

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2145318	(X3) Date Survey Completed 09/19/2022
Name of Provider or Supplier Geneticure	Street Address, City, State 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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records for at least 2 years. Findings are as follows: 1. The laboratory performed genotype to phenotype in silico characterization testing as confirmed by the Technical Supervisor (TS) during a remotely conducted survey at 2:05 p.m., on 09/15/22, and at 4:05 p.m., on 09/16/22. 2. The laboratory performed PT using blinded previously tested patient samples as defined in the IPT0001 Internal Proficiency Testing procedure, provided via email on 09/15/22, by the TS. 3. The following PT documentation was not present in laboratory records on date of survey. The laboratory was unable to provide these documents upon request. December 2020 / 2nd Event 4. In an interview at 4:30 p.m. on 09/16/22, the TS confirmed the above findings. .</p>
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by:</p>

. Based on a review of laboratory internal proficiency testing (PT) documentation and interviews with the Technical Supervisor, the Laboratory Director failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. Findings are as follows: The Laboratory Director failed to retain proficiency testing (PT) records for at least 2 years. See D3037 The Laboratory Director failed to investigate unacceptable PT results. See D5211. The Laboratory Director failed to perform and document activities used to verify the accuracy of the genotype to phenotype in silico characterization testing performed in the laboratory at least twice annually in 2021 and 2022. See D5217. The Laboratory Director failed to ensure that the laboratory follow a written proficiency testing procedure.. See D5221.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to investigate one unacceptable genotype to phenotype in silico characterization proficiency testing (PT) result in 2020. Findings are as follows: 1. The laboratory performed genotype to phenotype in silico characterization testing as confirmed by the Technical Supervisor (TS) during a remotely conducted survey at 2:05 p.m., on 09/15/22, and at 4:05 p.m., on 09/16/22. 2. The laboratory performed PT using blinded previously tested patient samples as defined in the IPT0001 Internal Proficiency Testing procedure, provided via email on 09/15/22, by the TS. 3. In an interview at 2:30 p.m. on 09/15/22, the TS indicated that Testing Personnel 1 (TP1) was unable to complete entry and analysis of the December 2020 / 2nd Event PT data. 4. Investigation of unacceptable PT results was required as established in the laboratory's IPT0001 Internal Proficiency Testing procedure, provided via email on 09/15/22, by the TS. 5. Investigation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 4:30 p.m. on 09/16/22, the TS confirmed the above findings. .

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 document review and interview with laboratory personnel, the laboratory failed to perform and document activities used to verify the accuracy of the genotype to phenotype in silico characterization testing performed in the laboratory at least twice annually in 2021 and 2022. Findings are as follows: 1. The laboratory performed genotype to phenotype in silico characterization testing as confirmed by the Technical Supervisor (TS) during a remotely conducted survey at 2:05 p.m., on 09/15/22 and at 4:05 p.m., on 09/16/22. 2. A set of 5 blinded previously tested patient samples was required twice annually as established in the IPT0001 Internal

Proficiency Testing procedure, provided via email on 09/15/22, by the TS. 3. Twice annual genotype to phenotype in silico characterization accuracy verification for the following scheduled timepoints were not found during review of laboratory records. The laboratory was unable to provide the missing accuracy verification documentation upon request. June 2021 / 1st Event December 2021 / 2nd Event June 2022 / 1st Event 4. The laboratory performed genotype to phenotype in silico characterization testing on 27 patients in 2021 as indicated in the "Geneticure Remote Inspection" PowerPoint document provided by the laboratory on the date of survey. 5. In an interview at 4:30 p.m. on 09/16/22, the TS confirmed that PT was not performed on the intended dates indicated above. . .

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to follow a written proficiency testing procedure. Findings are as follows: 1. The laboratory performed genotype to phenotype in silico characterization testing as confirmed by the Technical Supervisor (TS) during a remotely conducted survey at 2:05 p.m., on 09/15/22, and at 4:05 p.m., on 09/16/22. 2. The laboratory performed PT using blinded previously tested patient samples as defined in the IPT0001 Internal Proficiency Testing procedure, provided via email on 09/15/22, by the TS. 3. The following PT documentation was not present in laboratory records on date of survey. The laboratory was unable to provide these documents upon request. December 2020 / 2nd Event June 2021 / 1st Event December 2021 / 2nd Event June 2022 / 1st Event 4. In an interview at 4:30 p.m. on 09/16/22, the TS confirmed that PT was not performed on the intended dates indicated above. .