

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0384964	<b>(X3) Date Survey Completed</b>  04/24/2019
<b>Name of Provider or Supplier</b>  Greater Regional Health	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5020</b>	<p>ENDOCRINOLOGY CFR(s): 493.1212</p> <p>If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on lack of Insulin-line growth factor binding protein-1 procedures and test records and confirmed by laboratory personnel #2 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 4/24/19, the laboratory failed to meet the endocrinology requirements for: performing twice annual verification as specified in D5217; having a written procedure as specified in D5403; defining and documenting criteria for proper storage of reagents as specified in D5413, verifying the performance specifications as specified in D5421; performing a positive and negative control material as specified in D5449; and maintaining a record system as specified in D5787.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List &amp; Annual Volume form and confirmed by laboratory personnel #2 (refer to the Laboratory Personnel Report) at approximately 2:30 on 4/24/2019, the laboratory failed to verify the accuracy twice annually for the analyte, Insulin-line growth factor binding protein-1 (IGFBP-1). The</p>

findings include: 1. Laboratory personnel #2 confirmed that nursing staff started testing patients for the analyte, IGFBP-1 using the Actim Prom test kit sometime after the last Clinical Laboratory Improvement Amendments (CLIA) survey performed on 3/23/2017 (an exact implementation date could not be determined). 2. At the time of the survey, the laboratory did not have records indicating the twice annual verification of the analyte, IGFBP-1.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory policies and procedures and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), at approximately 2:30 pm on 4/24/2019, the laboratory failed to have a procedure: detailing the requirements for patient preparation, specimen collection, labeling, storage, transportation and processing; criteria for specimen acceptability and rejection; step-by-step performance of the test; control procedures; corrective action to take if control results are not acceptable; limitations in the test methodology; and the laboratory's system for entering results in the patient record for the analyte, Insulin-line growth factor binding protein-1 (IGFBP-1).

**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 lack of Insulin-like growth factor binding protein-1 (IGFBP-1) test records and confirmed by laboratory personnel #2 (refer to the Laboratory Personnel Report), the laboratory failed to define and document the temperature criteria essential for the proper storage of reagents and specimens for the analyte, IGFBP-1. The findings include: 1. Laboratory personnel #2 confirmed that nursing staff started testing patients for the analyte, IGFBP-1 using the Actim Prom test kit sometime after the last Clinical Laboratory Improvement Amendments (CLIA) survey performed on 3/23/2017 (an exact implementation date could not be determined). 2. At the time of the survey, the laboratory did not define the temperature criteria for reagent and specimen storage for the IGFBP-1 test. In addition, the laboratory did not have documentation of temperature records for reagent and specimen storage of the IGFBP-1 test.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on lack of validation test records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 4/24/2019, the laboratory failed to perform the performance specifications of accuracy and precision for the analyte, Insulin-like growth factor binding protein-1 (IGFBP-1). The findings include: 1. Laboratory personnel #2 confirmed that nursing staff started testing patients for the analyte, IGFBP-1 using the Actim Prom test kit sometime after the last Clinical Laboratory Improvement Amendments (CLIA) survey performed on 3/23/2017 (an exact implementation date could not be determined). 2. At the time of the survey, the laboratory did not have performance specification records for this analyte.

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on lack of quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 2:30 pm on 4/29/2019, the laboratory failed to perform and document a negative and positive control each day of patient testing for the analyte, Insulin-like growth factor binding protein-1 (IGFBP-1) . The findings include: 1. Laboratory personnel #2 confirmed that nursing staff started testing patients for the analyte, IGFBP-1 using the Actim Prom test kit

sometime after the last Clinical Laboratory Improvement Amendments (CLIA) survey performed on 3/23/2017 (an exact implementation date could not be determined). 2. At the time of the survey, the laboratory did not have any QC records for the analyte, IGFBP-1. 3. This test system is eligible for an Individualized Quality Control Plan.

**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 the BioFire Individualized Quality Control Plan (IQCP), quality control (QC) records and confirmed by laboratory personnel #2 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 4/24/2019, the laboratory failed to take and document corrective action when the positive Giardia lamblia QC failed for one out of one lot number of gastrointestinal (GI) panels in February 2019. The findings include: 1. The BioFire IQCP stated the laboratory would perform a positive and negative control with each new lot number of GI panels. 2. The laboratory performed QC on 2/21/2019, and accepted negative results for both QC levels 1 and 2 for the organism, Giardia lamblia. 3. The manufacturer stated for the organism, Giardia lamblia, the laboratory must receive a negative result for QC level 1 and a positive result for QC level 2. 4. At the time of the survey, the laboratory did not have any corrective action documented for the failed QC result.

