

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0865445	(X3) Date Survey Completed 05/21/2018
Name of Provider or Supplier Family Health Center Of Eagle Butte	Street Address, City, State 24337 Us Highway 212, Eagle Butte, 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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory director, the laboratory failed to achieve successful participation for the test method white blood cell differential. Unsatisfactory results had been received in two of three PT events (2017 Hematology/Coagulation 3rd event and 2018 Hematology /Coagulation 1st event) resulting in unsuccessful PT participation. Refer to D2130.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

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 with the laboratory director, the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the white blood cell differential test method in two out of three events (2017 Hematology/Coagulation 3rd event and 2018 Hematology/Coagulation 1st event) resulting in unsuccessful performance. Findings include: 1. Review of the laboratory's CASPER Reports 153D and 155D on 5/7/18 revealed the American Proficiency Institute PT scores for the white blood cell differential test method were less than the 80% required to pass an event per CLIA requirements found at CFR 493.861(a): a. 2017 Hematology/Coagulation 3rd event score = 67% (HSY-11, 12 and 15 were graded as unacceptable). b. 2018 Hematology/Coagulation 1st event score = 73% (HSY-01, 02 and 04 were graded as unacceptable). 2. Interview with the laboratory director on 5/14/18 confirmed the failure. He stated they were aware of the issue, had ceased testing, were retraining testing personnel in specimen handling, and were working with the analyzer's manufacturer to determine the issue.