Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2106196	06/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
My Family Healthcare, Llc	1708 Delivery Lane, Durant, OK	

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	The recertification survey was performed on 06/25/2024. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
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 a review of records, policies and procedures, and interview with the technical consultant and testing person #1, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for three of 15 lot numbers used during the review period of 06/01/2023 through 04/30/2024. Findings include: (1) On 06/25/2024 at 10:50 am, the technical consultant and testing person #1 stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Medonic M Series analyzer; (b) Three levels of Boule Con-Diff Tri-Level (Quality Control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of the "Laboratory Procedure Manual" identified a policy titled "QC Policy and Calibration", in section IV- Medonic M Series, Part F - Control Range Verification stated "Boule Con-Diff Controls should be run for 5 runs over 5 days to ensure that the new lot number of control is performing according to package insert ranges before being put into use. If a 5 day verification is unable to be performed, document the reason for the shortened new lot verification study and run a minimum of 3 times before putting into use." (3) A review of records for 15 control lot numbers used from 06/01/2023 through 04/30/2024 identified no

	documentation to prove three of the 15 lot numbers had been implemented per policy: (a) Level 1 lot #2231101, level 2 #2231102, and level 3 lot #2231103 used from 01/02 /2024 through 03/21/2024 - The controls had been tested as follows: (i) Once on 12/20 /2023 (ii) Once on 12/21/2023 (4) The findings were reviewed with the technical consultant who stated 06/25/2024 at 3:30 pm, the laboratory did not follow their written policy.