Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0046900	03/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Wilson Medical Center	2600 Ottawa Road, Neodesha, KS	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of instrument type and test settings, lack of reagent lot evaluation data, manufacturer's instructions, patient testing volumes and interview with general supervisor (GS) #1, the laboratory failed to follow manufacturer's instruction on reagent lot changes for both RecombiPlasTin 2G for prothrombin time (PT) and SynthASil reagent for partial thromboplastin time (PTT) prior to use for patient testing. Findings: 1. Prothrombin time (PT) and partial prothrombin time (PTT) testing are performed on the ACL Elite coagulation analyzer from Instrumentation Laboratory/Werfen. 2. ACL Elite coagulation analyzer instrument setting for PT testing showed RecombiPlasTin 2G reagent lot #N1127253, expiration 12/31/24. Mean normal patient (MNPT) was set at 11.1 seconds, and ISI value set at 1.04. 3. The surveyor requested documentation for the MNPT value determination used to calculate the international normalized ratio (INR) and the patient normal range values. No documentation was provided at the time of survey. 4. Manufacturer's instructions for RecombiPlasTin 2G contained under: a. Instrument/test procedures: "Enter the ISI value from the insert and establish the Mean of the PT Normal Range with each new lot. b. Expected values: "Due to many variables which may affect clotting time, each laboratory should verify its own normal range. 5. Lot #N1127253 was placed into use on 11/1/23 with 181 patient test results reported from 11/1/23 to 3/5/24. 6. ACL Elite instrument setting for PTT testing showed SynthASil reagent lot #N0431123, expiration 5/31/25. 7. Request was made to review the SynthASil reagent lot #N0431123 evaluation for normal values. No data was made available at the time of

	survey. 8. Manufacturer's instructions for SynthASil under expected values stated: "Due to many variables which may affect clotting times, each laboratory should establish its own normal range." 9. SynthASil reagent lot #N0431123 was placed into use on 11/1/23 with 106 patient results reported from 11/1/23 to 3/5/24. 10. Interview with GS#1 3/5/24 at 12:15 p.m. confirmed, the laboratory failed to follow manufacturer's instruction on reagent lot changes for both RecombiPlasTin 2G for prothrombin time (PT) and SynthASil reagent for partial thromboplastin time (PTT) prior to use for patient testing.