

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D2183799	(X3) Date Survey Completed 03/16/2021
Name of Provider or Supplier Midlands Family Urgent Care	Street Address, City, State 17650 Wright Street Ste 5, Omaha, 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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to perform the verification of performance specifications on the Beckman Coulter AU480 analyzer before patient testing. Refer to D5421.</p>
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 verification of performance specifications on Beckman Coulter AU480, review of Beckman Coulter AU480 instrument print outs, and review of laboratory's analytic quality check revealed the laboratory reported patient test results</p>

before verifying the performance specifications of the Beckman Coulter AU480. 1. Review of verification of performance specifications on Beckman Coulter revealed completion date of 11/11/2020. 2. Review of Beckman Coulter AU480 instrument print outs revealed nine patient results. Patient testing occurred on 10/5/2020, 10/6/2020, 10/9/2020, and 10/20/2020. 3. Review of laboratory's analytic quality check revealed the laboratory director reviewed the instrument print out from patient tested on 10/5/2020.