Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2077631	12/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Rocky Mountain Infectious Diseases	1450 East A Street, Casper, WY	

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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance (QA) documentation, staff interview, and policy and procedure review, the laboratory failed to implement their quality assurance plan for 8 of 8 quarters reviewed from October 2022 through October 2024. The findings were: 1. Review of the Quality Assurance Plan showed "Data review and internal (chart) audits The main elements of laboratory operations shall be subject to review by the laboratory director or technical consultant once every twelve months. Internal chart audits of all elements of the laboratory, both managerial and technical, shall be conducted on a quarterly basis by the lab director or the technical consultant. On a quarterly basis, the lab director will review a minimum of five (5) patient charts for accuracy and consistency of test results with clinical status. Any discrepant results will be investigated and reported on the Laboratory Corrective Action Form. The results of internal audits shall be kept in the binder that contains Corrective action forms." The section titled Quality Assurance Review showed "All QA activities must be reviewed with the staff. This could take on a monthly meeting with lab supervisor and semiannual meeting with lab director. The staff should be involved in QA review, suggesting corrective actions to minimize future errors. Minutes of the meetings as well as an attendance roster must be available." The section titled Quality Assurance Records showed "As with all of CLIA, documentation is the key. QA records as well as the policy manual should be available to the staff and reviewed and signed by the laboratory director." The

	following concerns were identified: a. Review of 8 sets of 5 patient test records, provided by the laboratory, from October 2022 through December 2022; January 2023 through March 2023; April 2023 through June 2023; July 2023 through September 2023; October 2023 through December 2023; January 2024 through March 2024; April 2024 through June 2024; July 2024 through September 2024 showed no evidence the data had been reviewed. In addition, the documentation showed the patient testing records had been printed in October of 2024. b. Review of the Corrective Action binder showed a 9/27/24 corrective action form related to failing to record the temperatures in the laboratory. There was no evidence the reviews outlined by the Quality Assurance Plan had been completed. c. Interview with testing personnel #1 on 12/3/24 at 11:26 AM confirmed no further documentation was available.