

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  53D2195828	<b>(X3) Date Survey Completed</b>  12/18/2025
<b>Name of Provider or Supplier</b>  Laramie Peak Rural Health Clinic	<b>Street Address, City, State</b>  1356 Shiek Street, Wheatland, WY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 personnel files, lack of documentation, review of policy and procedure, and staff interview, the laboratory director failed to complete an annual competency assessment for 2 of 3 testing personnel (TP #1, TP #2) reviewed. The findings were: 1. Review of the personnel file for TP #1 showed the last annual competency assessment was completed on 1/25/24. 2. Review of the personnel file for TP #2 showed the last annual competency assessment was completed on 1/25/24. 3. Interview with laboratory director on 12/18/25 at 12 PM confirmed no further documentation could be located. 4. Review of the "Training and Competency Monitoring of Laboratory Personnel", effective 2/2024, showed "1...d. Annual (Yearly) Assessment i. Annual assessment may be more or less than 12 months, depending on the month in which assessment is completed. ii. Annual competency must be completed for every test system an employee performs and must include all six elements of competency assessment for each test system..."</p>
<b>D5455</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(v)(g)</p> <p>(d)(3)(v) 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 molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative</p>

results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of patient testing records, review of quality control (QC) records, review of the laboratory's individualized quality control plan (IQCP), policy and procedure review, staff interview, and review of the manufacturer's instructions, the laboratory failed to ensure QC was performed weekly for the MedTox urine drug screen test system. This failure affected 3 of 12 patient tests performed between 12/19/24 and 11/24/25. The findings were: 1. Review of the "Orders Report by Provider" document, provided by the laboratory, showed a MedTox urine drug screen was performed on patient #082144500 and #102959682 on 6/19/25 with QC being performed on 6/2/25 and not again until 6/23/25. A urine drug screen was performed on patient #105549823 on 11/24/25 with the last documented QC being performed on 9/22/25. 2. Interview with the laboratory director (LD) on 12/18/25 at 12:17 PM revealed it was her expectation for staff to perform QC on a weekly basis. 3. Review of the MedTox drugs of abuse test system package insert showed external controls should be run routinely or as needed for any of the following reasons: "(1) to practice the test with a known control, (2) when you open a new lot of devices, (3) once a week, (4) if you suspect that the reader or test device is not working properly, (5) if you have had a repeated unexpected test result, or (6) if you suspect that the test devices have been stored improperly." 4. Review of the laboratory's IQCP, last approved by the LD on 12/1/25, showed "... IMPORTANT: The manufacturer's stated number and frequency for internal and external controls is the MINIMUM requirement...In the clinic locations where patient testing is performed less frequently than weekly, it is acceptable to perform QC testing on day of use based on the following: 1. Proficiency testing has been successful 2. QC performs as expected even when tested less than once each week 3. No harm to patients by performing QC testing only on day of patient testing rather than each week." 5. Review of the "Urine Drug Testing (Medical) 2200-1210" policy, last reviewed 3/5/24, showed "CONTROL PROCEDURE...You should run external controls routinely or as needed for any of the following reasons...3. Once per week in locations performing patient testing more often than weekly or on day of patient testing in locations performing testing less frequently than weekly."