Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407804	09/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Winner Regional Healthcare Center	745 East 8th Street, Winner, 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 9/11/18. The Winner Regional Healthcare Center laboratory was found not in compliance with the following requirements: D5217, D5435, and D5543.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation, annual test volume form, and laboratory supervisor interview, the laboratory failed to verify and document the accuracy of the test methods used for patient direct antiglobulin testing (DAT) twice a year for 20 of 20 months reviewed (January 2017 through August 2018). Findings include: 1. Review of the laboratory's PT documentation revealed there had been no documentation the accuracy of the DAT test had been verified twice a year or included in PT modules for the time frame above. During 2017, 229 patient DAT tests had been performed without the test method being verified for accuracy twice a year or included in PT. Interview on 9/11/18 at 11:05 a.m. with the laboratory's supervisor revealed PT had not been ordered for the DAT test in the two years she had been laboratory supervisor. She was not aware that the laboratory needed to do twice a year accuracy or proficiency testing for the DAT test.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check

	protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the immunohematology maintenance records, annual test volume survey form, and interview with the laboratory supervisor, the laboratory failed to evaluate the speed and timing of the bloodbank centrifuge to ensure the optimal length of time for the specimens to be centrifuged to provide accurate interpretation of the immediate spin crossmatch test method for 157 of 157 patient tests performed in 2017. Findings include: 1. Review of the 2017 and 2018 immunohematology maintenance records revealed the bloodbank centrifuge had not been evaluated to determine the best timing at the set speed of the bloodbank centrifuge to ensure an optimum blood cell dot formation had been formed. That test method had been used as part of the immediate spin crossmatch procedure for determining patient compatibility with donor blood units. Review of the annual test volume survey form revealed 157 immediate spin crossmatches had been performed on patient specimens during 2017. The centrifuge had not had its timing evaluated to establish the length of time necessary to produce ideal cell dot formation. Interview with the laboratory supervisor at 11:15 a.m. on 9/11/18 revealed the centrifuge calibration to determine optimum timing at the set speed had not been done during the two years she had been laboratory supervisor. She was not aware calibration of the centrifuge was necessary.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of body fluid procedure and interview with the laboratory supervisor, the laboratory failed to test an external quality control (QC) material with manual cell counts performed on cerebrospinal fluid for 20 of 20 months (1/1/17 to 8/31/18) reviewed using a hemocytometer. Findings include: 1. Review of the manual cell count procedure last reviewed march 2015 and signed by the laboratory director on 8 /18/18 revealed no mention of the use of an external QC material in the procedure. The procedure required the specimens to be counted in duplicate. Interview with the laboratory supervisor on 9/11/18 at 12:40 p.m. revealed the laboratory tested approximately two cerebral spinal fluid specimens in 2017 and two specimens in 2018. She was not aware external QC testing was necessary. They had not performed external QC for body fluid cell counts in the two years she had been laboratory supervisor.