Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0047322	11/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ashland Health Center	625 S Kentucky St, Ashland, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a lack of available documentation and confirmed during interview, the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use. Findings: 1. Upon review of the laboratory procedures, the current laboratory director did not approve, sign, and date the laboratory procedure for: Therapeutic Phlebotomy, Lab Blood and Blood Product Utilization and D-Dimer Test. 2. Interview with the Laboratory Director (LD) on November 19, 2019 at 2:00 p. m. confirmed, the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use.
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, reagent lot evaluation data, and interview, the laboratory failed to follow manufacturer's instruction for the patient geometric mean setting in prothrombin time testing. Findings: 1. Prothrombin time testing is performed on the Sysmex CA-660 using Innovin reagent. 2. Sysmex CA-

	660 instrument setting for prothombin time testing showed Innovin reagent lot #549750E, Normal patient geometric mean set at 10.4 seconds, and last modification date/time as June 9, 2019. 3. Prothrombin time (Protime) Roll-Over data for Innovin lot #549750E performed on June 5, 2019, defined the nomal patient geometric mean as 12.5 seconds. 4. Interview with Technical Consultant #2 November 19, 2019 at 12: 30 p.m. confirmed, the laboratory failed to follow manufacturer's instruction for the patient geometric mean setting in prothrombin time testing.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of documents and interview, the laboratory failed to establish and follow a routine accuracy check for the thermometers. Findings: 1. Request was made for accuracy check records for the five thermometers used in the laboratory. Only 2 of 5 documents was made available at the time of survey. 2. Interview with LD on November 19, 2019 at 11:15 a.m. confirmed, the laboratory failed to establish and follow a routine accuracy check for the thermometers.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and electronic final test reports and interview, the laboratory failed to have an adequate data entry system(s) review in place that ensured test results were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to the electronic medical record (EMR). Findings: 1. No documentation of a data entry system review was made available at the time of survey for the test records and electronic final test reports from November 2018 to November 2019. 2. Interview with LD on November 19, 2019 at 2: 00 p.m. confirmed, the laboratory failed to have an adequate data entry system(s) review in place that ensured test results were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to the electronic medical record (EMR).