Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D1069533	(X3) Date Survey Completed 10/20/2021
Name of Provider or Supplier Horizon Health Martin Medical	**Street Address, City, State** 109 Pugh Street, Martin, 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 with the technical consultant, 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 2021 1st and 2nd events) resulting in unsuccessful PT performance. 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 with the technical consultant, 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 2021 1st and 2nd events) resulting in unsuccessful performance. Findings include: 1. Review of the laboratory's CASPER Reports 153D and 155D revealed the American Proficiency Institute (API) 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. API Hematology /Coagulation 2021 1st event WBC differential score = 0% (survey results had not been submitted prior to the PT result due date). b. API Hematology/Coagulation 2021 2nd event WBC differential score = 20% *The neutrophil/granulocyte results for HSY-06, 07, 09, and 10 were graded as unacceptable. *The lymphocyte results for HSY 06, 08, and 10 were graded as unacceptable. *The monocyte results for HSY 06, 07, 08, 09, and 10 were graded as unacceptable. 2. Interview with the technical consultant on 9/28/21 confirmed the failures. He stated he was aware of the issues. During the first testing event, the laboratory had failed to submit their results prior to the PT result due date. Results for the 2nd testing event had been entered under the incorrect analyzer code.