GeneSight® MTHFR

Pharmacogenomic Test

genesight

Patient, Sample
Date of Birth: MM/DD/YYYY
Clinician: Sample Clinician

Order Number: 0000000
Report Date: MM/DD/YYYY
Reference: 000000

Questions about report interpretation?
Contact our Medical Information team:
855.891.9415 | medinfo@genesight.com

The GeneSight MTHFR test provides information about expected methylenetetrahydrofolate reductase (MTHFR) enzyme activity based on MTHFR genotype. Clinicians may consider using the results of the MTHFR test along with other factors to inform decisions regarding folate supplementation strategies for depression outcomes. While reduced MTHFR activity related to the T allele of the C677T polymorphism has been associated with decreased serum folate levels and increased homocysteine levels, there is minimal data on the impact of folate supplementation on depression outcomes in the context of MTHFR genotype. For more information: genesight.com/mthfr

MTHFR Genotype and Phenotype

Normal Activity	Moderately Reduced Activity	✔ Reduced Activity	T/T

This individual is homozygous for the T allele of the C677T polymorphism in the MTHFR gene (T/T genotype) and has two copies of the variant allele (T). This genotype is associated with reduced MTHFR enzyme activity.

Healthy individuals with a T/T genotype may have increased homocysteine levels and decreased folate levels versus C/C genotype; however, these levels may be impacted by other factors. This genetic result alone is not intended to determine treatment decisions regarding folate supplementation or measurement of serum levels of homocysteine or folate.

Test Information
The buccal swab sample was collected on MM/DD/YYYY and received in the laboratory on MM/DD/YYYY. Genomic DNA was isolated and the relevant genomic regions were amplified by polymerase chain reaction (PCR). Analysis of MTHFR was completed by using iPLEX MassARRAY® technology (Agena Bioscience). The following genetic variant may be detected in the assay: MTHFR 677C>T (NM_005957.4:c.665C>T).

This test was developed and its performance characteristics determined by Assurex Health. It has not been cleared or approved by the U.S. Food and Drug Administration. These interpretations are based upon data available in scientific literature and prescribing information for the relevant drugs. Interpretations are, in some instances, based on data regarding the pharmacokinetic, pharmacodynamic and pharmacogenomics properties of a drug derived from non-clinical studies (e.g. *in vitro* studies). Findings from studies performed in a non-clinical setting or clinical studies involving healthy subjects are not necessarily indicative of clinical performance in a particular patient.

This report was reviewed and verified on MM/DD/YYYY by:

Nina King

Nina E. King, PhD, HCLD(ABB), CC(NRCC), CQ(NYSDOH)

Genetic testing was completed by a CLIA and CAP accredited laboratory in the United States located at: 6000 Mason-Montgomery Road, Mason, OH 45040. CLIA ID: 36D1101772. The following personnel codes and lab director signature may reflect remote review of digital data: 5633

Disclaimer of Liability
The information contained in this report is provided as a service and does not constitute medical advice. At the time of report generation this information is believed to be current and is based upon published research; however, research data evolves and amendments to the prescribing information of the drugs listed will change over time. While this report is believed to be accurate and complete as of the date issued, THE DATA IS PROVIDED “AS IS”, WITHOUT WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. As medical advice must be tailored to the specific circumstances of each case, the treating healthcare provider has ultimate responsibility for all treatment decisions made with regard to a patient including any made on the basis of a patient’s genotype. A patient’s actual genotype or diplotype may be different from what is reported due to untested variants and technical limitations related to, but not limited to, phasing, copy number variations, and genetic variation in primer binding sites. This could impact patient phenotype and categorization results. Transplants, like bone marrow or liver, may also impact genotype results or applicability.

Laboratory Director: Nina King, PhD

Customer Service
Please contact 855.891.9415 or medinfo@genesight.com for assistance with report interpretation. For all other inquires please contact 866.757.9204 or support@genesight.com.

GeneSight MTHFR Test Version: 1.2