Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0519614	12/28/2023
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and email communications with the laboratory director, the laboratory failed to achieve satisfactory performance scores for the College of American Pathologists (CAP) PT for Toxicology for two out of three PT events, (event 2 in 2023 and event 3 in 2023), Gentamicin for two out of three PT events, (event 2 in 2023 and event 3 in 2023), and Phenytoin for two out of three PT events, (event 2 in 2023 and event 3 in 2023). See D2110.
D2110	TOXICOLOGY

	CFR(s): 493.845(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT), College of American Pathologists (CAP) reports, and email communication with the laboratory director, the laboratory failed to achieve a satisfactory score for Toxicology for event 2 in 2023 and event 3 in 2023, Gentamicin for event 2 in 2023 and event 3 in 2023 and failed to achieve a satisfactory score for Phenytoin for event 2 in 2023 and event 3 in 2023. Findings: 1. A review of the CMS-155 Individual Laboratory Profile on 12/27/2023, at 10:20 AM, revealed the CAP PT results for Toxicology testing scores for event 2 in 2023 was 57%, and 57% for event 3 in 2023. 2. A review of the CMS-155 Individual Laboratory Profile on 12/27/2023, at 10:20 AM, revealed the CAP PT results for Gentamicin testing scores for event 2 in 2023 was 0%, and 0% for event 3 in 2023. 3. A review of the CMS-155 Individual Laboratory Profile on 12/27 /2023, at 10:20 AM, revealed the CAP PT results for Phenytoin testing scores for event 2 in 2023 was 0%, and 0% for event 3 in 2023. 4. An email with the laboratory's director on 12/27/2023, at 03:35 PM, confirmed the laboratory failed to achieve satisfactory test performance for Toxicology, Gentamicin, and Phenytoin.