a warning that the "mean normal range number needs to</p>

be verified on each lot change of PT reagent as per your laboratory regulating agency." 9. A review on 8/8/18 at 12:00 p.m. of the laboratory supply card for RecombiPlasTin 2G included new lot numbers started on 1/6/16 and 3/17/17. 10. A review on 8/8/18 at 12:15 p.m. of the ACL Elite Operator's Manual included a section on the International Normalized Ratio (INR) calculation noting "that each lot number of reagent will have a unique ISI (International Sensitivity Index) value and mean of normal reference interval, which must be used as indicated." It also states "if the reagent lot number changes, then the new ISI value from the package insert and the new mean of normal range for that lot number of PT reagent must be entered."