

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2160566	(X3) Date Survey Completed 03/21/2024
Name of Provider or Supplier Vernal Urgent Care	Street Address, City, State 872 W Highway 40, Vernal, UT	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant (TC), the laboratory failed to perform proficiency testing (PT) using the laboratory's routine methods by not having all testing personnel (TP) perform PT. The laboratory performed approximately 500 hematology tests a year. Findings include: 1. Review of CMS-209 Laboratory Personnel Form showed the laboratory had 14 TP that performed hematology testing. 2. PT record review revealed that TC #1 performed PT for three out of three AAFP Hematology PT events in 2022, three out of three WSLH Hematology PT events in 2023, and one out of one WSLH Hematology PT events in 2024. 3. In an interview on 03/21/2024 at 11:55 AM, the TC confirmed that not all hematology TP performed PT.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)</p>

The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of the complete blood count procedure (CBC) manual and an interview with the technical consultant (TC), the laboratory failed to include reportable range for test results for the test system as established or verified, reference intervals, imminently life-threatening test results, or panic or alert values, and a description of the course of action to take if a test system becomes inoperable in their procedure manual. The laboratory performs approximately 500 hematology test a year. Findings include: 1. Review of the CBC procedure manual revealed a lack of reportable range for test results for the test system as established or verified. 2. Review of the CBC procedure manual revealed a lack of reference intervals. 3. Review of the CBC procedure manual revealed a lack of imminently life-threatening test results, or panic or alert values. 4. Review of the procedure manual revealed a lack of and a description of the course of action to take if a test system becomes inoperable. 5. Interview with the TC on 03/21/2024 at 11:40 AM confirmed the laboratory failed to include reportable range for test results for the test system as established or verified, reference intervals, imminently life-threatening test results, or panic or alert values, and a description of the course of action to take if a test system becomes inoperable in their CBC procedure manual.