Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0855724	07/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Red Cliff Community Health Center	36745 Aiken Rd, Bayfield, WI	

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
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with testing personnel, the laboratory has not specified the number, type, and frequency for testing control materials for the serum pregnancy test. Findings include: 1. Review of the laboratory procedures, including the serum pregnancy procedure and the quality control procedure, showed the quality control requirements for the serum pregnancy test are not specified. The procedure states "External controls may also be used" and provides two recommended controls but does not identify the type, number or frequency of controls required in this laboratory. 2. Interview with testing personnel on July 26, 2018 at 11:30 AM confirmed the procedures did not define the number, type or frequency of testing of quality control materials for the serum pregnancy test. This is a repeat deficiency, D5441 was previously cited June 11, 2008.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) and patient test records and procedures, and interview with testing personnel, the laboratory did not test positive and negative control material on three of four days of serum pregnancy testing from January through April 2018. Findings include: 1. Review of patient records showed serum pregnancy testing was performed on January 24, March 8, March 14, and April 10. 2. Review of QC records showed QC was performed three times from January through April 2018 on January 25, February 23 and April 10. 3. Review of the pregnancy test procedure and the laboratory's QC procedure showed no instructions for performance of QC materials with the serum pregnancy test. No evidence of an Individualized Quality Control Plan (IQCP) for serum pregnancy testing is present. 4. Interview with testing personnel on July 26, 2018 at 11:30 AM confirmed controls were not performed each day of patient testing and that an IQCP had not been developed for serum pregnancy testing.
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 surveyor review of proficiency testing results and interview with testing personnel, the laboratory director did not ensure that a corrective action plan was approved and followed when proficiency testing results were unacceptable. Findings include: 1. Review of proficiency testing results for 2018 showed unacceptable results for one of five samples tested for HDL (high density lipoprotein) cholesterol. The cover sheet for the event includes the following statement, "100% on all except 80% on HDL. Corrective action to follow." The sheet is signed by the laboratory director and dated February 28, 2018. No corrective action plan was available. 2. Interview with testing personnel on July 26, 2018 at 11:30 AM confirmed the laboratory director did not ensure a corrective action plan was developed and followed for the unacceptable proficiency testing results.