

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407349	(X3) Date Survey Completed 02/11/2026
Name of Provider or Supplier Sanford Deuel County Medical Center	Street Address, City, State 701 3rd Avenue South, Clear Lake, SD	
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
D0000	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 2/11/26. The Sanford Clear Lake Medical Center laboratory was found not in compliance.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to ensure quality control materials were changed before their expiration date for three of three hematology quality control (QC) vials. Findings include: 1. Observation on 2/11/26 at 1:00 p.m. of the laboratory reagent refrigerator revealed there were three vials of opened XN-L check hematology QC (levels one, two, and three). The opened date on all three vials was 1/24/26, and the expiration date was 2/7/26. Review of the QC manufacturers' 2025 instructions for use (IFU) revealed "open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 Celsius (C) after being re-capped." Review of the laboratory's hematology Sysmex XN-450 analyzer policy, last reviewed on 4/10/25, revealed open vial stability of QC samples was 15 days refrigerated. Review of the laboratory's hematology test records revealed that 9 patient samples were tested since the QC had expired on 2/7/26. Interview on 2/11/26 at 1:15 p.m. with testing personnel B revealed she did not realize the QC Vials had expired. She confirmed the open and expiration dates on the QC vials were correct. Interview on 2/11/26 at 1:30 p.m. with general supervisor A revealed that new QC vials were to be opened on 2/7/26. She confirmed that they used</p>

expired QC vials up to the date of the survey. She was unaware that the QC vials were not replaced since their expiration date of 2/7/26. She confirmed that the hematology QC was only stable for 15 days once opened.