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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 27D0409818 | (X3) Date Survey Completed 05/11/2021 |
| Name of Provider or Supplier Daniels Memorial Healthcare Center | Street Address, City, State 105 5th Avenue East, Scobey, 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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| 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 record review and interview with Technical Consultant (TC)#1, the laboratory director (LD)#1 failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Mycology (KOH Preps) and Parasitology (Wet Preps) for years 2019 and 2020. See D6015</p> |
| D5553 | <p>IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f)</p> <p>(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review of Transfusion Medicine, and interview with</p> |

Technical Consultant (TC)#1, the laboratory failed to document visual inspection and temperature of blood products upon receipt of new shipments and release of units to be transfused for years 2019 and 2020. Findings: 1. Review of Transfusion Medicine records lacked documentation of visual inspection and temperature checks upon receipt and release of blood components for years 2019 and 2020. 2. Observation of shipping containers revealed the lack of thermometers to monitor blood or blood components temperatures during shipment and upon receipt of units. 3. Review of American Red Cross Hospital Partner Resource Guide revealed (page 17), "If products are received out of shipping temperature range or are packed incorrectly, notify Red Cross Customer Service. These products will be managed based on the non-conformance." 4. Review of Daniels Transfusion Medicine Policy and Procedure revealed "Visual inspection of inventory is performed each day of testing and immediately prior to transfusion." 5. Interview with (TC)#1 on May 11, 2021 at 11:51 AM, confirmed the laboratory failed to document visual inspection and record the temperature of blood products upon receipt of new shipment and release of units to be transfused for years 2019 and 2020.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Consultant (TC)#1, the Laboratory Director (LD)#1 failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Mycology (KOH Preps) and Parasitology (Wet Preps) for years 2019 and 2020. Findings: 1. Review of Test Volume Report revealed 5 KOH Preps and 24 Wet Preps were performed for 2020. 2. Review of 2019 and 2020 American Proficiency Institute (API) Testing Program records lacked documentation of proficiency testing for KOH Preps and Wet Preps. 3. Review of Proficiency Testing Policy and Procedure revealed "Daniels Memorial Hospital Laboratory subscribes to the American Proficiency Institute (API) for all disciplines of the laboratory." 4. Review of Personnel Qualifications and Responsibilities Policy and Procedures revealed, "6. The lab director must: F. Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that the proficiency testing samples are tested as required under subpart H of this part ..." 5. Interview with the (TC)#1 confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for Mycology (KOH Preps) and Parasitology (Wet Preps) for years 2019 and 2020.