

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2006843	(X3) Date Survey Completed 10/02/2024
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 the performance verification procedures for the iStat prothrombin time (PT), patient results, and interview with the technical consultant (TC) #2, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the iStat showed the laboratory failed to verify that the manufacturer's reference interval (normal range) were appropriate for the laboratory's patient population for the analyte: prothrombin time prior to the beginning of patient testing in July 2024. 2. Review of the performance specifications for the iStat showed the laboratory failed to verify that the manufacturer's reportable range for the analyte: prothrombin time prior to the beginning of patient testing in July 2024. 3. Interview with the TC #2 on October 2, 2024 at 10:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.</p>