Questions? Call 855.891.9415 or
email medinfo@assurexhealth.com

ANTIDEPRESSANTS

USE AS DIRECTED
desvenlafaxine (Pristiq®)
levomilnacipran (Fetzima®)
sertraline (Zoloft®)
vilazodone (Viibryd®)

MODERATE GENE-DRUG INTERACTION	
citalopram (Celexa®)	1
escitalopram (Lexapro®)	1
selegiline (Emsam®)	1
trazodone (Desyrel®)	1

SIGNIFICANT GENE-DRUG INTERACTION	
bupropion (Wellbutrin®)	1,6
doxepin (Sinequan®)	1,6
fluoxetine (Prozac®)	1,6
mirtazapine (Remeron®)	1,6
venlafaxine (Effexor®)	1,6
amitriptyline (Elavil®)	1,6,8
clomipramine (Anafranil®)	1,6,8
desipramine (Norpramin®)	1,6,8
duloxetine (Cymbalta®)	1,6,8
fluvoxamine (Luvox®)	1,6,8
imipramine (Tofranil®)	1,6,8
nortriptyline (Pamelor®)	1,6,8
vortioxetine (Trintellix®)	1,6,8
paroxetine (Paxil®)	1,4,6,8

CLINICAL CONSIDERATIONS

1: Serum level may be too high, lower doses may be required.
4: Genotype may impact drug mechanism of action and result in reduced efficacy.
6: Use of this drug may increase risk of side effects.
8: FDA label identifies a potential gene-drug interaction for this medication.

All psychotropic medications require clinical monitoring.
This report is not intended to imply that the drugs listed are approved for the same indications or that they are comparable in safety or efficacy. The brand name is shown for illustrative purposes only; other brand names may be available. The prescribing physician should review the prescribing information for the drug(s) being considered and make treatment decisions based on the patient's individual needs and the characteristics of the drug prescribed. Propranolol might be considered off-label when being used for neuropsychiatric disorders. Please consult the FDA drug label for specific guidelines regarding its use.

Questions? Call 855.891.9415 or
email medinfo@assurexhealth.com

ANXIOLYTICS AND HYPNOTICS

USE AS DIRECTED	MODERATE GENE-DRUG INTERACTION	SIGNIFICANT GENE-DRUG INTERACTION	
alprazolam (Xanax®)		**propranolol** (Inderal®)	1,6,8
buspirone (BuSpar®)			
chlordiazepoxide (Librium®)			
clonazepam (Klonopin®)			
clorazepate (Tranxene®)			
diazepam (Valium®)			
eszopiclone (Lunesta®)			
lorazepam (Ativan®)			
oxazepam (Serax®)			
temazepam (Restoril®)			
zolpidem (Ambien®)			

CLINICAL CONSIDERATIONS

1: Serum level may be too high, lower doses may be required.
6: Use of this drug may increase risk of side effects.
8: FDA label identifies a potential gene-drug interaction for this medication.

All psychotropic medications require clinical monitoring.
This report is not intended to imply that the drugs listed are approved for the same indications or that they are comparable in safety or efficacy. The brand name is shown for illustrative purposes only; other brand names may be available. The prescribing physician should review the prescribing information for the drug(s) being considered and make treatment decisions based on the patient's individual needs and the characteristics of the drug prescribed. Propranolol might be considered off-label when being used for neuropsychiatric disorders. Please consult the FDA drug label for specific guidelines regarding its use.

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ANTIPSYCHOTICS

USE AS DIRECTED
asenapine (Saphris®)
cariprazine (Vraylar®)
lurasidone (Latuda®)
paliperidone (Invega®)
thiothixene (Navane®)
ziprasidone (Geodon®)

MODERATE GENE-DRUG INTERACTION	
fluphenazine (Prolixin®)	1
quetiapine (Seroquel®)	1
olanzapine (Zyprexa®)	3
clozapine (Clozaril®)	1,8
haloperidol (Haldol®)	1,8

SIGNIFICANT GENE-DRUG INTERACTION	
chlorpromazine (Thorazine®)	1,6
aripiprazole (Abilify®)	1,6,8
brexpiprazole (Rexulti®)	1,6,8
iloperidone (Fanapt®)	1,6,8
perphenazine (Trilafon®)	1,6,8
risperidone (Risperdal®)	1,6,8
thioridazine (Mellaril®)	1,6,9

CLINICAL CONSIDERATIONS

1: Serum level may be too high, lower doses may be required.
3: Difficult to predict dose adjustments due to conflicting variations in metabolism.
6: Use of this drug may increase risk of side effects.
8: FDA label identifies a potential gene-drug interaction for this medication.
9: Per FDA label, this medication is contraindicated for this genotype.

