Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407323	07/22/2026
Name of Provider or Supplier	**Street Address, City, State**	
Prairie Lakes Healthcare System	401 9th Avenue Northwest, Watertown, 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 from 7/21/26 through 7/22/26. Prairie Lakes Healthcare System, Inc, laboratory was found not in compliance.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform a positive and negative control to verify the accuracy of patient specimen test results for three of eighteen days reviewed (3/17/26, 3/29/26, and 5/15/26). Findings Include: 1. Review of laboratory blood bank records on 7/21/26 at 3:30 p.m. revealed the laboratory performed fetal-maternal hemorrhage (FMH) Screen testing. Quality Control (QC) results were not documented on 3/17/26, 3/29/26, and 5/15/26. Patient FMH Screen results were reported to the provider on these dates. Review of the Ortho Clinical Diagnostics FMH reagent instructions for use (IFU) revealed: "for a test result to be considered valid, the results of the negative control cells run at the same time must be negative, and the results obtained with the positive control cells run at the same time must be positive." Review of the laboratory's FMH Screen policy, last reviewed by the laboratory director in April 2026 revealed one positive and one negative control sample should be run with each patient test. Interview on 7/21/26 at 3:45 p.m. with technical supervisor A revealed QC results should always be documented in the blood bank logbook or in CPSI (electronic medical record system). Quality control should be run with each patient sample for FMH Screens. She confirmed QC was not documented on the dates above and that patient test results were reported.