Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2105334	11/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Greater Regional Medical Center Emergency Room	1700 West Townline St - Er, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the I-STAT cartridge storage requirements and temperature records, observations made during the survey, and confirmed by the laboratory personnel identifier #8 (refer to the Laboratory Personnel Report, CMS-209 Form) at approximately 11:30 am on 11/20/2019; the laboratory failed to monitor and document the room temperature of the storage area for i-STAT cartridges each day of operation for 30 out of 30 days in April 2019. The findings include: 1. According to the i-STAT cartridge package when not refrigerated, the laboratory needed to store the cartridges at a room temperature range of 64-86 degrees Fahrenheit or 18-30 degrees Celsius. 2. A tour of the laboratory was completed at 10:40 am on 11/20/2019. The surveyor noted the laboratory stored the i-STAT cartridges intended for immediate use at room temperature. 3. Temperature records for April 2019 revealed that the laboratory did not monitor and document the room temperature of the storage area for the i-STAT cartridges. 4. The laboratory personnel identifier #8, confirmed that the laboratory did not monitor and document the room temperature of the storage area.
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based upon review of patient test report for cord blood gases and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report, CMS-209 Form) at approximately 11:00 am on 11/20/2019, the laboratory test report failed to indicate the specimen source for one out of one patient (patient identifier A) from April 2019. The findings include: 1. The laboratory performed cord blood gases for patient identifier A on 04/17/2019. 2. Review of the patient test report revealed that the laboratory reported the test results as an arterial blood specimen instead of a cord blood specimen. The test report indicated the incorrect specimen source. 3. The laboratory personnel #8 confirmed that laboratory reported cord blood gases as arterial blood gas results because of their reporting system.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based upon review of patient test report for cord blood gases and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report, CMS-209 Form) at approximately 11:00 am on 11/20/2019, the laboratory test report failed to indicate the appropriate reference range (normal value) for cord blood gas results for one out of one patient (patient identifier A) from April 2019. The findings include: 1. The laboratory performed cord blood gases for patient identifier A on 04/17/2019. 2. Review of the patient test report revealed that the laboratory reported the test results as an arterial blood specimen instead of a cord blood specimen. The test report included reference ranges for an arterial blood specimen instead of a cord blood specimen. 3. The laboratory personnel #8 confirmed that laboratory reported cord blood gases as arterial blood gas results and used the incorrect reference ranges.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) reports for 2018 and 2019 and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report CMS-209 Form) at approximately 12:15 pm on 11/20/2019, the laboratory director failed to ensure the review of PT reports by the appropriate staff for five out of six testing events: 2018 events1-3 and 2019 events 1 and 3. Findings include: 1. Review of the PT reports for 2018 and 2019 revealed that the laboratory director and appropriate staff did not document their review with a signature and date of review for each event except for 2019 event 2. 2. Laboratory personnel identifier #8 confirmed that the laboratory director and appropriate staff did not document their review for each PT report.