

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385620	(X3) Date Survey Completed 01/23/2025
Name of Provider or Supplier Crawford County Memorial Hospital	Street Address, City, State 100 Medical Parkway, Denison, 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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on lack of calibration verification records, review of calibration records and confirmed by interview with technical consultant identifier #1 (TC 1) at 10:39 am on 1/23/2025, the laboratory failed to perform calibration verification every six months for four out of four time periods from 1/1/2023 - 1/23/2025 for the analyte, procalcitonin. The findings include: 1. Calibration records for the analyte procalcitonin revealed the laboratory used two calibrators to calibrate the analyzer. 2. TC 1 confirmed the laboratory did not perform calibration verification for the analyte procalcitonin from 1/1/2023 - 1/23/2025.</p>

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 procedure 134.314 Quality Control Acceptance Guidelines, ethanol quality control (QC) results and patient test reports and confirmed by interview with technical consultant identifier #1 (TC 1) at 10:39 am on 1/23/2025, the laboratory failed to take and document corrective action when ethanol QC results failed to meet the laboratory's established criteria for acceptability for one out of 31 days in October 2024. The findings include: 1. The 134.314 Quality Control Acceptance Guidelines procedure states, "Test are not acceptable if: ...One control falls beyond the 3rd standard deviation in any instance." 2. For ethanol QC level 1, the lab established a mean of 30.2 mg/dL with a standard deviation (SD) of 2.0 mg/dL. 3. On 10/1/2024 the laboratory performed ethanol QC on lot number 54411, expiration date 3/31/2025 of ethanol reagent. The laboratory accepted a result of 16.2 mg/dL for ethanol QC level 1 which was greater than 3 SDs below the mean. 4. The laboratory reported ethanol results for one patient on 10/1/2024. 5. TC 1 confirmed that the laboratory did not document corrective action when ethanol QC level 1 fell outside the laboratory's established range and reported patient results.