**D5787**

**TEST RECORDS**

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on lack of test records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 2:30 pm on 04/24/2019, the laboratory failed to maintain a record system that included: the positive identification of the specimen; the date and time of the specimen receipt; and records and dates of all specimen testing, including the manufacturer's package insert and records of each test kit lot number and expiration date, for the Insulin-like growth factor binding protein-1 (IGFBP-1) The findings include: 1. Laboratory personnel #2 confirmed that nursing staff started testing patients for the analyte, IGFBP-1 using the Actim Prom test kit sometime after the last Clinical Laboratory Improvement Amendments (CLIA) survey performed on 3/23/2017 (an exact implementation date could not be

	<p>determined). 2. At the time of the survey, the laboratory did not have record system that included: the positive identification of the specimen; the date and time of the specimen receipt; and records and dates of all specimen testing, including the manufacturer's package insert and records of each lot number and expiration date, for the analyte, IGFBP-1 and Actim Prom test system.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on lack of Insulin-line growth factor binding protein-1 procedures and test records and confirmed by laboratory personnel #2 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 4/24/19, the laboratory director failed meet the responsibilities of the overall operation of the laboratory including: ensuring that verification procedures are used to determine the accuracy and precision of the test system as specified in D6013; ensuring that a quality control program is established and maintained as specified in D6020, ensuring that prior to testing patient's specimens, all personnel have received the appropriate training for the type and complexity of the services offered as specified in D6029; and ensuring that an approved procedure is available to all personnel responsible for the testing process as specified in D6031.</p>
<p><b>D6013</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(ii)</p> <p>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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on lack of validation test records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 4/24/2019, the laboratory director failed to ensure the laboratory performed the performance specification of accuracy and precision for the analyte, Insulin-like growth factor binding protein-1 (IGFPB-1). Refer to D5241.</p>
<p><b>D6019</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iv)</p> <p>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</p>

director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 4/24/2019, the laboratory director failed to ensure the laboratory documented corrective action for unsatisfactory PT scores for two out of six testing events (2017 event 2 and 2019 event 1) from April 2017 - April 2019. The findings include: 1. For 2017 testing event 2, the laboratory received an unsatisfactory score of 20% for the analyte, methemoglobin. 2. For 2019 testing event 1, the laboratory received an unsatisfactory score of 80% for the analytes: hemoglobin, methemoglobin, and oxyhemoglobin. 3. At the time of the survey, the laboratory did not have corrective action for the unsatisfactory PT scores.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on lack of quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 2:30 pm on 4/29/2019, the laboratory director failed to ensure the laboratory established and maintained a QC program which included performing a negative and positive control each day of patient testing for the analyte, Insulin-like growth factor binding protein-1 (IGFBP-1). Refer to D5449.

**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 #2 (refer to Laboratory Personnel Report) at approximately 2:30 pm on 04/24/2019, the laboratory director failed to ensure that prior to testing patient specimens, testing personnel performing Insulin-like growth factor binding protein-1

(IGFBP-1) received the appropriate training for 14 out of 14 testing personnel (laboratory personnel identifiers #4 - #17). The findings include: 1. Laboratory personnel #2 confirmed that nursing staff started testing patients for the analyte, IGFBP-1 using the Actim Prom test kit sometime after the last Clinical Laboratory Improvement Amendments (CLIA) survey performed on 3/23/2017 (an exact implementation date could not be determined). 2. At the time of the survey, the laboratory did not have training records available for laboratory personnel identifiers #4 - #17.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of the laboratory policies and procedures and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), at approximately 2:30 pm on 4/24/2019, the laboratory director failed to ensure the laboratory had a written and approved procedure detailing the requirements for patient preparation, specimen collection, labeling, storage, transportation and processing; criteria for specimen acceptability and rejection; step-by-step performance of the test; control procedures; corrective action to take if control results are not acceptable; limitations in the test methodology; and laboratory's system for entering results in the patient record for the analyte, Insulin-like growth factor binding protein-1 (IGFBP-1).

**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 #2 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 04/24/2019, 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.

**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 laboratory personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 04/29/2019, the laboratory failed to have documentation to qualify 14 out of 18 testing personnel (identifiers #4 - #17) classified to perform moderate complexity testing.