Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0455760	04/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Grand Island Clinic Inc	2444 W Faidley Ave, Grand Island, 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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of centrifuge tachometer checks, manufacturer's instructions, validation procedures and interview with the general supervisor at 11:50 AM on 4/18 /2018 the laboratory failed to validate performance characteristics for the urine centrifuge used for the preparation of urine sediment. Findings are: 1. Review of the tachometer checks for the centrifuge used for the preparation of urine sediment revealed a tachometer reading of 9808 revolutions per minute (RPM) on 2/1/2018. With the 4 centimeter radius of this centrifuge this results in a relative centrifugal force (RCF) of 4302. 2. Review of the manufacturer's instructions indicated this high speed centrifugation for 45 seconds with no textbook references or references by the manufacturer that urinary casts could be detected by this method. 3. Review of the 12 patient samples used by the laboratory to validate this method did not include urinary casts in any of the 12 samples tested. 4. Interview with the general supervisor confirmed the laboratory did not include samples with possible casts and had not observed any casts present in samples since this centrifuge with increased speed had been put in use in July of 2017.