Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0309391	(X3) Date Survey Completed 07/24/2023
Name of Provider or Supplier Family Medicine Center	**Street Address, City, State** 2700 Westside Drive, Nw, Ste 103, Cleveland, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, quality control (QC) records, patient Complete Blood Count (CBC) logs and CBC analyzer patient review logs, and interview with the lead testing personnel, the laboratory failed to follow the quality control policy for two of 31 days in August 2022. The findings include: 1. Review of the laboratory's policy titled, "Out of Range Control Policy" revealed the following statement, "We always run 3 levels of controls; low, normal, high. If you are unable to get all 3 levels to run, you may run a patient as long as 2 out of 3 levels work". 2. Review of quality control records revealed two of three levels of quality control (low and normal) were ran and unacceptable on 08.23.2022 and 08.25.2022. 3. Review of patient CBC logs and CBC analyzer patient review logs revealed five patient samples for CBC were ran and reported on 08.23.2022 and three patient samples for CBC were ran and reported on 08.25.2022 when two of three levels of quality control were unacceptable. 4. Interview with the lead testing personnel on July 24, 2023 at approximately 12:30 p.m. confirmed the laboratory failed to follow the policy for performance of acceptable QC for two of 31 days in August 2022 with patient testing performed.