Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384964	06/30/2021
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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifiers #1 and #13 (refer to the Laboratory Personnel Report) at approximately 8:30 am on 06/30/2021, the laboratory failed to take and document corrective action for three unacceptable PT scores from two out of seven PT testing events (2019 event 2 and 2020 event 1) from 01/01/2019- 06/30/2021. The findings include: 1. For 2019 testing event 2, the laboratory received unacceptable PT test scores for the following: *2019 Core Chemistry 2nd event- methemoglobin (specimen BLX-09) and hemoglobin, blood oximetry (specimen BLX-09) 2. For 2020 testing event 1, the laboratory received unacceptable PT scores for the following: *2020 Core Chemistry 2nd event- methemoglobin (specimen BLX-05) 3. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores.
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 Vitros 7600 chemistry analyzer quality control records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 5:45 pm on 06/30/2021, the laboratory failed to meet chemistry requirements for: ensuring quality control results meet the laboratory's criteria for acceptability before reporting patient test results as specified in D5481; and taking corrective action when quality control results failed to meet the laboratory's established criteria for acceptability as specified in standard D5783.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 8: 30 am on 06/30/2021, the laboratory failed to perform a self evaluation of ungraded PT scores for three out of seven PT testing events from 01/01/2019- 06/30/2021 (2020 events 2 and 3 and 2021 event 1). The findings include: 1. For 2020 testing event 2, the laboratory received ungraded PT test scores for the following: *2020 Immunology /Immunohematology 2nd event- anti-HIV 1/2 (specimen VM-09) 2. For 2020 testing event 3, the laboratory received ungraded PT test scores for the following: *2020 Microbiology 3rd event- wound culture, anaerobic (specimen WO-02) *2020 Microbiology 3rd event- urine culture MIC value (specimen UR-11, all antibiotic results) *2020 Immunology/Immunohematology 3rd event- antibody test (specimen SER-11); DAT, polyspecific (specimen DAT-06); and anti-HIV 1/2 (specimen VM-12) *2020 Hematology and Coagulation 3rd event- blood cell identification (specimen BCL-11) 3. For 2021 testing event 1, the laboratory received ungraded PT test scores for the following: *2021 Microbiology 1st event- CSF culture MIC value (specimen SF-01, all antibiotic results) *2021 Microbiology 1st event- urine culture MIC value (specimen UR-01, all antibiotic results) 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores.
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 Test List & Annual Volume form, proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the

