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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 13D0520463 | (X3) Date Survey Completed 04/15/2021 |
| Name of Provider or Supplier Bear Lake Memorial Hospital | Street Address, City, State 164 S 5th St, Montpelier, ID | |
| 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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| D5415 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on a direct observation and an interview with the laboratory manager on 4/15 /2021, the laboratory failed to label containers with the identity, preparation and expiration dates and other pertinent information required for proper use. The findings include: 1. A direct observation in the laboratory on 4/15/2021 identified three unlabeled containers in the hematology department. 2. An interview with the laboratory manager on 4/15/2021 at 10:24 am identified that the contents were wright-giemsa stain and confirmed that they were not properly labeled.</p> |
| D5451 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p> |

Based on a random review of immunohematology quality control (QC), patient records and an interview with the laboratory manager on 4/14/2021, the laboratory failed to document control material results with graded or titered reactivity and include negative control material. The findings include: 1. A random record review of immunohematology QC and immunohematology patient logs for 2019 and 2020 identified that the laboratory failed to document QC with a graded or titered reactivity and a negative control on 6/7/2019, 1/31/20 and 4/13/2020. 2. One patient blood and Rh type, antibody screen and crossmatch was performed on 6/7/2019 and the laboratory failed to document positive QC (1-4+) and negative QC as required by regulation for immediate spin crossmatch testing. 3. One patient blood and Rh type was performed on 1/31/2020 and the laboratory failed to document positive QC (1-4+) and negative QC as required by regulation for all immunohematology testing. 4. Two patient blood and Rh types, and one antibody screen and crossmatch were performed on 4/13/2020 and the laboratory failed to document positive QC (1-4+) and negative QC as required by regulation for antibody screen testing. 5. An interview with the laboratory manager on 4/14/2021 at 1:00 pm confirmed the above findings. 4. The laboratory reports performing 418 immunohematology tests annually.