Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384033	09/08/2022
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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance policy, calibration records, and confirmed by laboratory personnel identifier #13 (refer to the Laboratory Personnel Report) at approximately 8:00 am on 09/08/2022, the laboratory failed to perform and document calibration procedures on the Beckman Coulter DXH 600 hematology instrument (complete blood counts) every six months for three out of four time periods from 09/18/2020- 09/08/2022. The findings include: 1. The laboratory's Quality Assurance policy stated that the laboratory would perform a calibration on the hematology instrument every six months. 2. Calibration records revealed that the laboratory performed calibrations on 09/18/2020, 07/15/2021, and 03/07/2022. 3. At the time of the survey, laboratory personnel identifier #13 confirmed that the laboratory did not have calibration records for the time periods between 09/18/2020-07/15/2021, 07/15/2021- 03/07/2022, or 03/07/2022- 09/08/2022.
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 Dimension EXL quality control (QC) records and confirmed by laboratory personnel identifier #13 (refer to the Laboratory Personnel Report) at approximately 3:15 pm on 09/07/2022, the laboratory failed to perform two levels of QC each day of patient testing for three out of seven days of patient testing reviewed from 02/13/2022- 02/19/2022. The findings include: 1. Review of chemistry QC records revealed that the laboratory performed one level of QC and reported patient test results on the following dates for the specified analytes: *02/14/2022- c-reactive protein (level 1); 11 patients reported *02/14/2022- ferritin (level 1); 2 patients reported *02/16/2022- ferritin (level 1); 3 patients reported 2. Review of chemistry QC records revealed that the laboratory did not perform any QC and reported 2 patient test results for acetaminophen on 02/18/2022. 3. At the time of the survey, personnel identifier #13 confirmed that the laboratory did not have additional QC records for the dates and analytes listed above. This is a repeat deficiency cited on 08/16/2018.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records, the Dimension EXL operator's guide, and confirmed by laboratory personnel identifier #13 (refer to the laboratory personnel report) at approximately 3:15 pm on 09/07/2022, the laboratory failed to perform and document corrective action when the chemistry equipment failed to meet the laboratory's established operating parameters for two out of seven days of testing reviewed from 02/13/2022- 02/19/2022. The findings include: 1. Review of QC records revealed that for the following dates, the system flagged hemoglobin A1C QC results with the test report message "abnormal assay": *02/16/2022- level 1; 10 patient results reported *02/17/2022- level 1; 10 patient results reported 2. The Dimension EXL operator's guide stated that results with the abnormal assay flag cannot be reported and must be rerun. 3. At the time of the survey, personnel identifier #13 confirmed that additional action had not been taken for QC results with abnormal assay flags.
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 erythrocyte sedimentation rate (ESR) quality control (QC) records and confirmed by laboratory personnel identifier #13 (refer to the Laboratory Personnel Report) at approximately 5:00 pm on 09/07/2022, the laboratory failed to take and document corrective action when ESR QC fell outside the laboratory's established criteria for acceptability for four out of 28 days of patient testing in February 2022. The findings include: 1. The laboratory performs ESR testing on the ESR Stat test system. 2. For level 2 ESR QC, the laboratory had an acceptable range of 96- 112 mm/hr. 3. Review of level 2 ESR QC records revealed that the laboratory had out of control results without corrective action on the following dates: *02/15 /2022 (94 mm/hr) *02/20/2022 (95 mm/hr) *02/24/2022 (95 mm/hr) *02/25/2022 (93 mm/hr) 4. At the time of the survey, personnel identifier #13 confirmed that the laboratory did not have documented corrective action for the out of control QC results listed above.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #13 (refer to the Laboratory Personnel Report) at approximately 1: 30 pm on 09/07/2022, the laboratory director failed to ensure that an approved corrective action plan is followed when the laboratory received three unacceptable PT scores from two out of five PT testing events (2022 events 1 and 2) from 01/01/2021-09/07/2022. The findings include: 1. For 2022 testing event 1, the laboratory received unacceptable PT test scores for the following: *2022 Core Chemistry 1st event- human chorionic gonadotropin (HCG) (specimens HCG-01 and HCG-04) 2. For 2022 testing event 2, the laboratory received unacceptable PT scores for the following: *2022 Core Chemistry 2nd event- blood urea nitrogen (BUN) (specimen BG-09) 3. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores listed above. This is a repeat deficiency cited on 12/18/2020.
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 #13 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 09/07/2022, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing high complexity testing received the appropriate training for one out of three new testing personnel (laboratory personnel identifier #9) hired since the last survey on 12/18/2020. At the time of the survey, the laboratory did not have training records available for laboratory personnel identifier #9. This is a repeat deficiency cited on 08/16/2018.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records, immunohematology performance specification records, and confirmed by personnel identifier #13 (refer to the Laboratory Personnel Report) at approximately 8:15 am on 09/08/2022, the technical supervisor failed to document training for testing personnel using the Grifols DG Gel immunohematology test system prior to reporting patient test results for four out of six testing personnel (personnel identifiers #5- #7, and #10). The findings include: 1. The laboratory implemented and began using the Grifols DG Gel immunohematology test system in June 2021. 2. At the time of the survey, the laboratory did not have documented training on the Grifols DG Gel immunohematology test system for personnel identifiers #5- #7 or #10.