	Laboratory Personnel Report) at approximately 8:30 am on 06/30/2021, the laboratory failed to verify the accuracy of serum human chorionic gonadotropin (HCG) qualitative testing and fibrin degradation product (FDP) testing at least twice annually for two out of two time periods from 01/01/2020- 12/31/2020. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have additional records indicating the verification of accuracy for serum HCG qualitative and FDP testing from 01/01/2020- 12/31/2020. THIS IS A REPEAT DEFICIENCY.
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: A. Based on review of the Vitek 2 Compact maintenance records from January- May 2021 and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 5:00 pm on 06/30/2021, the laboratory failed to document weekly maintenance on the Vitek 2 Compact instrument for 14 out of 21 weeks of patient testing from 01/04/2021- 05/29/2021. The findings include: 1. According to the Vitek 2 Compact System Preventative Maintenance Checklist, the manufacturer requires the laboratory to perform and document a saline sterility check weekly. 2. The Vitek 2 Compact System Preventative Maintenance Checklist indicated that the laboratory did not document weekly maintenance during the following weeks: 01/03/21, 01/17/21, 01/31/21, 02/06/21, 02/22/21, 02/28/21, 03/21 /21, 03/28/21, 04/04/21, 04/11/21, 04/18/21, 05/02/21, 05/16/21, and 05/23/21. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory failed to document weekly maintenance on the Vitek 2 Compact instrument as required by the manufacturer for the dates listed above. B. Based on review of the Vitek 2 Compact maintenance records from January- May 2021 and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 5:00 pm on 06/30/2021, the laboratory failed to document monthly maintenance on the Vitek 2 Compact instrument for five out of five months of patient testing from January- May 2021. The findings include: 1. According to the Vitek 2 Compact System Preventative Maintenance Checklist, the manufacturer requires the laboratory perform and document the following monthly maintenance: *Clean carousel *Clean cassettes *Clean optics *Clean waste collection bin *Clean filler station *Clean load/unload station *Clean DensiCHEK Plus *Check performance verification of DensiCHEK Plus *Print monthly instrument QC 2. At the time of the survey, personnel identifier #1 confirmed that the laboratory failed to document monthly maintenance on the Vitek 2 Compact instrument as required by the manufacturer.
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 the laboratory's MTS Dispenser Quality Control log and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:20 pm on 06/30/2021, the laboratory failed to perform and document quarterly volume checks on the blood bank saline dispensers for eight out of eight quarters from 07/01/2019- 06/30/2021. The findings include: 1. The laboratory began using the MTS Ortho gel system in May 2019, including both a 0.5 mL and 1.0 mL saline dispenser. 2. Review of the MTS Dispenser Quality Control log revealed that dispenser volume checks are to be performed quarterly. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not perform and document dispenser volume checks from 07/01/2019- 06/30/2021.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 5: 45 pm on 06/30/2021, the laboratory failed to ensure that results of Vitros 7600 chemistry analyzer QC were acceptable before reporting patient test results for 15 out of 30 days of testing in April 2021. The findings include: 1. The laboratory implemented and began using two new Vitros 7600 chemistry analyzers in March 2021. 2. Review of QC records from the Vitros 7600 analyzer labeled as "Turner" indicated that the laboratory did not have at least two levels of acceptable QC prior to reporting patient test results on the following dates: 04/03/20, 04/09/21, 04/13/21, 04 /17/21, 04/18/21, 04/24/21, 04/25/21, 04/27/21, and 04/28/21. 3. Review of QC records from the Vitros 7600 analyzer labeled as "Hooch" indicated that the laboratory did not have at least two levels of acceptable QC prior to reporting patient test results on the following dates: 04/08/21, 04/10/21, 04/15/21, 04/20/21, 04/21/21, and 04/29/21. 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have additional QC records for the dates listed above.
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: A. Based on review of immunohematology records, and confirmed by laboratory

	personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2: 20 pm on 06/30/2021, the laboratory failed to perform comparison studies between the automated Ortho Vision and manual Ortho MTS gel card systems for immunohematology testing twice annually for four out of four semiannual time periods from 06/01/2019- 06/30/2021. The findings include: 1. The laboratory implemented and began using the Ortho Vision automated analyzer to perform immunohematology testing in May 2019. It also implemented and began using the manual Ortho MTS gel card system at the same time as a back-up test system. 2. Personnel identifier #1 confirmed that the laboratory did not perform and document twice annual comparisons for the Ortho Vision and Ortho MTS gel card test systems from 06/01/2019- 06/30/2021. B. Based on review of proficiency testing (PT) records, the Laboratory Test List and Annual Volume report, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 8: 30 am on 06/30/2021, the laboratory failed to perform comparison studies between serum human chorionic gonadotropin (HCG) qualitative and quantitative testing methods twice annually for four out of four semiannual time periods from 06/01 /2019- 06/30/2021. The findings include: 1. The Laboratory Test List and Annual Volume report listed serum HCG testing performed by both quantitative and qualitative methods. 2. Review of PT records indicated the laboratory performed PT testing for the quantitative HCG method, but not the qualitative HCG method. 3. At the time of the survey, the laboratory did not have additional records indicating that it had performed comparison studies between the quantitative and qualitative HCG methods twice annually from 06/01/2019- 06/30/2021.
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: A. Based on review of quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 5: 00 pm on 06/30/2021, the laboratory failed to take and document corrective action when Vitros 7600 chemistry analyzer QC fell outside the laboratory's established criteria for acceptability for 15 out of 30 days of testing in April 2021. The findings include: 1. The laboratory implemented and began using two new Vitros 7600 chemistry analyzers in March 2021. 2. Review of QC records from the Vitros 7600 analyzer labeled as "Turner" indicated that the laboratory had out of control results without corrective action on the following dates: *04/03/21: total bilirubin (level 3); and unconjugated bilirubin (level 1) *04/09/21: calcium (level 3) *04/13/21: chloride (level 1) *04/17/21: iron (level 3) *04/18/21: sodium (level 1); chloride (level 1); and alcohol (levels 1 and 3) *04/24/21: chloride (level 1); carbon dioxide (levels 1 and 3); alcohol (levels 1 and 3); and unconjugated bilirubin (level 1) *04/25/21: sodium (level 1); triglycerides (level 3); chloride (level 1); carbon dioxide (levels 1 and 3); alcohol (levels 1 and 3); and unconjugated bilirubin (level 1) *04/27/21: total bilirubin (level 3) *04/28/21: total bilirubin (level 3); triglycerides (level 3); carbon dioxide (level 3);

