Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0320648	01/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Norton Community Medical Associates-Shepherdsville	115 Huston Drive, Shepherdsville, KY	

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
D0000	A recertification survey was conducted on 01/09/2023, and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR, Part 493.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview and review of the facility's policies, it was determined the facility failed to monitor the accuracy and precision of complete blood count (CBC) quality controls over time using Levey-Jennings charts. This had the potential to impact the accuracy of patient testing and affect all patients, as trends and shifts in instrument performance may have gone undetected. The findings include: Review of the facility's policy titled, "Controls "Out of Control"", dated 07/12/2017, revealed "CBC controls must fall within the designated limits as calculated for each analyte by the manufacturer. Any control that is greater than two (2) standard deviations (SD) from the mean is considered to be "Out of Control". When tri-level CBC controls are used, it is acceptable for two (2) out of three (3) controls to be in range, if the third control is within three (3) SD of the mean. Laboratory personnel will review Levy-Jennings

	charts weekly to look for shifts and trends. If a control is consistently one (1) SD above or below the mean seven (7) days in a row, remedial action must be taken". The policy further revealed the Laboratory Director "reviews and signs off on the control results and Levy-Jennings charts monthly". Interview with the Technical Consultant (TC), on 01/09/2023 at 11:40 AM, revealed he was shown the "Controls "Out of Control"" policy and directed to the section which indicated that laboratory personnel were required to review Levey-Jennings charts weekly, and the Laboratory Director reviewed and signed off on the control results and Levey-Jennings charts monthly. The TC was asked to provide the Levey-Jennings charts and documentation of review by laboratory personnel and the Laboratory Director, and he could not produce these documents for review. He further revealed the procedure to evaluate CBC quality controls over time using the Levey-Jennings charts was not being performed.