

|  |  |   |
|--|--|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>35D2100388     | <b>(X3) Date Survey Completed</b><br><br>03/25/2025 |
| <b>Name of Provider or Supplier</b><br><br>Coal Country Community Health Center  | <b>Street Address, City, State</b><br><br>220 4th Ave Sw Suite C, Killdeer, ND |   |
| 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>D5449</b>              | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review, policy review, and staff interview, the laboratory failed to perform a positive and negative control each day of patient testing for urine drug screens on the MedTox Scan analyzer for 2 of 3 patient testing days (02/04 and 02/18) in February 2025. The laboratory performed four urine drug screen patient tests on days with no quality control (QC) performance in February 2025. Findings include: 1. Reviewed on 03/25/25, the patient testing records for urine drug screens on the MedTox Scan analyzer indicated performance of patient testing on the following days in February 2025: 02/04, 02/18, and 02/24. 2. Reviewed on 03/25/25, the February 2025 QC records for urine drug screens failed to include evidence of the performance of positive and negative controls on the following patient testing days: 02/04 and 02/18. 3. Reviewed on 03/25/25, the policy "Quality Control Policy," dated 02/2020, stated, ". . . 4. Miscellaneous Tests . . . A positive and negative test will be done each day of testing for the following tests: . . . MedTox Drug Screens . . ." 4. During interview at 1:25 p.m. on 03/25/25, a technical consultant (#1) confirmed the laboratory failed to perform QC each day of patient testing for urine drug screens on the MedTox Scan analyzer in February 2025.</p> |