Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0041965	(X3) Date Survey Completed 11/04/2019
Name of Provider or Supplier Big Horn Hospital Association	Street Address, City, State 17 North Miles Avenue, Hardin, MT	

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	Based on an off-site proficiency testing desk review on 11/4/19, deficiencies were cited for Big Horn County Memorial Hospital in Hardin, MT.
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 routine desk audit of CMS-153 and 155 reports of proficiency testing performance and interview, the laboratory failed to achieve satisfactory performance for digoxin for two consecutive events (2019 event 2 and 2019 event 3), resulting in unsuccessful proficiency testing performance. See D2118.
D2118	TOXICOLOGY

	CFR(s): 493.845(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 proficiency testing scores and interview, the laboratory failed to achieve a score of 80 percent for digoxin in two consecutive events in 2019, resulting in unsuccessful performance. The findings include: 1. During a review on 11/4/19 at 7: 45 a.m. of the CMS-153 Unsuccessful Proficiency Testing Report included Big Horn County Memorial Hospital with unsuccessful proficiency testing scores for digoxin. 2. During a review on 11/4/19 at 8:00 a.m. of the CMS-155 report, the American Proficiency Institute (API) digoxin score for event 2 of 2019 was 20%. 3. During a review on 11/4/19 at 8:00 a.m. of the CMS-155 report, the API digoxin score for event 3 of 2019 was 40%. 4. On 11/4/19 at 12:39 p.m., the laboratory manager stated the failing test scores were due to cartridge storage.