Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384253	08/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kossuth Regional Health Center	1515 South Phillips Street, Algona, IA	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of cryostat temperature records and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 08/15/2018, the laboratory failed to document cryostat temperatures for one out of one day of patient testing (06/21/2018) in June 2018. At the time of the survey, the laboratory did not have cryostat temperature records for 06/21/2018.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

	This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 08/15/2018, the laboratory failed to take and document corrective action when the chemistry QC (albumin) failed to meet the laboratory's established criteria for one out of 31 days of patient testing (03/21/2018) from 03/01 /2018- 03/31/2018. The findings include: 1. The Bio-Rad Liquid Assayed Multiqual QC package insert stated for lot number 45773, the acceptable range for the analyte, albumin, was 4.05-4.66 g/dL. 2. On 03/21/2018, the laboratory recorded the albumin QC result as 4.70 g/dL for QC lot number 45773. 3. Personnel identifier #9 confirmed that the laboratory performed albumin patient testing on 03/21/2018. 3. At the time of the survey, the laboratory did not have corrective action for the out of range QC.
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 patient test records, erythrocyte sedimentation rate (ESR) instrument tapes, and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 08/15/2018, the laboratory failed to have a system in place to ensure manually transcribed test results are accurately and reliably sent from the point of data entry to final report destination for one out of one patient (patient identifier B) having ESR testing performed in March 2018. The findings include: 1. Patient B had an ESR performed on 03/15/2018 with a result of 73 mm/hr. 2. Testing personnel entered the ESR result of 72 mm/hr into the electronic health record (EHR). 3. Laboratory personnel identifier #8 confirmed that the patient test report was not accurate and the ESR value should have been 73 mm /hr.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of testing personnel records, the STAT-Site M Beta-Hydroxybutyrate (BHB) Analyzer and ActimProm Rupture of Membranes (ROM) performance specification records, and confirmed by laboratory personnel identifier

	#8 (refer to the Laboratory Personnel Report) at approximately 1:45 pm on 08/15 /2018, the technical consultant failed to document training for the STAT-Site M BHB Analyzer and ActimProm ROM test systems prior to reporting patient test results for seven out of 10 testing personnel (personnel identifiers #9- #14 and #18). The findings include: 1. The laboratory began using the STAT-Site M BHB Analyzer test system in December 2017. 2. The laboratory began using the ActimProm ROM test system in June 2018. 2. At the time of the survey, the laboratory did not have STAT-Site M BHB Analyzer and ActimProm ROM test system training records for testing personnel identifiers #9- #14 and #18.