Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0880535	06/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Broadlawns Community Clinic At Drake	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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results and confirmed by interview with technical consultant identifier #1 (TC #1) at 11:19 am on 6/26/2025, the laboratory failed to take and document corrective action for unacceptable PT scores for the analytes sodium and total cholesterol received on one out of five PT events from 1/1/2024 - 6/20/2025. The findings include: 1. For 2024 event 1, the laboratory received unacceptable PT scores of zero for the analytes sodium and total cholesterol. 2. TC #1 confirmed at the time of the survey, the laboratory did not document corrective action for the unacceptable PT scores.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At

	least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List & Annual Volume form, calibration verification and calibration records and confirmed by interview with technical consultant identifier #1 (TC #1) at 11:43 am on 6/26/2025, the laboratory failed to perform calibration verification every six months for three out of three time periods from 1/1/2024 - 6/26/2025 for the analytes: albumin, alkaline phosphatase, alanine transaminase, aspartate aminotransferase, amylase, urea nitrogen, total cholesterol, creatinine, carbon dioxide, chloride, glucose, high density lipoprotien, lipase, total bilirubin, low density lipoprotein, and total protein. The findings include: 1. The Laboratory Test List & Annual Volume form confirmed the laboratory used the Beckman Coulter AU480 chemistry analyzer to perform albumin, alkaline phosphatase, alanine transaminase, aspartate aminotransferase, amylase, urea nitrogen, total cholesterol, creatinine, carbon dioxide, chloride, glucose, high density lipoprotien, lipase, total bilirubin, low density lipoprotein, and total protein testing. 2. Calibration records for the above referenced analytes revealed the laboratory used two calibrators to calibrate the analyzer. 3. TC #1 confirmed the laboratory did not perform calibration verification for the above listed analytes from 1/1/2024 - 6/26/2025.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) and calibration records, the Beckman Coulter AU 480 instructions for use, and confirmed by interview with technical consultant identifier #1 (TC #1) at 11:43 am on 6/26/2025, the laboratory failed to perform two levels of QC after calibrating the chemistry analyzer for three out of 31 days for the analytes: creatinine, total cholesterol and urea nitrogen from 3/1/2025 - 3/31/2025. The findings include: 1. The Beckman Coulter AU 480 instructions for use for the analytes creatinine, total cholesterol and urea nitrogen state, "During

	operation of Beckman Coulter AU analyzer at least 2 levels of an appropriate quality control material should be tested a minimum of once per day. In addition, controls should be performed after calibration, with each new lot of reagent, and after specific maintenance or troubleshooting." 2. TC #1 confirmed that the laboratory protocol included performing two levels of QC after calibrating the analyzer. 3. On 3/4/2025 the urea nitrogen level 1 QC fell outside the established range. As part of the troubleshooting process the laboratory recalibrated the urea nitrogen reagent. After calibrating the analyte the laboratory only performed level 1 of urea nitrogen QC. 4. On 3/8/2025 the total cholesterol level 1 QC fell outside of the established range. As part of the troubleshooting process the laboratory recalibrated the total cholesterol reagent. After calibrating the analyte the laboratory only performed level 1 of total cholesterol QC. 5. On 3/17/2025 the creatinine level 1 QC fell outside of the established range. As part of the troubleshooting process the laboratory recalibrated the creatinine reagent. After calibrating the analyte the laboratory only performed level 1 of creatinine QC. 6. At the time of the survey, TC #1 confirmed the laboratory did not perform two levels of QC for the above dates when the reagent needed additional calibrations as part of the QC troubleshooting process.