

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D2304389	(X3) Date Survey Completed 11/19/2024
Name of Provider or Supplier Recovery Centers Of Montana, Llc	Street Address, City, State 2620 Connery Way, Missoula, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of verification records, patient's results report, and an interview with general supervisor (GS) #1, the laboratory failed to verify that the normal reference ranges for pH and creatinine were appropriate for the laboratory's patient population prior to patient testing from May 15, 2024 to November 19, 2024. Findings: 1. A review of the patient's results report (UR24-0629) listed creatinine and pH test results plus reference ranges under specimen validity testing. 2. The laboratory failed to provide a study to verify that the normal reference ranges were appropriate for the laboratory's patient population prior to patient testing for pH and creatinine performed on the Mindray BS-480 Chemistry Analyzer. 3. An interview with GS #1 on November 19, 2024, at 3:26 PM confirmed their normal reference ranges for pH and creatinine are from another laboratory and had not been verified by the laboratory prior to patient testing from May 15, 2024 to November 19, 2024.</p>