

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407349	(X3) Date Survey Completed 10/31/2018
Name of Provider or Supplier Sanford Deuel County Medical Center	Street Address, City, State 701 3rd Avenue South, Clear Lake, 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 supervisor, the laboratory failed to achieve successful performance for the test method erythrocyte count. Unsatisfactory results had been received in two of three PT events (Hematology/Coagulation 2017 3rd and 2018 2nd events) resulting in unsatisfactory PT performance. 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 supervisor, the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the erythrocyte count test method in two out of three events (Hematology/Coagulation 2017 3rd and 2018 2nd events) resulting in unsuccessful performance. Findings include: 1. Review of the laboratory's CASPER Reports 153D and 155D revealed the American Proficiency Institute PT scores for the erythrocyte count (RBC) test method were less than the 80% required to pass the RBC test per CLIA requirements found at CFR 493.861(a): a. 2017 Hematology/Coagulation 3rd event RBC score = 40% (HSY-11, 12, and 14 were graded as unacceptable). b. 2018 Hematology/Coagulation 2nd event RBC score = 0% (HSY-06, 07, 08, 09, and 10 were graded as unacceptable). 2. Interview with the laboratory supervisor on 8/20/18 confirmed the failure. She stated they were aware of the issue. She stated they had been having issues with the Abbott Emerald hematology analyzer and service had been contacted. The Hematology /Coagulation PT 2017 3rd and 2018 2nd events had been performed and reported on the older Abbot Emerald hematology analyzer. She stated they were in the process of validating a new replacement Abbott Emerald hematology analyzer. The new analyzer was put into use 7/17/18.