| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 27D0410720 | 05/16/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Deer Lodge Medical Center | 1100 Hollenback Lane, Deer Lodge, 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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| **D3021** | REQUIREMENTS FOR TRANSFUSION SERVICES<br>CFR(s): 493.1103(c)(1)<br><br>Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Immunohematology records, policies, and interview with technical supervisor (TS) #1, the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood or blood products from September 16, 2022, to May 16, 2023. Findings: 1. A review of Immunohematology records revealed the laboratory failed to take and document the temperatures of blood or blood products upon receipt of new shipments from September 16, 2022, to May 16, 2023. 2. A review of "Receipt and Processing of Blood Products" policy lacked a temperature requirement for the acceptance of blood or blood product and instructions for documentation. 3. An interview with TS #1 on May 16, 2023 at 11:00 AM, confirmed laboratory staff failed to take the temperature upon receipt of new shipments of blood or blood products and document the information from September 16, 2022 to May 16, 2023. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in |

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| | 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of bacteriology, chemistry, hematology, and blood bank records, and policies, the laboratory failed to verify the laboratory's patient population reference ranges (normal values) for the chemistry and hematology analyzers (See D5421); failed to establish the mean and standard deviation for each new lot of unassayed Bio-Rad chemistry controls (See 5469); failed to perform quality checks and record visual checks for each new lot or shipment of microbiology media (See 5477); failed to perform one control in duplicate on the hemocytometer (See 5543); failed to follow their procedure to perform visual inspection checks of blood or blood products upon receipt (See D5553); and failed to follow their procedure to perform and document monthly alarm checks for blood bank refrigerator and freezer (See D5555). |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review of policies and interview with technical supervisor (TS) #1, the laboratory failed to include in their chemistry and hematology procedures the reference intervals (normal values), calibration and calibration verification, a hemocytometer procedure, process for verification of new lots of quality controls (QC) or reagents, criteria to determine acceptable control results, corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability; failed to include in their immunohematology policy the temperature requirement for the acceptance of blood or blood products; failed to have an Individualized Quality Control Plan (IQCP) for quality control of microbiology media: and failed to have a quality assurance plan policy from May 16, 2021 to May 16, 2023. Findings: 1. No reference intervals (normal values) were available in the procedure manual for the Siemens Dimension EXL chemistry analyzer and Sysmex XN-1000 hematology analyzer. 2. A review of the Avoximeter and Opti CCA-TS2 blood gas analyzer's IQCP lacked instructions to perform, evaluate and document |

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| | calibration verification every six months. 3. A review of Vidas immunoassay analyzer procedures lacked instructions to perform, evaluate and document calibration verification every six months for d-dimer and procalcitonin. 4. No step-by-step procedure to perform manual cell counts on the hemocytometer was available for review. 5. The "Receipt and Processing of Blood Products" policy lacked a temperature requirement for the acceptance of blood or blood product and instructions for documentation. 6. A review of microbiology procedures lacked an IQCP to allow for the acceptance of manufacturer's QC instead of end user QC check each lot and shipment of media before use. 7. Chemistry and hematology procedures lacked instructions for crossover studies of new lots of control materials or reagents, criteria for acceptable control results, corrective action to take when controls reflect an unusual trend or are outside of the acceptable limits and direction on how to correct the problem. 8. No quality assurance plan policy was available for review. 9. Interview on May 16, 2023, at 5:30 PM with the TS #1, confirmed the laboratory failed provide the above elements in their procedures from May 16, 2021 to May 16, 2023. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review of patient results reports, policies, and interview with the technical supervisor (TS) #1, the laboratory failed to establish and verify the reference ranges (normal values) for the laboratory's patient population for the Siemens Dimension EXL chemistry analyzer and Sysmex XN-1000 hematology analyzer from May 16, 2021, to May 16, 2023. Findings: 1. A review patient results reports (#230460001CD and 230460001HD) for comprehensive metabolic panel and complete blood count w/differential listed reference ranges in the report. 2. No patient population verification studies for the Siemens Dimension EXL chemistry analyzer and Sysmex XN-1000 hematology analyzer were available for review to support the references ranges (normal ranges) listed in the laboratory's patient results reports. 3. An interview with the TS #1 on May 16, 2023, at 3:00 PM, stated the reference ranges (normal values) were established by a different laboratory from May 16, 2021, to May 16, 2023. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value |

