Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0698570	01/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Avera St Benedict Crhc/Lake Andes	756 East Lake Street, Lake Andes, 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, the laboratory failed to achieve successful participation for the erythrocyte (red blood cell) count test method. Unsatisfactory results had been received in two of three PT events (2021 American Proficiency Institute Hematology/Coagulation second and third testing events) resulting in unsuccessful PT participation. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f)

	Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of CASPER Reports and interview, the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the erythrocyte (red blood cell) count test method in two out of three events (2021 American Proficiency Institute [API] Hematology/Coagulation second and third testing events) resulting in unsuccessful performance. Findings include: 1. Review of the laboratory's CASPER Reports 153D and 155D on 1/14/22 revealed the API PT scores for the erythrocyte count test method were less than the 80% required to pass an event per Clinical Laboratory Improvement Amendments requirements found at CFR 493.861(a): a. 2021 Hematology/Coagulation second event score = 60% (HSY-07 and HSY-09 were graded as unacceptable). b. 2021 Hematology/Coagulation third event score = 60% (HSY-13 and HSY-14 were graded as unacceptable). 2. Interview with the laboratory supervisor via eamil on 1/11/22 revealed:*She confirmed the unsuccessful PT performance. *She had reviewed the daily maintenance logs, background counts, analyzer calibrations, and quality control records. *Three patient specimens were sent to a nearby hospital laboratory for comparison testing. *She reviewed the proper procedure for processing PT specimens with the laboratory's testing personnel.