| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 17D0047295 | 11/16/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Rawlins County Health Center | 707 Grant Street, Atwood, KS | |

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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| **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 review of performance verification documentation for the Sysmex XN-450 hematology analyzer, non-waived test lists, and interview, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population prior to performing patient testing. Findings: 1. Review of the verification documentation of the Sysmex XN-450 hematology analyzer, S/N 12571, for the analytes: White Blood Cell Differential, Red Blood Cell Count, Hemoglobin, Hematocrit, White Blood Cell Count, and Platelet testing showed no verification of normal values at time of survey. Document listed patient testing began 6/23/21. 2. Review of the KS-CLIA-PS02 non-waived test lists showed the XN-450 test volume from 6/23/21 to date of survey to be 19,950 patient test results. 3. Interview with General Supervisor on 11/16/22 at 1:40 p.m. confirmed, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population prior to performing patient testing. |
| **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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of 2021 and to date of survey blood bank temperature monitoring records without review documentation, lack of acceptable alarm check records, and interview, the laboratory failed to maintain an adequate temperature alarm system for the storage of blood products. Findings: 1. Review of monitoring records found 24 hour monitoring system in place with paper graphs for temperature records. Records examined showed no review documentation to ensure acceptable temperatures were maintained since 11/18/2020. 2. Review of Hi/Lo alarm check records showed the secondary monitoring process (laboratory was not staffed 24 hours a day, 7 days a week) was nonfunctional for the checks performed on 3/31/22 and 9/30/22. The last acceptable alarm check was recorded on 8/10/21. 4. Review of patient records found 10 patients received 22 units of blood from 8/10/21 to 11/16/22. 5. Interview with the general supervisor on 11/16//22 at 11:05 a.m. confirmed, the laboratory failed to maintain an adequate temperature alarm system for the storage of blood products. |