Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407818	11/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mobridge Regional Hospital	1401 10th Ave West, Mobridge, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory supervisor, the laboratory failed to achieve successful particpation for the human chorionic gonadotropin (HCG) test method. Unsatisfactory results had been received in two of three PT events (2018 Chemistry-Core-2nd and 3rd events) resulting in unsuccessful PT participation. Refer to D2107.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CASPER Reports 153D and 155D and interview with the laboratory supervisor, the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the human chorionic gonadotropin (HCG) test method in two out of three events (2018 Chemistry Core second and third events) resulting in unsuccessful performance. Findings include: 1. Review of the laboratory's CASPER Reports 153D and 155D revealed the American Proficiency Institute (API) PT scores were less than the 80% required to pass the HCG test per CLIA requirements found at CFR 493.861(a): a. API Chemistry Core 2018 second event HCG score = 60% (HCG-07 and HCG-08 were graded as unacceptable). b. API Chemistry Core 2018 third event HCG score = 60% (HCG-13 and HCG-14 were graded as unacceptable). 2. Interview with the laboratory supervisor on 11/01/18 at 8:30 am confirmed the failure. She stated the laboratory had reviewed the data for the two surveys and found no clerical errors, quality control and calibration were accetable. The laboratory retested the missed samples and results fell within the acceptable range. The laboratory has ordered a self evaluation study and an off cycle survey to assist with the investigation of the unacceptable PT results.