Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2184312	07/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Grand River Medical Group West	4025 Westmark Dr Ste 100, Dubuque, IA	

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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the Alfa Wasserman ACE Alkaline Phosphatase (ALP) reagent package insert, the manufacturer's quality control (QC) package inserts, the laboratory QC records, the Quality Control Program procedure, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1: 30 pm on 7/31/2023, the laboratory failed to verify the criteria for acceptable control ranges as specified in D5469 and failed to document corrective action when QC fell outside the manufacturer's established ranges as specified in D5783.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must

	document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Alfa Wasserman ACE Alkaline Phosphatase (ALP) reagent package insert, the manufacturer's quality control (QC) package inserts, and the laboratory's QC ranges and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 7/31/2023, the laboratory failed to verify the criteria for the acceptable control ranges for the analytes: ALP, aspartate transferance (AST), alanine transaminase (ALT), glucose, and total bilirubin for Level 1 and/or Level 2 of quality controls used from 6/1/2023 - 6/30/2023. The findings include: 1. The Alfa Wasserman ALP reagent package insert states, "The mean values and expected ranges printed on the control package inserts are derived from interlaboratory data. The expected range includes instrument, reagent and environmental variations. This laboratory's mean of several determinations may not duplicate the mean value printed on the insert, but should fall within the expected range. Each laboratory should establish its own mean and precision parameters." 2. For level 1 chemistry control (1501UNCM, expiration date 2024-11-28), the manufacturer stated the following as 3 SD expected ranges: *ALP 53 - 79 *ALT 43 - 64 *AST 39 - 59 *Total bilirubin 1.2 - 2.0 *Glucose 83 - 101 3. For level 1 chemistry control (1501UNCM, expiration date 2024-11-28), the laboratory established QC ranges outside of the manufacturer's expected ranges for the following analytes: *ALP 52.8 - 71.2 *ALT 38 - 52 *AST 37.4 - 50.60 *Total bilirubin 1.14 - 1.66 *Glucose 89.8 - 102.2 4. For level 2 chemistry control (1166UECM, expiration date 2024-11-28), the manufacturer stated the following as 3 SD expected ranges: *ALP 320 - 480 *ALT 111 - 167 5. For level 2 chemistry control (1166UECM, expiration date 2024-11-28), the laboratory established QC ranges outside of the manufacturer's expected ranges for the following analytes: *ALP 298.6 - 405.4 *ALT 105.6 - 142.4 6. Laboratory personnel identifier #1 confirmed that the laboratory's ranges fell outside the of manufacturer's established ranges.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, the Quality Control Program procedure, QC manufacturer's package insert and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 7/31/2023, the laboratory failed to document corrective action when the alkaline phospatase (ALP) QC results fell outside the manufacturer's established ranges for two out of 22 days from 6/1/2023 - 6/30/2023. The findings include: 1. The Quality Control Program procedure stated, "One level outside of 2SD. Assay repeated w/fresh aliquot of control... Patient samples are not to be performed until resolved." 2. The manufacturer's package insert for QC level 2 (lot number 1166UECM, expiration date

	2024-11-28) gave a 3SD range of 320 - 480 for the analyte, ALP. 3. On 6/5/2023 the laboratory accepted an ALP QC result for level 2 of 309. 4. On 6/6/2023 the laboratory accepted an ALP QC result for level 2 of 305. 5. The laboratory reported ALP results for 48 patients on 6/5 - 6/6/2023. 6. At the time of the survey, the laboratory did not have corrective action for the out of range ALP QC.