Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 28D2175691	**(X3) Date Survey Completed** 06/14/2023
Name of Provider or Supplier Grand Island Regional Medical Center	**Street Address, City, State** 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**
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory's list of tests performed, 2022 proficiency testing records, 2023 proficiency testing records, interview with the technical consultant (TC) #1, and technical consultant (TC) #2, the laboratory failed to enroll in an approved proficiency testing program for immunoglobulin IgA, immunoglobulin IgG, and immunoglobulin IgM. Findings are: 1. Review of the laboratory's list of tests revealed the laboratory performs testing for immunoglobulin IgA, immunoglobulin IgG, and immunoglobulin IgM. 2. Review of the laboratory's 2022 proficiency testing and 2023 proficiency testing revealed the laboratory failed to enroll in an approved program for immunoglobulin IgA, immunoglobulin IgG, and immunoglobulin IgM. 3. Interview with TC #1 and TC #2 on June 14, 2023 at 3:02 PM confirmed the laboratory did not enroll in an approved program for for immunoglobulin IgA, immunoglobulin IgG, and immunoglobulin IgM. 4. Interview with TC #1 and TC #2 on June 14, 2023 at 3:02 PM revealed the laboratory performed 211 immunoglobulin IgA tests, 246 immunoglobulin IgG tests, and 214 immunoglobulin IgM tests .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's list of tests performed, interview with the technical consultant (TC) #1, and technical consultant (TC) #2, the laboratory failed to have a system of verifying the accuracy of testing for the following tests: hemoglobin A1c, haptoglobin, urine sodium, urine chloride, and urine potassium. Findings are: 1. Review of the laboratory's list of tests performed revealed the laboratory performs testing for hemoglobin A1c, haptoglobin, urine sodium, urine chloride, and urine potassium. 2. Interview with TC #1 and TC #2 on June 14, 2023 at 3:02 PM confirmed the laboratory reported 2918 hemoglobin A1c tests, 118 haptoglobin tests, 216 urine sodium tests, nine urine chloride tests, and ten urine chloride tests. 3. Interview with TC #1 and TC #2 on June 14, 2023 at 3:02 PM confirmed the laboratory did not perform accuracy verification at least twice annually for hemoglobin A1c, haptoglobin, urine sodium, urine chloride, and urine potassium.