	alcohol (level 3); and alkaline phosphatase (level 3) 3. Review of QC records from the Vitros 7600 analyzer labeled as "Hooch" indicated that the laboratory had out of control results without corrective action on the following dates: *04/08/21: alcohol (level 1) *04/10/21: sodium (level 1); and alcohol (level 1) *04/15/21: total bilirubin (level 1) *04/20/21: total protein (level 1); and alcohol (levels 1 and 3) *04/21/21: total bilirubin (level 1); and unconjugated bilirubin (level 1) *04/29/21: total bilirubin (level 1) 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have documented corrective action for the out of control QC results listed above. B. Based on review of quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 5:00 pm on 06/30/2021, the laboratory failed to take and document corrective action when Vitek 2 Compact gram positive identification system QC fell outside the laboratory's established criteria for acceptability for one out of one lot number of gram positive identification cards (lot 2421589203, expiration 04/03/2022). The findings include: 1. The laboratory uses the following organisms to perform QC on new lots of gram positive identification cards: *Enterococcus casseliflavus 700327 *Enterococcus saccharolyticus 43076 *Kucuria kristinae BAA-752 *Listeria monocytogenes BAA-751 *Staphylococcus saprophyticus BAA- 750 *Streptococcus equi ssp. zooepidemicus 43079 *Streptococcus pneumoniae 49619 *Streptococcus thermophilus 19258 2. On 01/02/2021, the laboratory had the following out of range QC result for organism Streptococcus pneumoniae 49619: *Biochemical test code SAL, well 59= negative reaction (acceptable= positive reaction) 3. At the time of the survey, the laboratory did not have documentation of corrective action for the out of range QC. THIS IS A REPEAT DEFICIENCY.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 06/30/2021, the laboratory director failed to ensure that prior to testing patient specimens, testing personnel performing insulin-like growth factor binding protein-1 (IGFBP-1) testing received the appropriate training for five out of five new testing personnel (laboratory personnel identifiers #23- #25, #28, and #30) hired since the last survey on 04/24/2019. At the time of the survey, the laboratory did not have have training records available for personnel identifiers #23- #25, #28, and #30. THIS IS A REPEAT DEFICIENCY.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification

	requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel records, review of the Laboratory Personnel Report Form CMS-209, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 06/30/2021, the technical consultant failed to meet responsibility requirements including: ensuring testing personnel received training as specified in D6045 and performing annual competency evaluations for testing personnel as specified in D6054.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 06/30/2021, the technical consultant failed to ensure that five out of five new testing personnel received documented training prior to performing moderate complexity testing. Refer to D6029.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 06/30/2021, the technical consultant failed to assess and document the competency of individuals performing insulin-like growth factor binding protein-1 (IGFBP-1) testing at least annually for 10 out of 10 testing personnel (personnel identifiers #16- #22, #26, #27, and #29) in 2020.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by:

	Based on review of laboratory personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12: 00 pm on 06/30/2021, the laboratory failed to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform moderate complexity as specified in standard D6065. THIS IS A REPEAT DEFICIENCY.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 06/30/2021, the laboratory failed to have documentation to qualify four out of 20 testing personnel (identifiers #24, #28, #30, and #31) classified to perform moderate complexity testing. THIS IS A REPEAT DEFICIENCY.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 06/30/2021, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing high complexity testing received the appropriate training for three out of three new testing personnel (laboratory personnel identifiers #7, #9, and #10) hired since the last survey on 04/24/2019. At the time of the survey, the laboratory did not have training records available for laboratory personnel identifiers #7, #9, and #10.