

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520679	(X3) Date Survey Completed 07/30/2024
Name of Provider or Supplier North Canyon Medical Center	Street Address, City, State 267 North Canyon Dr, Gooding, 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
D0000	During an offsite paper revisit the laboratory was found to be in compliance with the CLIA regulations (42 CFR Part 493 effective April 24, 2003.) No deficiencies were cited.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of maintenance logs and interviews with the technical supervisor (TS) on 7/29/2024 and 7/30/2024, the laboratory failed to perform maintenance as required by the manufacturer in 2023 and 2024. The findings include: 1. A review of Cepheid GeneXpert maintenance logs identified that the laboratory failed to perform the quarterly maintenance of disinfection of the cartridge bay interior and the plunger rod for three of four quarters in 2023 and two of two quarters in 2024 as required by the manufacturer. 2. A review of the Capture CSW100 and Immucor Solid Phase Washer maintenance logs identified that the laboratory failed to perform monthly maintenance in 2023 and 2024 as required by the manufacturer for the following: Capture CSW100: replace exhaust filters and verification of fill check. Immucor Solid Phase Washer: decontaminate external surfaces, run maintenance decontamination, run day rinse DI, prime all buffers and verification of fill check. 3. An interview with the TS on 7/29/2024 at 3:50 pm and 7/30/2024 at 8:09 am confirmed the above findings. 4. The laboratory reports performing 1069 tests annually on the Cepheid and 720 immunohematology tests annually.</p>