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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 13D0522232 | (X3) Date Survey Completed 05/11/2021 |
| Name of Provider or Supplier Shoshone Medical Center | Street Address, City, State 25 Jacobs Gulch Rd, Kellogg, 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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| D5407 | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and an interview with the laboratory manager on 5/11/2021, the Laboratory Director failed to approve, sign and date the laboratory policies and procedures. The findings include: 1. A record review of laboratory policies and procedures identified that the laboratory has 250 policies and procedures electronically stored on the hospitals computer system in the program PolicyTech. The Laboratory Director failed to approve, sign or date 154 of the 250 laboratory policies and procedures. 2. An interview with the laboratory manager on 5 /11/2021 at 8:50 am, confirmed that the Laboratory Director has not approved, signed or dated 154 of the laboratory policies and procedures. 3. The laboratory reports performing 92,546 moderate and high complexity tests annually.</p> |
| D5447 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a random record review of Quality Control (QC) documentation and</p> |

interviews with the laboratory manager on 5/10/2021 and 5/11/2021, the laboratory failed to successfully perform two levels of QC daily for each quantitative procedure. The findings include: 1. A random record review of QC from the Tosoh AIA identified that the laboratory did not have an acceptable result for level 1 and level 2 QC for Beta-human chorionic gonadotropin (B-hCG) on 4/7/2020. The laboratory performed and released one patient B-hCG test on 4/7/2020. 2. A random record review of QC from the Ortho Vitros 4600 identified that the laboratory did not have an acceptable result for level 1 QC for creatine kinase (CK) on 4/10/2020. The laboratory performed and released one patient CK test on 4/10/2020. 3. Interviews with the laboratory manager on 5/10/2021 and 5/11/2021 confirmed that the laboratory failed to have acceptable QC for the above dates and tests.