

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D2070510	(X3) Date Survey Completed 10/31/2018
Name of Provider or Supplier Horizon Health Yankton Medical & Dental	Street Address, City, State 920 Broadway Ave, Yankton, 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 performance for the test method white blood cell differential. Unsatisfactory results had been received in two of three PT events (Hematology/Coagulation 2017 3rd and 2018 2nd events) resulting in unsuccessful 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 director, the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the white blood cell (WBC) differential 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 WBC differential test method were less than the 80% required to pass the WBC differential test per CLIA requirements found at CFR 493.861(a): a. Hematology/Coagulation 2017 3rd event WBC differential score = 0% (HSY-11, 12, 13, 14, and 15 were graded as unacceptable). b. Hematology/Coagulation 2018 2nd event WBC differential score = 67% (The neutrophil/granulocyte results for HSY-06, 07, 08, 09, and 10 were graded as unacceptable). 2. Interview with the laboratory director on 8/20/18 confirmed the failure. He stated they were aware of the issue. The neutrophil/granulocyte absolute counts had been entered as percentage results on both surveys.