Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2227819	06/02/2025
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on record review, product inserts, and an interview with a laboratory representative (not listed on the CMS-209 form), laboratory staff failed to follow the manufacturer's instructions to perform external positive and negative quality control (QC) onsite for each new shipment of Abbott ID Now kits from June 2, 2023, to June 2, 2025. Findings: 1. A review of quality control (QC) records for Abbott ID Now assays (Influenza A & B (Flu A & B), 2019 Coronavirus Disease (COVID-19), Respiratory Syncytial Virus (RSV) and Group A streptococcus (Strep A) revealed the laboratory failed to perform external positive and negative quality control onsite with each new shipment received per the manufacturer's instructions. 2. An interview with the laboratory representative (not listed on the CMS-209 form) on June 2, 2025, at 4: 00 PM confirmed testing personnel failed to perform an external positive and negative quality control onsite with each new shipment of Flu A & B, COVID-19, RSV and Strep A kits received from June 2, 2023, to June 2, 2025.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) (b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with the general supervisor (GS) #1, the laboratory failed to verify the number and frequency of the quality control for two of two Individualized Quality Control Plans (IQCP) used for the Quidel Triage and the Sure Vue pregnancy kit for serum hCG from June 2, 2023, to June 2, 2025. Findings: 1. A review of the laboratory Individual Quality Control Plan (IQCP) records failed to have a verification study performed onsite that supports the quality control (QC) frequency for the Quidel Triage (d-dimer, creatine kinase, myoglobin (CK-MB), and troponin I) and Sure Vue pregnancy kit for serum hCG. 2. An interview with GS #1 on June 2, 2025, at 10:20 AM, confirmed the laboratory failed to provide QC data that verified their IQCP quality control number and frequency for the assays performed on the Quidel Triage (d-dimer, CK-MB, and troponin I) and the Sure Vue pregnancy kit for serum hCG, from June 2, 2023, to June 2, 2025. 3. A review of the test volume sheet revealed 358 troponin I and 341 d-dimer patient tests were performed in the last 12 months (May 1, 2024, to May 30, 2025).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on a review of proficiency testing records, the CMS-209 Laboratory Personnel Report, and an interview with a laboratory representative (not listed on the CMS-209 form), the laboratory director failed to ensure all proficiency testing reports were received, reviewed and approved by the appropriate staff from June 2, 2023, to June 2, 2025. Findings: 1. A review of API and WSLH proficiency testing events failed to be reviewed by the laboratory director or designee (listed in the laboratory director's delegation of duties) for the following events: WSLH 2024-Chem/Endo/Tx3 attestation, summary, and PT Failure Corrective Action Worksheet for BNP WSLH 2024-Micro QA2 attestation and summary WSLH 2024-Micro QA3 attestation WSLH 2024-CoagQA2 attestation and summary 2. A review of API and WSLH proficiency testing events revealed that the laboratory director failed to ensure all proficiency testing reports were received and reviewed for the following events: WSLH 2023-Chem/Endo/Tx2 WSLH 2023-Chem/Endo/Tx3 WSLH 2024-Chem/Endo /Tx1 WSLH 2024-Chem/Endo/Tx2 WSLH 2024-Micro QA1 WSLH 2024-Coag QA1 API 2024 Chemistry Core Event 2 API 2023 Chemistry Core Event 2 and Event 3 3. An interview with the laboratory representative (not listed on the CMS-209 form) on June 2, 2025, at 11:00 AM confirmed the laboratory director listed on the CMS-209 form failed to ensure all proficiency testing reports were received, reviewed and approved by the appropriate staff from June 2, 2023, to June 2, 2025.