| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 24D2145318 | 02/14/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Geneticure | 4 3rd St Sw, Ste 305, Rochester, MN | |

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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the laboratory failed to ensure quality control procedures (7) were included in the procedure manual. Findings are as follows: 1. The laboratory performed in silico Chemistry testing as confirmed by the General Supervisor (GS) during the entrance interview on 02/14/19 at 10:00 a.m. 2. A quality control (QC) procedure for the in silico Chemistry test was not found in the laboratory's electronic document program MediaLab. The laboratory was unable to provide a QC procedure upon request. 3. In an interview on 02/14/19 at 12:50 p.m., the GS confirmed a QC procedure had not been established. |

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| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the laboratory failed to perform required quality control activities for an in silico Chemistry test. Findings are as follows: 1. The laboratory performed in silico Chemistry testing as confirmed by the General Supervisor (GS) during the entrance interview on 02/14/19 at 10:00 a.m. 2. A quality control (QC) procedure for the in silico test was not included in the laboratory's electronic document program MediaLab. See D5403 3. An Individualized Quality Control Plan (IQCP) to reduce the required quantity and frequency of QC for the in silico test was not found in MediaLab. The laboratory was unable to provide an IQCP upon request. 4. QC records associated with the sole test performed on 01/23/19 were not found on date of survey. 5. In an interview on 02/14 /19 at 12:50 p.m., the GS confirmed QC activities had not been performed for the in silico testing. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the laboratory failed to ensure the test report included the address of the laboratory location (c)(2). Findings are as follows: 1. The laboratory performed in silico Chemistry testing as indicated by the General Supervisor (GS) during the entrance interview on 02/14/19 at 10:00 a.m. 2. A test report for the patient listed below was reviewed on date of survey. Patient ID Date of testing GEE1448 01/23/19 3. The address of the laboratory was not indicated on the test report for the patient listed above. 4. In an interview on 02/14/19 at 12:55 p.m., the GS confirmed the above finding. |