

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0648034	(X3) Date Survey Completed 09/18/2026
Name of Provider or Supplier Sioux Center Health	Street Address, City, State 1101 9th Street Se, Sioux Center, 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)(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 Laboratory Test and Volume Annual form, chemistry quality control (QC) records and confirmed by interview with general supervisor identifier #1 (GS #1) at 12:48 pm on 9/18/2026, the laboratory failed to document corrective action when level 1 QC fell outside of the established range for five out of 16 days for the analytes, magnesium (Mg) and urea nitrogen (BUN); and when level 3 QC fell outside of the established range for 15 out of 16 days for the analytes, carbon dioxide (CO2), total cholesterol (T. Chol) and total iron binding capacity (TIBC) from 4/1/2026 - 4/16/2026. The findings include: 1. The laboratory's QC report included the QC result, but did not include standard deviations or QC ranges. 2. Interview with GS #1 revealed that if QC fell outside the established range the QC would flag either "ROM" or "MW". GS #1 stated that the laboratory could not accept QC with an "ROM" or "MW" flag. 3. QC records revealed the laboratory had "ROM" flags on the following dates for QC level 1: *4/1/26 6:45 am - Mg *4/3/26 10:28 am - BUN *4/3/26 10:29 am - Mg *4/4/26 6:46 am - Mg *4/5/26 6:35 am - Mg *4/12/26 6:36 am - Mg 4. QC records revealed the laboratory had "ROM" flags on the following dates for QC level 3: *4/1/26 6:46 am - CO2 *4/1/26 6:47 am - T. Chol *4/2/26 6:45 am - CO2 *4/2/26 6:45 am - T. Chol *4/2/26 7:17 am - CO2 *4/2/26 7:38 am - CO2 *4/2/26 7:45 am - CO2 *4/4/26 6:47 am - T. Chol *4/5/26 6:35 am - T. Chol *4/6/26 6:45 am - T. Chol *4/7/26 6:37 am - T. Chol *4/8/26 6:42 am - CO2 *4/8/26 6:43 am - T. Chol *4/9/26

	6:38 am - CO2 *4/9/26 6:38 am - T. Chol *4/10/26 6:35 am - CO2 *4/10/26 6:36 am - T. Chol *4/10/26 6:52 am - TIBC *4/11/26 9:09 am - T. Chol *4/12/26 6:38 am - T. Chol *4/13/26 6:41 am - T. Chol *4/14/26 6:31 am - CO2 *4/14/26 6:32 am - T. Chol *4/15/26 6:42 am - CO2 *4/15/26 6:42 am - T. Chol *4/16/26 6:28 am - CO2 *4/16/26 6:29 am - T. Chol *4/16/26 8:42 am - CO2 *4/16/26 8:43 am - T. Chol 5. GS#1 confirmed at the time of the survey, the laboratory did not document corrective action for the above QC with "ROM" flags. 6. On average the laboratory performs 41 magnesium, 688 BUN, 639 CO2, 198 T. Chol, and 26 TIBC tests per month.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel records, the Laboratory Personnel Report, and confirmed by interview with the general supervisor identifier #1 (GS #1) at 8:15 am on 9/18/2026 at 8:15 am, the technical consultant failed to document annual competency assessments for eight out of 37 testing personnel who performed rupture of membrane (ROM) testing in 2025. The findings include: 1. GS #1 confirmed that testing personnel identifiers #1 - #37 on the Laboratory Personnel Report all performed ROM testing. 2. The laboratory did not have 2025 annual ROM testing competencies for testing personnel identifiers #10, #11, #14, #25, #27, #29, #34 and #36. 4. GS #1 confirmed at the time of the survey, the laboratory did not have 2025 ROM competency assessments for the above testing personnel.