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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 26D0681861 | (X3) Date Survey Completed 05/03/2018 |
| Name of Provider or Supplier Nevada Medical Clinic | Street Address, City, State 900 S Adams St, Nevada, MO | |
| 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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| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, documentation of freezer temperatures and observation of quality control (QC) material stored in the freezer revealed, and interview with the laboratory director confirmed, the laboratory failed to follow the manufacturer's instructions for storage of control material for 7 of 66 testing days since February 1, 2018 through May 3, 2018. Findings: 1. Review of the manufacturer's instructions for Bio-Rad liquichek specialty immunoassay control and Bio-Rad liquichek immunoassay plus control states controls must be stored at minus 20 degrees Celsius (C) to minus 70 degrees C. 2. Review of the laboratory's temperature chart showed a defined acceptable range of minus 25 degrees C +/- 6 degrees C. 7 of 66 testing days that failed to meet the manufacturer's required minus 20 to minus 70 degree C range. 3. Observation of the laboratory freezer showed 1 box of Bio-Rad liquichek immunoassay control level I(lot # 40941), 1 box of Bio-Rad liquichek immunoassay control level III(lot #40943), 1 box Bio-Rad liquichek immunoassay control level II(lot 40942) and 1 box level III(lot 60233) Bio-Rad liquichek specialty immunoassay control, 1 box Bio-Rad liquichek specialty immunoassay control level I(lot 60231) and 1 box level II(lot 60232) Bio-Rad liquichek specialty immunoassay control currently in use in the laboratory. 4. Interview with the laboratory director on May 3, 2018 at 11:00 AM confirmed the</p> |

laboratory failed to properly monitor the freezer and store QC materials and supplies per manufacturer's instructions.