Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384964	07/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Greater Regional Health	1700 West Townline Street, Creston, 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
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 Vitros 7600 chemistry analyzer instructions for use (IFU), quality control (QC) records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), the laboratory failed to appropriately establish criteria for acceptability of amylase and lipase control materials for two out of two lot numbers of QC used from 07/11/2021- 07/17/2021. The findings include: 1. The laboratory uses Bio-Rad Liquid Unassayed Multiqual QC for amylase and lipase controls and during the week of 07/11/2021- 07/17/2021, the laboratory used lot 56631, expiration 2022-04-30 (level 1) and lot 56633, expiration 2022-04-30 (level 3). 3. Review of the Vitros amylase slide IFU indicated that the instrument's reportable range for amylase is 30-1200 U/L. 4. For level 1 QC (lot 56631, expiration 2022-04-30), the laboratory established the following acceptable range for amylase testing: 26.6- 36.6 U/L. 5. Review of the Vitros lipase slide IFU indicated that the instrument's reportable range for lipase is 10-2000 U/L. 6. For level 3 QC (lot 56633, expiration

	2022-04-30), personnel identifier #2 stated that during establishment of the acceptable QC range for lipase testing, the laboratory never achieved results below 2000 U/L. Because they exceeded the instrument's reportable range, the results of each run were always ">2000 U/L" and a range could not be established. 7. Personnel identifier #2 confirmed that the laboratory's established amylase and lipase QC ranges listed above for lot 56631, expiration 2022-04-30 (level 1) and lot 56633, expiration 2022-04-30 (level 3) exceeded the reportable ranges for the Vitros instrument and were not appropriately established.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of quality control records and interview with laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), the laboratory director failed to meet responsibility requirements including: ensuring testing personnel are performing test methods as required as specified in D6087; ensuring a quality control program is established and maintained as specified in D6093; ensuring a quality assessment program is established and maintained as specified in D6094; ensuring the laboratory has taken and documented corrective action for deviations from the laboratory's established performance characteristics as specified in D6096; and ensuring patient test results are reported only when test systems are functioning properly as specified in D6097.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), the laboratory director failed to ensure laboratory personnel are performing test methods as required for accurate and reliable results for seven out of seven days of patient testing from 07 /11/2021- 07/17/2021. The findings include: 1. The laboratory failed to appropriately establish criteria for acceptability of amylase and lipase control materials for two out of two lot numbers of QC used from 07/11/2021- 07/17/2021. Refer to D5469. 2. The laboratory failed to take and document corrective action when amylase and lipase QC fell outside the laboratory's established criteria for acceptability for seven out of seven days of testing from 07/11/2021- 07/17/2021. Refer to D5783.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify

	failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), the laboratory director failed to ensure that quality control programs were established and maintained to assure the quality of chemistry testing and identify failures in quality as they occur for seven out of seven days of patient testing from 07/11/2021- 07/17/2021. Refer to D5469, D5481, and D5783.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of chemistry testing and identify failures in quality as they occur for seven out of seven days of patient testing from 07/11/2021- 07/17/2021. Refer to D5469, D5481, and D5783.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), the laboratory director failed to ensure that the laboratory has taken and documented corrective action for deviations from the laboratory's established performance characteristics for seven out of seven days of patient testing from 07/11/2021- 07/17/2021. The findings include: 1. The laboratory failed to appropriately establish criteria for acceptability of amylase and lipase control materials for two out of two lot numbers of QC used from 07/11/2021- 07/17/2021. Refer to D5469. 2. The laboratory failed to take and document corrective action when amylase and lipase QC fell outside the laboratory's established criteria for acceptability for seven out of seven days of testing from 07/11 /2021- 07/17/2021. Refer to D5783.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly.

	This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), the laboratory director failed to ensure that patient test results were reported only when the Vitros 7600 test system properly functioned for seven out of seven days of patient testing from 07/11/2021- 07/17/2021. Refer to D5481.