

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384033	(X3) Date Survey Completed 08/28/2026
Name of Provider or Supplier Hancock County Health System	Street Address, City, State 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of performance specification records and confirmed by interview with General Supervisor #1 (GS #1) at 11:40 am on 08/28/2026, the laboratory failed to verify the performance specification of reportable range prior to testing and reporting patient specimens on the Triage Meter test system for four out of four analytes. The findings include: 1. The laboratory began using the Triage Meter test system to perform patient testing in November 2025 for the following analytes: myoglobin, creatine kinase-MB, troponin-I, and d-dimer. 2. Review of the Triage Meter verification of performance specification records indicated the laboratory failed to verify the reportable range for myoglobin, creatine kinase-MB, troponin-I, and d-dimer testing. 3. At the time of the survey, GS #1 confirmed that the laboratory failed to have documentation of verification of the performance specification of reportable range for the analytes listed above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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 Beckman Coulter DxC 500i chemistry quality control (QC) records, the laboratory's QC policy/procedure, the HCHS Lab Troubleshooting QC job aid, the Biorad Liquid Assayed Multiquel package insert, and confirmed by interview with General Supervisor #1 (GS #1) at 12:20 pm on 08/28/2026, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for 1 out of 31 days of patient testing reviewed from 05/01/2026- 05/31/2026 for the following analytes: albumin (ALB), sodium (NA), potassium (K), chloride (CL), creatinine (CREA), glucose (GLU), lactic acid (LA), magnesium (MG), phosphorus (PHOS), total protein (TP), lipase (LIP), and total bilirubin (TBIL). The findings include: 1. The laboratory performs chemistry testing on a Beckman Coulter DxC 500i instrument. 2. The laboratory uses Biorad Liquid Assayed Multiquel (levels 1 & 3) controls. For each analyte, the Liquid Assayed Multiquel package insert included a manufacturer assigned mean and reference values that are plus or minus 3 standard deviations (SD) from the mean. 3. The laboratory's Quality Control Review policy stated that when control values fall outside 2 SD just once, the laboratory will accept the result. However, if the same control or both levels of the same analyte fall outside 2 SD, the laboratory will troubleshoot. In addition, it stated that all controls are reviewed before reporting patient results and if not acceptable, test results are not reported. 4. The HCHS Lab Troubleshooting QC job aid included the following progressive actions to take for unacceptable QC runs: rerun QC, use a new lot of reagent, perform a calibration, check if QC is within the manufacturer's package insert ranges, and consult the laboratory director. 5. Review of chemistry QC records and the Biorad Liquid Assayed Multiquel package insert revealed that QC values fell outside of the laboratory's established 2 SD reference range and the manufacturer's package insert 3 SD reference range on 05/30/2026 for the following analytes and QC levels: *ALB- level 1 and 3 *NA- level 3 *K- level 3 *CL- level 3 *CREA- level 3 *GLU- level 1 and 3 *LA- level 3 *MG- level 3 *PHOS- level 3 *TP- level 1 and 3 *LIP- level 3 *TBIL- level 3 6. On 05/30/2026, the laboratory performed the following number of patient tests for each analyte: *ALB- 5 patients *NA- 9 patients *K- 9 patients *CL- 9 patients *CREA- 9 patients *GLU- 9 patients *LA- 1 patient *MG- 4 patients *PHOS- 1 patient *TP- 5 patients *LIP- 1 patient *TBIL- 5 patients 7. At the time of the survey, GS #1 confirmed that the laboratory failed to take and document corrective action for the unacceptable QC results listed above.