Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0725757	11/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Canyon View Medical Group Springville	5 E 400 N, Springville, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation and interview with staff, the director failed to sign as attesting to the laboratory's declaration proficiency tests samples were performed in the same manner as patient samples for 4 of 6 American Academy of Family Physicians (AAFP) hematology proficnecy testing events reviewed. Findings include: 1. Proficiency testing records reviewed lacked the director's signature as attesting proficiency samples were tested the same number of times and in the same manner as patient samples for AAFP hematology events B and C of 2019 and 2020. 2. In an interivew with staff, the laboratory manager confirmed the director had not attested via signature and date that he declared the lab performed proficnecy testing in the same manner as patients were tested.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

	and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on competency evaluations review, lack of documentation, and interview with staff, the laboratory failed to establish and follow written policies and procedures to assess employee competency evaluations from the initial competency evaluation prior to reporting patient test results through the semi-annual competency evaluation the first year of testing and annually every year thereafter unless a new test is introduced for 7 of 7 testing personnel's complete blood cell count competency evaluations reviewed over 2 years of testing reviewed (November 2018 to November 2020). The laboratory performed approximately 15 to 20 complete blood cell counts per week. Findings include: 1. Competency evaluations review failed to include a competency evaluation for the laboratory manager. Testing person C lacked competency evaluations for 2018 and 2019. Testing persons D-F lacked documentation the technical consultant directly observed testing personnel prepare, process, and test specimens, monitor the recording and reporting of test results, review intermediate test results or worksheets, quality control record and/or proficiency testing results, and preventive maintenance records; direct observation of performance of instrument maintenance and function checks; and assess the performance through testing previously analyzed specimens, internal blind testing of samples or external proficiency testing samples. 2. In an interview conducted on 11/19/2020 at approximately 3:50 P.M. staff confirmed the technical consultant did not directly observe each testing person perform each of the required tasks for each competency evaluation. Staff confirmed competency evaluations were based on written quizzes to confirm complete blood cell counting competency.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on quality control records review, lack of corrective action documentation, and interview with staff, the laboratory failed to take corrective actions for 1 of 1 day when 2 of 3 complete blood count (CBC) controls failed to meet the laboratory's established criteria for acceptability. The laboratory performed from 3 to 5 CBC tests per day. Findings include: 1. Quality Control records review for testing performed on 02/24/2020 failed to include corrective actions taken for out of range normal control for White Blood Cell counts of 3.73 for lot number 079100 (Assay value was 4.09 with an acceptable range of +/- 0.2) and 17.2 White blood cell count for the high control 079300 (Assay value 18.5 +/- 1.1). 2. In an interview conducted on 11/19 /2020 the laboratory manager confirmed the laboratory failed to document corrective

	actions taken when 2 levels of controls failed to meet the laboratory's criteria for acceptability and no corrective actions were taken prior to reporting patient test results.