

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382617	(X3) Date Survey Completed 11/07/2018
Name of Provider or Supplier Audubon County Memorial Hospital	Street Address, City, State 515 Pacific Avenue, Audubon, 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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of chemistry calibration and control records for the analyte, Aspartate Aminotransferase (AST), from April 2018 and the laboratory's Quality Control Protocol and confirmed by the laboratory supervisor at 11:30 am on 11/07/2018, the laboratory failed to take and document corrective action when the calibration and control results from 1:50 pm 04/10/2018 and control results from 6:01 am 04/11/2018 were unacceptable and to evaluate patient test results to determine if the results had been adversely affected for 24 out of 24 patients tested for AST from 1:50 pm 04/10/2018 to 6:00 am 04/12/2018. The findings include: 1. Calibration records for AST from 1:50 pm 04/10/2018 revealed that the calibration failed when the high level control results were outside the acceptable range of 243-259. The initial control results were 264. The laboratory retested the control three times (264, 263 and 264) and the results were still outside the acceptable range. The laboratory did not take and document any other corrective action. 2. Control results for AST from 6:01 am 04/11/2018 revealed the high level control remained outside of the acceptable range with results of 261 and 262. The laboratory did not take and document any other corrective action other than to repeat the control testing. 3. The laboratory procedure, Quality Control Protocol, stated that control and patient results were to be rejected when both controls are greater than 2 standard deviations (SD), one control is greater than 3 SD,</p>

or same control is outside of 2 SD on consecutive runs. The protocol did not include (1) the course of action to be taken if a calibration failed and (2) to document the corrective actions taken for unacceptable calibration and control results. 4. Control results for AST from 6:00 am 04/12/2018 revealed the high level control results were acceptable (250 and 251). 5. The laboratory supervisor confirmed that the laboratory reported AST results for 24 patients from 1:50 pm 04/10/2018 until 6:00 am 04/12/2018. The laboratory supervisor also confirmed that the laboratory failed to evaluate the patient test results to determine if they had been adversely affected.