

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2145485	(X3) Date Survey Completed 04/10/2024
Name of Provider or Supplier Wind River Cares-Riverton	Street Address, City, State 511 N 12th E, Riverton, WY	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's individualized quality control plans (IQCP), staff interview, and review of the manufacturer's instructions for use, the laboratory failed to ensure the IQCP met the regulatory requirements for 2 of 2 IQCPs reviewed (Group A Streptococcus antigen, Troponin I). The findings were: 1. Review of the Group A Streptococcus antigen IQCP, last approved by the laboratory director (LD) on 4/6/22, showed the following concerns: a. The IQCP failed to include a quality control plan which included the minimum manufacturer's instruction requirements for external quality control. b. There was no documentation the laboratory had evaluated the IQCP plan for effectiveness since it was adopted on 9/21/21. 2. Review of the Troponin I IQCP, approved by the LD on 4/6/22, showed the following concerns: a. The IQCP failed to include a quality control plan which included the minimum manufacturer's instruction requirements for external quality control. b. There was no documentation the laboratory had evaluated the IQCP plan for effectiveness since it was adopted on 4/6/22. 3. Interview with the technical consultant on 4/11/24 at 1:38 PM confirmed the IQCP had not been reviewed since its inception and failed to include a quality control plan.</p>