Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D1088593	09/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Siouxland Adult Medicine	1605 Douglas Street, Sioux City, 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	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 the Quality Assessment policy, Alfa Wassermann quality control (QC) ranges, and Alfa Wassermann quality control records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 8:45 am on 10/4/2021, the laboratory failed to take and document corrective action when QC fell outside the laboratory's established criteria of acceptability for one out of ten days of patient testing from 4/19/21 - 4/30/21. The findings include: 1. The Quality Assessment policy stated, "Reject run if a) Both controls are greater than 2 SD from the mean. b) One control is greater than 2 SD and less than 3SD on two consecutive runs. c) One control is greater than 3SD from the mean." 2. Level 1 chemistry control ranges for Lot 1213UNCM, expiration date 5/31 /21 listed the following 3SD range: *Alkaline phosphatase (ALP) 55-83 U/L 3. On 4 /20/21, the laboratory reported the following unacceptable QC results for ALP: *8:25 am - 86 U/L 4. Level 2 chemistry control ranges for Lot 937UECM, expiration date 5 /31/21 listed the following 3SD range: *Chloride - 73.8 -90.2 mmol/L 5. On 4/20/21, the laboratory reported the following unacceptable QC results for chloride: *8:25 am - 94.0 mmol/L *9:37 am - 94.8 mmol/L *9:49 am - 94.8 mmol/L 6. Laboratory personnel identifier #1 confirmed that the laboratory reported ALP and chloride patient testing on 4/20/21. 7. At the time of the survey, the laboratory did not take and

	document corrective action when the above QC fell outside the laboratory's established criteria for acceptability.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are 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 #1 (refer to the Laboratory Personnel Report) at approximately 8: 20 am on 9/29/2021, the laboratory director failed to ensure the laboratory documented corrective action when the laboratory received unacceptable PT scores for one out of five PT events from 1/1/2020 - 10/4/2021. The findings include: 1. For 2020 event 3, the laboratory received an unacceptable score of 80% for percent lymphocytes. 2. At the time of the survey, the laboratory did not document corrective action for the above unacceptable score.