Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384964	05/24/2023
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
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 DrugCheck Dip Drug Test records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3: 30 pm on 5/24/2023, the laboratory failed to establish the performance specifications of analytical sensitivity and analytical specificity for the DrugCheck Dip Drug Testing. The findings include: 1. Laboratory Personnel identifier #1, confirmed the laboratory used the DrugCheck Dip Drug Test for patient drug screening. 2. The DrugCheck Dip Drug Test has not been approved by the Food and Drug Administration (FDA). 3. In May 2023, the laboratory established the performance specifications of accuracy and precision. 4. The laboratory did not establish the performance specifications of analytical sensitivity and analytical specificity.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Performance Testing of Serofuge and Cell Washer procedure and blood bank logs and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 5/24/23, the laboratory failed to document the daily volume check for the blood bank cell washer for 28 out of 28 days from 2/1/2023 - 2/28/2023. The findings include: 1. The Performance Testing of Serofuge and Cell Washer procedures states, "On a daily basis, the cell washer's dispense volume must be checked. The target value for this volume is 40 mls, per manufacturer's recommendation. The results of this check are recorded on the blood bank preventive mainenace chart." 2. At the time of the survey, the laboratory did not record the daily volume check for the blood bank cell washer from 2/1/2023 - 2/28/2023.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of blood bank procedures, lack of cell washer maintenance records and confirmed by laboratory personnel identifer #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 5/24/2023, the laboratory failed to define the frequency for performing the optimum spin time function check on the cell washer. In addition, the laboratory failed to perform the optimum spin time function check on the cell washer from 1/1/2022 - 5/24/2023.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of an Individualized Quality Control Plan (IQCP), review of quality

	control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 5/24/2023, the laboratory failed to perform a positive and negative control each day of patient testing for the Rupture of the Membranes (ROM Plus) and DrugCheck Dip Drug Test for 28 out of 28 days from 2/1/2023 - 2/28/2023. The findings include: 1. For the ROM Plus and DrugCheck Dip Drug Test, the laboratory performed QC with each new lot and/or shipment of test kits. 2. Laboratory personnel identifier #1 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 3. At the time of the survey, the laboratory did not have an IQCP for the either of the test kits.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory test volume form and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1: 00 pm on 5/24/23, the laboratory failed to perform twice annual comparison testing for three out of three time periods from 1/1/2022 - 5/24/2023 for the analytes: influenza A, influenza B, SARS-CoV-2, and respiratory syncytial virus (RSV). The findings include: 1. The laboratory performed influenza A, influenza B, SARS-CoV-2, and RSV testing using both the Biofire and Cepheid test systems. 2. The laboratory did not perform comparison testing for influenza A, influenza B, SARS-CoV-2, and RSV from 1/1/2022 - 5/24/2023.