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| | of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of chemistry quality control (QC) records and policies and an interview with the technical supervisor (TS) #1, the laboratory failed to establish acceptable criteria (mean and standard deviation) for new lots of Bio-Rad liquid unassayed Multiqual controls performed on the Siemens Dimension EXL chemistry analyzer from May 16, 2021, to May 16, 2023. Findings: 1. No correlation studies of new lots of Bio-Rad liquid unassayed Multiqual controls were available for review that showed an established mean and standard deviation for each analyte performed on the Siemens Dimension EXL chemistry. 2. The laboratory failed to establish a step-by-step procedure on how to perform and determine the statistical parameters for new lots of unassayed control material. 3. An interview with TS #1 on May 16, 2023, at 1: 10 PM confirmed the laboratory failed to establish and document acceptable statistical parameters for new lots of Bio-Rad liquid unassayed Multiqual controls performed on the Siemens Dimension EXL chemistry analyzer from May 16, 2021, to May 16, 2023. |
| **D5477** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(4)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, and interview with technical supervisor (TS) #1, the laboratory failed to perform quality checks (QC) for sterility and ability to support growth for each new lot or shipment of microbiology media and document visual checks of new shipment of media received in the laboratory from May 16, 2021, to May 16, 2023. Findings: 1. A review of the microbiology records lacked documentation of media QC to support growth and sterility for new shippments or lots of media including Bactec blood medium. 2. A review of new shipment documents of media lacked date received, initials and acceptability of media upon intake. 3. A review of microbiology procedures lacked an Individualized Quality Control Plan (IQCP) for alternative QC practices. 4. An interview with TS #1 on May 16, 2023, at 4:30 PM confirmed the laboratory failed to perform quality checks and record visual checks for each new lot or shipment of microbiology media. |
| **D5543** | HEMATOLOGY<br>CFR(s): 493.1269(a)(d) |

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| | (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of hematology quality control (QC) records, patient results report, and interview with the technical supervisor (TS) #1, the laboratory failed to obtain and perform one control material in duplicate for manual cell counts performed using the hemocytometer from May 16, 2021, to May 16, 2023. Findings: 1. A review of patient results reports (#231170034HD) for Cell Count Body Fluid performed on April 27, 2023, revealed the laboratory failed to perform one QC in duplicate the day of testing. 2. No procedure for performing manual cell counts on the hemocytometer was available for review. 3. A review of the test volume sheet revealed the laboratory performed 10 manual red blood cell counts from May 16, 2022, to May 16, 2023 (12-month period). 4. An interview with TS #1 on May16, 2023, at 1:30 PM, confirmed the laboratory failed to purchase and perform one control material in duplicate for the hemocytometer from May 16, 2021, to May 16, 2023. |
| **D5553** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(b)(f)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of immunohematology records, policies, and interview with technical supervisor (TS) #1, the laboratory failed to follow their policy to perform visual inspection checks of blood or blood products upon receipt from September 16, 2022, to May 16, 2023. Findings: 1. A review of immunohematology records revealed the laboratory failed to perform and document visual inspection of blood or blood products upon receipt of new shipments to the laboratory from September 16, 2022, to May 16, 2023.. 2. A review of "Receipt and Processing of Blood Products" policy revealed the laboratory failed to follow their policies as stated, "Examine all units for any visual contamination". 3. An interview with TS #1 on May 16, 2023, at 11:30 AM, confirmed laboratory staff failed to perform visual inspection of blood or blood products received in the laboratory per their policies and document their findings from September 16, 2022, to May 16, 2023. |
| **D5555** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(c)(f)<br><br>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of policies, records of blood bank alarm checks, and interview with the technical supervisor (TS) #1, the laboratory failed to follow their policies to perform and document alarm checks monthly for one of one blood bank refrigerator and freezer from May 16, 2021, to May 16, 2023. Findings: 1. A review of "Blood Bank Alarm Check Monthly" log revealed the laboratory failed to perform monthly alarm tests and document the low activation temperature and high activation temperature from May 16, 2021, to May 16, 2023 2. A review of "Blood Bank Refrigerator and Freezer Alarm Checks" revealed the laboratory failed to follow their policy as stated, "The temperature of activation in blood storage refrigerators should be checked at least once a month ... The high and low temperatures of activation must be checked, and the results recorded." 3. An interview with TS #1 on May 16, 2023, at 11:35 AM confirmed the laboratory failed to perform alarm checks at the frequency dictated by their policy from May 16, 2021, to May 16, 2023. |