Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2300136	07/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Kansas Medical Clinic	1261 E Tulsa Ave, Kansas, 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 initial survey was performed on 07/09/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, observation, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) On 07/09/2024 at 1:05 pm the technical consultant stated that the laboratory performed PT/INR (Protime/International Normalized Ratio) testing using the Coaguchek XS analyzer; (2) Review of the manufacturers package insert for the test strips stated, "Each test kit contains a Test Strip Code Chip, which contains specific information that calibrates the system for use with a particular lot of test strips. The Test Strip Code Chip must be inserted into the monitor when you open a new lot of test strips"; (3) Observation of the code chip that was inserted in the analyzer and the three digit code printed on the test strips currently in use (lot 127) on 07/09/2024 at 1:05 pm, identified the codes did not correlate; (a) The three digit code on the code chip was 127 (b) The three digit code on the test strip container was 132. (4) The findings were reviewed with the technical consultant who stated on 07/09/2024 at 1:05 pm, the laboratory was not aware the code chip did not match the three number code on the test strip container.