Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0454765	02/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Crete Area Medical Center Friend Medical Clinic	1210 2nd Street, Friend, NE	

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 review of the demonstration of performance specifications and an interview with the laboratory director at 9:35 AM on 2/27/2018, the laboratory failed to demonstrate the reportable range for a new hematology instrument. Findings are: 1. Review of the validation of performance specifications for a new instrument used for complete blood counts (CBC's) (patient testing started on 12/15/2017), revealed no checks for reportable ranges had been included in the instrument validation. 2. Interview with the laboratory director confirmed a linearity or reportable range study had not been performed prior to patient testing.