| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 27D2227819 | 01/07/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Benefis Helena Northeast | 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 |
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| **D0000** | A proficiency testing desk review was completed on December 24, 2024. At the time of the desk review, it was determined that the laboratory was not in compliance with all conditions required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). The following condition level deficiencies were cited: 493.803 Condition: Successful participation. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Based on an off-site review of the CMS-155 reports of proficiency testing |

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| | performance, American Proficiency Institute (API) proficiency testing (PT) scores and corresponding laboratory records, and email communication with testing personnel (TP) #1, the laboratory failed to achieve satisfactory performance for hematology for three out of four testing events, resulting in subsequent unsuccessful proficiency testing performance in 2023 and 2024. See D2130 |
| **D2130** | HEMATOLOGY<br>CFR(s): 493.851(f)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on an off-site review of American Proficiency Institute (API) proficiency testing (PT) scores and corresponding laboratory proficiency testing records submitted by email on January 02, 2025, by testing personnel (TP) # 1, the laboratory failed to prevent a subsequent unsuccessful performance in the specialty of hematology for manual cell differentials performed in 2023 and 2024. Findings: 1. A review of API's hematology PT records on January 02, 2025, revealed the laboratory failed to achieve a satisfactory performance score of 80% or greater for the following events: 2023 Blood Cell Identification Event 3 - 0% 2024 Blood Cell Identification Event 2 - 60% 2024 White Blood Cell Differential Event 3 - 64% 2. An email communication with TP #1 on January 02, 2025, at 1:14 PM, confirmed the laboratory's subsequent unsuccessful proficiency testing scores were due to failure to submit results, transcription errors, and proper sample handling. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on an off-site review of 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) scores and corresponding laboratory records, and email communication with technical supervisor (TS) #1, the laboratory director failed to provide overall management of the proficiency testing program to ensure laboratory staff perform and submit their proficiency testing results for 2023 Hematology /Coagulation - 3rd Event. (Refer to D6089). |
| **D6089** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(i)<br><br>(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on an off-site review of 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) scores and corresponding laboratory records, and an email |

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| | communication with technical supervisor (TS) #1, the laboratory director failed to ensure laboratory staff perform and submit their proficiency testing results for 2023 Hematology/Coagulation - 3rd Event. Findings: 1. A review of API's Performance Summary Form for 2023 Hematology/Coagulation - 3rd Event revealed the laboratory's "failure to participate" resulting in an overall score of 0%. 2. A review of the laboratory's Performance Review and Corrective Action Documentation signed on 11/8/2024 by the technical supervisor (TS)#1, revealed that the "entire survey was missed", "results were not transmitted to API" and "an evaluation was not performed. 3. An email communication with TS# on November 10, 2024, at 7:11 PM confirmed the laboratory's unsuccessful PT scores were due to failure to perform and submit results to the API. |