

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0409886	(X3) Date Survey Completed 01/11/2023
Name of Provider or Supplier Colstrip Medical Center	Street Address, City, State 6230 Main Street, Colstrip, MT	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, product inserts, instrument manuals and interview with the Laboratory Director (LD) #1, the laboratory failed to follow manufacturer's instructions for the intended use of UniStrip 1 Generic Blood Glucose Test Strips analyzed on the OneTouch Ultra meter from January 1, 2021 to January 11, 2023 and for testing quality control (QC) material on the Siemens DCA Vantage from May 1, 2022 to January 11, 2023. Findings: 1. A review of American Proficiency Institute revealed the laboratory had unsuccessful whole blood glucose (waived) proficiency testing results for 2022 Events 2 and 3, due to not following manufacturer's instructions to enter the correct calibration code. 2. A review of UniStrip 1 Generic Blood Glucose Test Strips product insert revealed the laboratory failed to follow manufacturer's intended use as stated, "This device is not intended for use in healthcare or assisted use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in theses settings" from January 1, 2021 to January 11, 2023. 3. A review of hemoglobin A1C quality control records revealed the laboratory failed to perform normal and abnormal QC with the control card as recommended by the DCA Vantage Operator's Guide, DCA Hemoglobin A1c Control product insert and the DCA Systems HbA1c reagent cartridges product insert from May 1, 2022 to January 11, 2023. 4. Interview with LD #1 on January 11, 2023 at 1:00 PM, confirmed laboratory staff failed to follow manufacturer's instructions for running QC on the DCA Advantage from May 1, 2022 to January 11, 2023 and removed the UniStrip 1 Generic Blood Glucose Test Strips and the OneTouch Ultra meter for glucose testing on January 11, 2023.</p>

D2009**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(1)

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on a review of American Proficiency Institute (API) records and an interview with the laboratory director (LD) #1, the laboratory testing personnel (TP) failed to review, sign, and date the Proficiency Testing Attestation Statement forms for four out of 12 events in 2022. Findings: 1. A review of API's Proficiency Testing Attestation Statement lacked the signatures of the testing person(s) performing the test for the following proficiencies: a) 2022 Chemistry Core - 2nd Event b) 2022 Chemistry-Miscellaneous - 2nd Event c) 2022 Hematology/Coagulation - 3rd Event d) 2022 Chemistry Core - 3rd Event 2. Review of Standard Operating Procedures revealed that four out of four TP failed to follow their procedures as stated, "The Laboratory Director and all testing personnel will sign the attestation statement for each testing event they participate in". 3. An interview with LD #1 on January 11, 2023 at 12:30 PM confirmed four out of four TP failed to follow their procedures to sign and date API's Proficiency Testing Attestation Statement forms for four out of 12 events in 2022.