

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0880535	(X3) Date Survey Completed 01/30/2024
Name of Provider or Supplier Broadlawns Community Clinic At Drake	Street Address, City, State 2970 University Ave, Des Moines, IA	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals, instrument operator's manuals, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 11:45 am on 01/30/2024, the laboratory director failed to approve, sign, and date all laboratory policies and procedures, including the Beckman Coulter AU480 and Beckman Coulter DxH520 instrument operator's manuals.</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 performance specification records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 11:00 am on 01/30/2024, the laboratory failed to verify the performance specifications of precision for the analytes, total protein and blood urea nitrogen (BUN), and reportable range for</p>

the analyte, total protein. The findings include: 1. The laboratory began using the Beckman Coulter AU480 instrument to perform chemistry testing in September 2023. 2. At the time of the survey, the laboratory did not have verification of performance specification documentation of precision for the analytes, total protein and BUN, or reportable range for the analyte, total protein.