

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D2227819	(X3) Date Survey Completed 11/12/2024
Name of Provider or Supplier Benefis Helena Northeast	Street Address, City, State 2960 N Washington St, Helena, MT	
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 a review of American Proficiency Institute records and an interview with the technical supervisor, the laboratory failed to achieve satisfactory performance for Blood Cell Identification which includes Eosinophils, Neutrophil, segmented, Neutrophil, band, and Lymphocytes for two out of three testing events, resulting in unsuccessful proficiency testing performance. (See 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 a review of American Proficiency Institute (API) proficiency testing (PT) scores and an interview with technical supervisor (TS) # 1, the laboratory failed to achieve a score of at least 80% for two out of three testing events for Blood Cell Identification. Findings: 1. A review of the API Blood Cell Identification which includes Eosinophils, Neutrophil, segmented, Neutrophil, band and Lymphocytes proficiency testing scores revealed that in 2023, Event 3 scored 0% and in 2024, Event 2 scored 60%. 2. An interview with TS #1 on November 10, 2024, at 7:11 PM confirmed the laboratory's unsuccessful proficiency testing scores were due to failure to submit results to API and transcription errors.