Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2169046	02/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Murfreesboro Medical Clinic	3626 Shelbyville Pike-Main Lab Floor 1, Murfreesboro, TN	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) Hematology evaluation report for 2023 FH 13-C and staff interview, the laboratory failed to evaluate 7 of 10 unacceptable or ungraded Blood Cell ID results and 10 of 10 nRBC results in 2023. The findings include: 1. Review of the CAP Hematology evaluation report for 2023 FH 13-C revealed the following sample numbers scored as unacceptable: BCP-23, BCP-25, and the following sample numbers noted as ungraded: FH 13-11, FH 13-12, FH 13-13, FH 13-14, FH 13-15 for nRBC/100 WBC and nRBC Absolute, and BCP-26, BCP-27, BCP-28, BCP-29, and BCP-30 for Blood Cell ID. The evaluation report was signed by the technical consultant with no documentation of corrective action or evaluation to determine cause of unacceptable scores or evaluation of ungraded scores. 2. Interview with the technical consultant, chief tech, and testing personnel on 2/12/24 at 1:30 p.m. confirmed the laboratory failed to investigate the cause of unacceptable proficiency scores and to evaluate ungraded proficiency scores in 2023.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic

	examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the final patient test report, the laboratory procedure manual, and staff interview, the laboratory procedure manual lacked the established reference ranges currently in use by the laboratory. The findings include: 1. Observation of the laboratory on 2/12/24 at 8:15 a.m. revealed the Beckman Coulter DxC AU 700 (SN 83231229/2023023418) test system in use for chemistry testing since 6/19/23. 2. Review of the final patient test report for one of one patient revealed the following ALT and AST reference ranges: Test report reference ranges: ALT(SGPT): 0 - 52 U/L AST(SGOT): 0 - 50 U/L 3. Review of the laboratory procedure manual revealed the following ranges for ALT and AST that were different than the ranges on the final patient test report. Adult range for ALT: 7 - 52 U/L Adult range for AST: 13 - 39 U/L 4. Interview with the technical consultant, the chief tech, and testing personnel on 2/12/24 at 1:30 p.m. confirmed that the manufacturer's reference ranges found in the procedure manual had not been updated with the established reference ranges currently in use by the laboratory.