

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2006843	(X3) Date Survey Completed 01/11/2023
Name of Provider or Supplier Mercy Pain Management	Street Address, City, State 2230 E Glenstone Ave, Springfield, MO	
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 review of performance specification records for iStat and interview with the technical consultant (TC), the laboratory failed to provide documentation for accuracy and precision after the iStat was moved. Findings 1. Review of performance verification records for iStat, serial number 302376, showed no documentation for accuracy and precision after being moved to current facility October 20, 2022. 2. Interview with TC on January 11, 2023 at 9:00 AM confirmed the laboratory failed to provide documentation for accuracy and precision after the iStat was moved.</p>