

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0677171	(X3) Date Survey Completed 03/06/2024
Name of Provider or Supplier Decatur County Hospital	Street Address, City, State 1405 Nw Church Street, Leon, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 8:35 am on 03/06 /2024, the laboratory failed to take and document corrective action for five unacceptable PT scores from three out of six PT testing events from 01/01/2022- 12/31 /2023. The findings include: 1. For 2022 testing event 1, the laboratory received unacceptable PT test scores for the following: *2022 Core Chemistry 1st event- creatine kinase- myocardial band (CK-MB) (specimen CM-01) 2. For 2023 testing event 1, the laboratory received unacceptable PT scores for the following: *2023 Core Chemistry 1st event- total iron-binding capacity (TIBC), measured (specimen CH-05) and salicylates (specimen CH-05) 3. For 2023 testing event 2, the laboratory received unacceptable PT test scores for the following: *2023 Core Chemistry 2nd event- partial pressure of carbon dioxide (PCO2) (specimen BG-09) and lipase (specimen CH-09) 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores.</p>
D6055	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on review of personnel records, the MiniiSED performance verification records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), at 9:20 am on 03/06/2024, the technical consultant failed to document training for the MiniiSED test system prior to reporting patient test results for three out of eight testing personnel (identifiers #3, #4, and #6). The findings include: 1. The laboratory began using the MiniiSED test system in September 2022. 2. At the time of the survey, the laboratory did not have training records on the MiniiSED test system for testing personnel identifiers #3, #4, or #6.