

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D2227819	<b>(X3) Date Survey Completed</b>  02/05/2025
<b>Name of Provider or Supplier</b>  Benefis Helena Northeast	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Based on an off-site complaint survey finalized on February 05, 2025, 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: CFR(s): 493.801 ENROLLMENT AND TESTING OF SAMPLES Definitions: Laboratory #1 located in Helena, MT Laboratory #2 located in Great Falls, MT
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on an off-site review of American Proficiency Institute (API) proficiency testing (PT) records, laboratory policy and procedures, and e-mail communications with testing personnel (TP) #1 located at laboratory #1, technical supervisor (TS) #1, and laboratory manager located at laboratory #2, the laboratory failed to ensure laboratory staff did not engage in inter-laboratory communications (refer to D2012) and failed to ensure the laboratory director signed the proficiency testing attestation page, final results, and corrective action forms per their policy and procedure (refer to D2014).</p>

**D2012**

**TESTING OF PROFICIENCY TESTING SAMPLES**

(b)(4) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

Based on an off-site review of American Proficiency Institute (API) proficiency testing (PT) records, laboratory policy and procedures, and e-mail communications with testing personnel (TP) #1 located at laboratory #1 and technical supervisor (TS) located at laboratory #2, the laboratory failed to follow their procedure and ensure staff from laboratory #1 did not send their proficiency testing results to laboratory #2 to be entered into the American Proficiency Institute portal before the event cutoff date of November 29, 2023. Findings: 1. A review of the API 2023 Catalog revealed that the PT results for the 2023 Hematology/Coagulation - 3rd Event's due date was November 29, 2023. 2. A review of email communication between TP #1 and TS #1 on Friday, November 10, 2023, regarding API, revealed TP #1 stated at 10:55 AM that TP #2 will send PT results when she gets done. 3. A review of PT records for laboratory #1 revealed the laboratory's attestation was signed by TP#2 on November 15, 2023. 4. A review of the laboratory's 2023 Hematology/Coagulation-3rd Event "Performance Review and Corrective Action Documentation" and "Corrective Action Checklist" signed by TS#1 on 11/08/2024 revealed laboratory #1's practice to send their API PT results to laboratory #2 for data entry into the API portal prior to the due date: "Results will be entered in Helena at that location, rather than send to Great Falls for entry."; and "Survey results will be entered into the API portal by assigned leads at this location, rather than routing results to the main campus." 5. A review of laboratory #1's "Proficiency Testing" policy and procedure revealed staff failed to follow their procedure to prevent inter-lab communication as stated: "Communication concerning survey samples with other laboratories is prohibited until after the deadline for submission of data to the PT provider." 6. An email communication with TP #1 on January 15, 2025, at 12:49 PM, confirmed laboratory #1 submitted their API PT results to laboratory #2 for data entry into API's portal.

**D2014**

**TESTING OF PROFICIENCY TESTING SAMPLES**

(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on an off-site review of American Proficiency Institute (API) proficiency

testing (PT) records, laboratory policy and procedures, and e-mail communications with testing personnel (TP) #1 located at laboratory #1 and laboratory manager located at laboratory #2, the laboratory director (LD) #1 failed to follow their procedure and sign the attestation page, final PT results, and corrective action from November 15, 2023, to February 5, 2025. Findings: 1. A review of laboratory #1's "Proficiency Testing" policy and procedure revealed that LD #1 failed to follow their procedure and sign the attestation page, final PT results, and corrective action for the following records: 2023 Hematology/Coagulation - 3rd Event's Performance Review and Corrective Action 2023 Hematology/Coagulation - 3rd Event's Corrective Action Checklist 2023 Hematology/Coagulation - 3rd Event's Attestation Statement 2024 Hematology/Coagulation - 2nd Event's Performance Review and Corrective Action 2024 Hematology/Coagulation - 2nd Event's Corrective Action Checklist 2024 Hematology/Coagulation - 2nd Event's Attestation Statement 2024 Hematology/Coagulation - 3rd Event's Performance Review and Corrective Action 2024 Hematology/Coagulation - 3rd Event's Corrective Action Checklist 2024 Hematology/Coagulation - 3rd Event's Attestation Statement 2. An email communication to TP#1 and the laboratory manager located at laboratory #2 on 1/30/2025 at 8:55 AM requested signed proficiency testing documentation, a CMS-209 laboratory personnel report, and a delegation of duties from the laboratory director. The laboratories failed to submit the requested documents as of February 5, 2025.