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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 27D0652495 | (X3) Date Survey Completed 02/05/2025 |
| Name of Provider or Supplier Benefis Health System East Campus | Street Address, City, State 1101 26th Street South, Great Falls, 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 | 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 |
| D2000 | <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) and laboratory manager located at laboratory #2, the laboratory failed to ensure laboratory staff did not engage in inter-laboratory communications (refer to D2012).</p> |
| D2012 | <p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(4) Laboratories that perform tests on proficiency testing samples must not engage</p> |

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 e-mail communications with testing personnel (TP) #1, technical supervisor (TS) #1, and laboratory manager for laboratory #2, the laboratory failed to ensure staff did not accept another laboratory's proficiency testing results 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 #2's practice to accept laboratory #1's API PT results and enter them 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. 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. 6. An email communication on 01/23/2025 at 11:48 AM with the laboratory manager confirmed receiving PT results from laboratory #1 and that laboratory #2 "does not use API for PT so we did not see a conflict of interest by entering their results at this location."