Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0450897	07/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
South Central Kansas Medical Center	6401 Patterson Parkway, Arkansas City, 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
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 upon laboratory OSMO Flu A&B (Influenza Type A&B) IQCP policy and procedure, review of laboratory records from the period 3/13/18 to 5/24/18 and staff interview, the laboratory failed to follow their procedure to perform Quality Control. Findings were: a. A review of the laboratory's IQCP policy/procedure under External QC Failure Stares "One positive and one negative is done with each kit and or every 30 days of patient testing".. b. Based upon review of A&B patient log revealed the laboratory failed to follow the IQCP policy 3/13/18 through 5/24/2018 Quality Control was performed on 3/13/18 25 patients were tested This was confirmed in interview with General Supervisor # 1 from the CMS form 209 on 07/09/2018 at 14: 00 hrs .
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:

	A review of manufacture's package QuickVue H Pylori Test under limitations states this assay has not been established for patients under 18 years of age revealed the laboratory failed to follow manufactures instructions. Findings were as follows a. Based upon a review of the H Pylori Test revealed the laboratory performed 5 patients under the age of 18 01/01/2018 through 07/06/2018 24 patients were tested. Therefore, the accuracy of the testing cannot be verified.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based upon direct observation during a tour of the laboratory, review of manufacturer's reagent labels and staff interview, the laboratory failed to ensure that reagents in use were not expired. Findings were: 1. During a tour of the lab the surveyor observed Buffer Blood Bank Saline, Isotonic Solution 0.85% w/v lot # 255716 unopened expiration date of 8/2019 was placed in use 6/1/2018. The manufacture label on the box states use within one month of opening, which made the saline expired 7/1/2018. Observation was made on 07/09/2018 which made the saline expired by eight days. This Buffer Blood Bank Saline, Isotonic Solution 0.85% is used by South Central Kansas Medical Center to perform blood bank testing (i.e., ABO RH typing, washing red blood cells, and cross matching.) This was confirmed by interview with the General Supervisor at 10:30 am on 07/09/2018 in the laboratory. 2. Upon review of blood bank records, twelve patients samples had ABO RH types performed using the expired blood bank saline after July 1, 2018. Of those twelve patient samples, nine red blood cell units were crossmatched using the expired blood bank saline and six of those crossmatched red blood cell units were transfused. This was also confirmed by the General Supervisor at 10:45 am on 7/9/2018.