Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D2175691	10/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Grand Island Regional Medical Center	3533 Prairieview St, 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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control logs and an interview with the technical supervisor the laboratory failed to perform controls each day of testing for the Amnisure testing system for the detection of placental alpha microglobulin-1 (PAMG-1). Findings are: 1. Review of quality control logs for Amnisure testing revealed quality control testing was performed monthly and with every new shipment/new lot. 2. Interview with the technical supervisor on 9/30/2021 at 4:00 PM confirmed controls were run monthly and with every new shipment/new lot. Technical supervisor confirmed 24 patients were tested for PAMG-1 since testing started in July 2021. 3. Interview with the technical supervisor on 9/30/2021 at 4:00 PM confirmed the laboratory had not implemented an individual quality control plan for the Amnisure test.