

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1044291	(X3) Date Survey Completed 04/15/2019
Name of Provider or Supplier Rock Run Family Medicine	Street Address, City, State 5640 S 3500 W, Roy, UT	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on an on-site unannounced complaint survey conducted on 04/15/2019, the laboratory failed to follow the Afinion HbA1C (Hemoglobin A1C) and Alere Cholestech Lipid test cartridge manufacturer's instructions to label cartridges with the dates the cartridges were removed from 2 to 8 degree storage, and document they performed quality control for HbA1C cartridges.</p>