Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2180383	03/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Canyon View Medical Group Mapleton	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on Standard Operating Procedure (SOP) manual review, lack of documentation, and interview with laboratory supervisor, the laboratory failed to provide specific instructions for reporting hematology patient results, or actions to take if a the Sysmex instrument system becomes inoperable. Findings include: 1. SOP manual review included a manufacturer's operator manual signed by the laboratory director and laboratory supervisor is in place of a laboratory developed SOP for operating the Sysmex hematology analyzer. 2. Manufacturer's operator manual does not provide laboratory specific instructions for reporting patient results, or actions to take if the Sysmex hematology analyzer becomes inoperable. 3. In an interview conducted on 3/9 /2021 at approximately 11:30 am the laboratory supervisor confirmed there is no laboratory specific SOP for the Sysmex instrument other than the manufacturer's operator manual.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on temperature and humidity log review, lack of a Standard Operating Procedure (SOP), and interview with laboratory supervisor, the laboratory failed to establish criteria for monitoring and documenting temperature and humidity readings as required for 1 of 1 tests performed. The laboratory performed approximately 5 complete blood counts per day. Findings include: 1. Laboratory procedure manual (SOP) review failed to include instruction for monitoring and documenting temperature and humidity, and the corrective actions to take when temperature and humidity are out of range. 2. Temperature log review included an acceptable range for room temperature listed in degrees Celsius, but temperature is recorded in degrees Farenheit. 3. Humidity log review included an acceptable range of 20-85%. 4. Humidity records included 18 of 21 days of recorded humidity in January and February of 2021 to be 16% humidity. No corrective actions are noted. 5. Temperature log review failed to include an acceptable temperature range for the freezer. 5. Temperature log review failed to include recorded temperatures for Fridge 2. 6. In an interview with the laboratory supervisor on 3/9/2021 at approximately 11: 30 am, the laboratory supervisor confirmed that there is no SOP for temperature or humidity monitoring or corrective actions, temperatures and humidity are not properly recorded or monitored, and that Fridge 2 has been taken out of service.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on personnel training and competency review and interview with the laboratory supervisor, the technical consultant failed to evaluate and document the performance of all testing personnel at least annually. Findings include: 1. Training and competency review failed to include annual competency review for 1 of 7 testing personnel in 2020. 2. In an interview on 3/9/2021 at approximately 1:00 pm, the laboratory supervisor confirmed that competency review of testing personnel 1 was not evaluated in 2020.