Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0962844	08/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Rexburg Community Care	404 N 2nd St E, Rexburg, ID	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a record review of the Reichert Unistat instrument verification and an interview with the technical consultant (TC) on 8/18/2023, the laboratory failed to verify the manufacturer's instrument performance specifications before beginning patient testing. The findings include: 1. A record review of the new instrument verification for the Reichert Unistat, used for bilirubin testing, identified that the laboratory failed to verify instrument performance specifications for reportable range and normal values for their patient population before beginning patient testing on 4/11/2022. 2. An interview with the TC on 8/18/2023 at 11:20 am confirmed that the laboratory failed to verify instrument performance specifications before beginning patient testing. 3. The laboratory reports performing 730 bilirubin tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on a review of Sysmex XP300 maintenance logs and an interview with the technical consultant (TC) on 8/18/2023, the laboratory failed to perform and document maintenance with the frequency defined by the manufacturer. The findings include: 1. A review of Sysmex XP300 maintenance logs from 2022 and 2023 identified the laboratory failed to perform and document quarterly maintenance three of four quarters in 2022 and two of two quarters in 2023. 2. An interview with the TC on 8/18/2023 at 9:56 am confirmed the above finding. 3. The laboratory reports performing 26,280 patient tests on the Sysmex XP300 annually.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a record review of the Reichert Unistat instrument verification and an interview with the technical consultant (TC) on 8/18/2023, the laboratory director failed to ensure that the instrument verifications were adequate before patient testing began. The findings include: 1. A record review of the new instrument verification for the Reichert Unistat, used for bilirubin testing, identified that the laboratory director failed to review and approve the verification results for accuracy and precision to ensure that they were adequate before beginning patient testing on 4/11/2022. 2. An interview with the TC on 8/18/2023 at 11:20 am confirmed that the laboratory director failed to review and approve instrument performance specifications before patient testing began. 3. The laboratory reports performing 730 bilirubin tests annually.