

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0455707	(X3) Date Survey Completed 05/17/2023
Name of Provider or Supplier Providence Medical Center	Street Address, City, State 1200 Providence Road, Wayne, NE	
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 surveyor review of list of tests performed, interview with the laboratory manager, and lack of documentation the laboratory failed to verify performance specifications on four moderate complexity test kits. 1. Review of the list of tests performed, presented by the laboratory, included four new moderate complexity test kits. The four new moderate complexity test kits include: Test kit #1 giardia /cryptosporidium Test kit #2 campylobacter Test kit #3 shiga toxin producing escherichia coli Test kit #4 lactoferrin 2. Interview with the laboratory manager on 5 /17/2023 at approximately 3:00 pm confirmed patient testing began on June 2022 for test kit #1 giardia/cryptosporidium, test kit #2 campylobacter, test kit #3 shiga toxin producing escherichia coli, and test kit #4 lactoferrin. 3. Interview with the laboratory manager on 5/17/2023 at approximately 3:00 pm the laboratory manager indicated the laboratory manager did not know if the laboratory had verified performance specification for test kit #1 giardia/cryptosporidium, test kit #2 campylobacter, test kit #3 shiga toxin producing escherichia coli, and test kit #4 lactoferrin. 4. No documentation of verification of performance specifications was found during the survey.</p>