Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0519614	02/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Grand River Medical Center	501 Airport Rd, Rifle, CO	

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
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 review of the quality assessment (QA) plan, personnel competency assessment records and staff interview, the laboratory failed in 2019 to follow their written policy to assess competency of all testing personnel who performed patient testing in the specialty of Hematology and Immunohematology after a change in instrumentation occurred. Findings include: a. The QA plan states that all lab staff will be assessed initially, at 6 months after hire, at 12 months and then annually thereafter. b. No documentation existed to show 10 of 10 established testing personnel were assessed in 2019 prior to changes in instrumentation in the specialties of Hematology in December 2019 and in the specialty of Immunohematology in April 2019. c. The laboratory director and laboratory manager confirmed that competency assessements were not performed on testing personnel prior to reporting patient test results in the specialty of Hematology and Immunohematology after implementation of new testing instrumentation.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) plan, personnel competency assessment records and staff interview, the laboratory failed to follow the establish QA plan and monitor that competency assessment was performed on 10 of 10 testing personnel who perform testing in the specialty of Hematology and Immunohematology prior to reporting patient test result after implementation of new instrumentation in 2019. Findings include: a. The QA plan states that all laboratory staff will be assessed initially, at 6 months after hire, at 12 months and then annually thereafter. b. No documentation existed to show 10 of 10 testing personnel were assessed in 2019 in the specialties of Hematology and Immunohematology. c. The general supervisor stated that personnel competency assessments of testing personnel were not completed prior to reporting patient test results. d. The laboratory director and general supervisor confirmed the laboratory failed to follow their QA plan and did not perform competency assessments on testing personnel prior to reporting patient test results in the specialties of Hematology and Immunohematology after implementation of new instrumentation in 2019.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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) 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 review of the procedure manual and staff interview, the laboratory failed to have complete written procedures in place that contain all required elements for testing personnel to follow for the DxH Hematology analyzers placed into service in December 2019 and for the Ortho Clinical Diagnostics placed into service in April 2019. Findings include: a. The laboratory uses the manufacturer manual for the DxH 900 CBC analyzers and the manufacturer manual for the Ortho Clinical Diagnostics analyzer to perform antibody screens. b. The manuals fail to include requirements for specimen labeling, criteria for specimen acceptability and rejection, the description of the course of action to take if the test system becomes inoperable, Quality Control procedures, instructions for reporting patient test results and pertinent literature references. c. A total of 1030 CBC samples were tested from 12.4.2019 through 1.8.2020. d. A total of 235 antibody screens were performed between 4.1.2019 and

	1.8.2020. e. The lab director and general supervisor confirmed that the current procedures for the DxH Hematology analyzers and the Ortho Clinical Diagnostics antibody screening instrument did not contain all applicable procedureal elements.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of standard operating procedures and staff interview, the laboratory director failed to ensure that procedures and changes in procedures for the DxH 900 Hematology analyzer and the Ortho Clinical Diagnostics antibody screen instrument were approved and signed prior to use by the testing personnel.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratories Quality Assurance (QA) plan, QA records, procedure manuals, personnel competency assessment documentation and lab director interview, the laboratory director failed to provide the overall management of the laboratory where QA policies were not followed (Ref: D6094), personnel competency was not performed prior to reporting patient test results (Ref: D6102) and procedures were not established and made available to all testing personnel in the specialties of Hematology and Immunohematology (Ref: D6106).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory Quality Assurance (QA) plan, competency assessment records, and interview, the laboratory director failed to ensure adequate QA monitoring and reiview of established procedures was performed in 2019 where 10 of 10 testing personnel did not have competency assessment performed in the specialties of Hematology and Immunohematolgy and failed to ensure that written procedures were available to testing personnel prior to reporting patient test results. Reference D5209, D5291, D5403 and D5407.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)

	The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel competency records and lab director interview, the lab director failed to ensure that 10 of 10 testing personnel had a competency assessment performed after changes to instrumentation occurred in the specialties of Hematology and Immunohematology in 2019. Reference D5209.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the procedure manual and lab director interview, the laboratory director failed to ensure that procedures were established, approved and available to all testing personnel in the specialties of Hematology and Immunohematology after changes in instrumentation occurred in 2019. Reference D5403 and D5407.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on review of the laboratories Quality Assurance (QA) plan, personnel competency records and general supervisor interview, the general supervisor failed to perform competency assessments on 10 of 10 testing personnel prior to performing patient testing in the specialties of Hematology and Immunohematology after implementation of new instrumentation in 2019. Findings Include: a. The laboratory placed into service two new DxH 900 Hematology analyzers into service on 12.4.2019. b. A total of 1030 patient samples were tested between 12.4.2019 and 1.8.2020. c. The laboratory placed a new Ortho Clinical Diagnostics analyzer used for performing antibody screens in April 2019. d. A total of 235 patients were screened between 4.1.2019 and 1.8.2020. e. No documentation existed that the testing personnel received training and competency assessment prior to reporting patient results for either the new Hematology or Immunohematology analyzers. f. The lab director and general supervisor confirmed that competency assessments were not performed as specified in the QA plan prior to implementation of the new instrumentation in the specialties of Hematology and Immunohematology prior to reporting patient test results.