Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384033	08/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hancock County Health System	532 First Street Nw, Britt, 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
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 2018 ACL Top 300 test system records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 08/16/2018, the laboratory failed to verify the manual calculation of the international normalized ratio (INR) for one out of one lot number of thromboplastin (N0378719, expiration 2019-03) in January 2018. The findings include: 1. The laboratory started using thromboplastin reagent lot number N0378719 in January 2018. 2. The coagulation reagent verification records did not include verifying the INR calculation from the instrument by another method.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of erythrocyte sedimentation rate (ESR) quality control (QC) records

	and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 08/16/2018, the laboratory failed to perform two levels of ESR QC materials each day of patient testing for one out of 16 days of patient testing (08/01/2018) from 08/01/2018- 08/16/2018. The findings include: 1. The laboratory performed an ESR test for patient B on 08/01/2018. 2. At the time of the survey, the laboratory did not have ESR QC records for 08/01/2018.
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, i-STAT arterial blood gas instrument strips, and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 08/16/2018, 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 A) having arterial blood gas testing performed in March 2018. The findings include: 1. Patient A had an arterial blood gas test performed at 6:23 pm on 03 /30/2018. The instrument result strip showed an oxygen saturation of 67%. 2. Testing personnel entered an oxygen saturation of 44% into the electronic health record (EHR). 2. Patient A had a second arterial blood gas test performed at 7:15 pm on 03/30 /2018. The instrument result strip showed an oxygen saturation of 88%. 2. Testing personnel entered an oxygen saturation of 46% into the EHR. 3. Laboratory personnel identifier #6 confirmed that both of the patient test reports were not accurate and the oxygen saturation values should have been 67% at 6:23 pm and 88% at 7:15 pm on 03 /30/2018.
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 ESR STAT Plus and Beckman Coulter DXH600 performance specification records, and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 1: 00 pm on 08/16/2018, the technical consultant failed to document training for the ESR STAT Plus test system prior to reporting patient test results for four out of six testing

	personnel (laboratory personnel identifiers #6 and #9- #11) and Beckman Coulter DXH600 test system for five out of six testing personnel (laboratory personnel identifiers #6 and #8- #11). The findings include: 1. The laboratory began using the ESR STAT Plus test system in June 2018. 2. The laboratory began using the Beckman Coulter DXH600 test system in March 2018. 3. At the time of the survey, the laboratory did not have ESR STAT Plus test system training records for personnel identifiers #6 and #9- #11 or Beckman Coulter DXH600 test system training records for personnel identifiers #6 and #8- #11.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 8:30 am on 08/16/2018, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing high complexity testing received the appropriate training for four out of four new testing personnel (laboratory personnel identifiers #8- #11) in 2017. The findings include: 1. The laboratory hired personnel identifiers #8 and #11 in May 2017. 2. The laboratory hired personnel identifier #10 in June 2017. 3. The laboratory hired personnel identifier #9 in September 2017. 4. At the time of the survey, the laboratory did not have training records available for laboratory personnel identifiers #8- #11.