

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2077631	(X3) Date Survey Completed 11/28/2022
Name of Provider or Supplier Rocky Mountain Infectious Diseases	Street Address, City, State 1450 East A Street, Casper, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel records, policy and procedure review, and staff interview, the laboratory failed to ensure a competency assessment had been completed for the technical consultant (TC) for 2 of 2 years (2021, 2022) reviewed. The findings were: 1. Review of the TC's personnel record showed no evidence a competency assessment had been completed in 2021 or 2022. 2. Review of the laboratory's Quality Assessment Policy under "6.0 Personnel, Training and Competency", effective 8/1/14, failed to include a procedure for assessing the competency of the TC. 3. Interview with the TC on 11/28/22 at 1:41 PM confirmed the competency assessments had not been completed.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, review of the UNICO Power Spin Centrifuge</p>

operator's manual, review of the laboratory's policy, and staff interview, the laboratory failed to follow the manufacturer's instructions and the laboratory's policy to perform function checks on the UNICO centrifuge. The findings were: 1. Review of the laboratory's documentation showed no evidence the revolutions per minute (RPM) or the timer was checked as directed. 2. Review of the Miscellaneous Equipment policy under "1. General Purpose Centrifuges" showed i. "RPM-RPMs will be checked with a tachometer annually and after repairs...ii. Timer - If the centrifuge is equipped with a timer, it will be checked at least annually against a standard time source..." 3. Review of the UNICO Power Spin Centrifuge operator's manual showed "It is recommended that your centrifuge's RPM be calibrated at least every 6 months." 4. Interview with the laboratory manager on 11/28/22 at 2:48 PM confirmed the function checks had not been performed as required.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on lack of documentation and staff interview, the laboratory failed to verify the statistical parameters of quality control material prior to use for 1 of 2 test systems (hematology) reviewed. The findings were: 1. There was no documentation the laboratory had verified new lot numbers of quality control material prior to being used on the hematology analyzer. 2. Interview with the laboratory manager on 11/28/22 at 2:50 PM confirmed the statistical parameters of the quality control materials had not been verified.