

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D2180383	<b>(X3) Date Survey Completed</b> 06/12/2023
<b>Name of Provider or Supplier</b> Canyon View Medical Group Mapleton	<b>Street Address, City, State</b> 1429 South 1600 W, Mapleton, UT	
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>D2007</b>	<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 a review of the attestation statements for the American Academy of Family Physicians (AAFP) Proficiency Testing (PT) and for the Wisconsin State Laboratory of Hygiene (WSLH) PT, and an interview with the Laboratory Supervisor, the laboratory failed to have PT samples for the Complete Blood Count (CBC) tested by personnel who routinely perform the testing in the laboratory for 7 of 7 events reviewed. Finding include: 1. A review of the PT attestation statements at approximately 11:10 AM on 6/12/23, revealed that Testing Personnel (TP) 1, had performed all PT testing for the following events: AAFP-PT 2021-A, AAFP-PT 2021-B, AAFP-PT 2021-C, AAFP-PT 2022-A, AAFP-PT 2022-B, AAFP-PT 2022-C, and WSLH PT 2023-HemeReg1. 2. TP2 - TP11 as listed on the CMS-209, Laboratory Personnel Report, had not participated in any of the PT events as listing in Finding #1. 3. An interview with the Laboratory Supervisor at approximately 11:15 AM on 6/12/23, confirmed that only TP1 had performed PT testing and that other personnel who routinely perform CBC testing had not participated in any of the PT events listed in Finding #1.</p>
<b>D5403</b>	<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</p>

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) 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 laboratory's Standard Operating Procedures (SOP) and an interview with the Laboratory Supervisor, it was determined that the laboratory failed to include the reference intervals (normal values) for the Complete Blood Count (CBC) testing in the SOP manual. Findings include: 1. The following policies from the laboratory SOP manual, concerning CBC testing on the Sysmex Hematology Analyzer, were reviewed at approximately 11:25 AM on 6/12/23: Quality Control Hematology, Sysmex, Sysmex CBC Control Acceptance, and Critical Value Procedure. 2. A review of the laboratory policies listed in Finding #1 revealed that the laboratory had failed to include the reference intervals for the CBC testing performed on the Sysmex Hematology Analyzer. 3. An interview with the Laboratory Supervisor at approximately 11:30 AM on 6/12/23, confirmed that the laboratory had failed to include the reference intervals for the CBC testing performed on the Sysmex Hematology Analyzer in the laboratory SOP manual.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based upon a review of Complete Blood Count (CBC) test reports and an interview with the Laboratory Supervisor, the laboratory failed to include the address of the laboratory location where the test was performed on the test report. The laboratory performs approximately 1044 CBC's annually. Findings include: 1. A review of CBC test reports at approximately 11:45 AM on 6/12/23 revealed that the laboratory had failed to include the address of the laboratory location where the test was performed on the test reports for 3 of 3 reports reviewed. 2. An interview with the Laboratory Supervisor at approximately 11:50 AM on 6/12/23, confirmed that had failed to

include the address of the laboratory location where the test was performed on the test reports.