All psychotropic medications require clinical monitoring.
This report is not intended to imply that the drugs listed are approved for the same indications or that they are comparable in safety or efficacy. The brand name is shown for illustrative purposes only; other brand names may be available. The prescribing physician should review the prescribing information for the drug(s) being considered and make treatment decisions based on the patient's individual needs and the characteristics of the drug prescribed. Propranolol might be considered off-label when being used for neuropsychiatric disorders. Please consult the FDA drug label for specific guidelines regarding its use.

Questions? Call 855.891.9415 or
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MOOD STABILIZERS

USE AS DIRECTED	MODERATE GENE-DRUG INTERACTION	SIGNIFICANT GENE-DRUG INTERACTION
carbamazepine (Tegretol®)		**lamotrigine** (Lamictal®) 2
oxcarbazepine (Trileptal®)		
valproic acid/divalproex (Depakote®)		

NO PROVEN GENETIC MARKERS

gabapentin (Neurontin®)	10	**topiramate** (Topamax®)	10
lithium (Eskalith®)	10		

CLINICAL CONSIDERATIONS

2: Serum level may be too low, higher doses may be required.
10: This medication does not have clinically proven genetic markers that allow it to be categorized.

All psychotropic medications require clinical monitoring.
This report is not intended to imply that the drugs listed are approved for the same indications or that they are comparable in safety or efficacy. The brand name is shown for illustrative purposes only; other brand names may be available. The prescribing physician should review the prescribing information for the drug(s) being considered and make treatment decisions based on the patient's individual needs and the characteristics of the drug prescribed. Propranolol might be considered off-label when being used for neuropsychiatric disorders. Please consult the FDA drug label for specific guidelines regarding its use.

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PATIENT GENOTYPES AND PHENOTYPES

PHARMACODYNAMIC GENES

PD

SLC6A4 **Normal Response**

L/L

This patient is homozygous for the long promoter polymorphism of the serotonin transporter gene. The long promoter allele is reported to express normal levels of the serotonin transporter. The patient is predicted to have a normal response to selective serotonin reuptake inhibitors.

HTR2A **Increased Sensitivity**

G/G

This individual is homozygous variant for the G allele of the -1438G>A polymorphism for the Serotonin Receptor Type 2A. They carry two copies of the G allele. This genotype has been associated with an increased risk of adverse drug reactions with certain selective serotonin reuptake inhibitors.

HLA-B*1502 **Lower Risk**

Not Present

This patient does not carry the HLA-B*1502 allele or a closely related *15 allele. Absence of HLA-B*1502 and the closely related *15 alleles suggests lower risk of serious dermatologic reactions including toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS) when taking certain mood stabilizers.

HLA-A*3101 **Lower Risk**

A/A

This patient is homozygous for the A allele of the rs1061235 A>T polymorphism indicating absence of the HLA-A*3101 allele. This genotype suggests a lower risk of serious hypersensitivity reactions, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), maculopapular eruptions, and Drug Reaction with Eosinophilia and Systemic Symptoms when taking certain mood stabilizers.

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PATIENT GENOTYPES AND PHENOTYPES

PHARMACOKINETIC GENES

PK

CYP1A2 **Extensive (Normal) Metabolizer**

-163C>A - C/A, 5347C>T - C/T

This genotype is most consistent with the extensive (normal) metabolizer phenotype.

CYP2B6 **Intermediate Metabolizer**

*1/*6

CYP2B6*1 allele enzyme activity: Normal
CYP2B6*6 allele enzyme activity: Reduced

This genotype is most consistent with the intermediate metabolizer phenotype. This patient may have reduced enzyme activity as compared to individuals with the normal phenotype.

CYP2C19 **Extensive (Normal) Metabolizer**

*1/*17

CYP2C19*1 allele enzyme activity: Normal
CYP2C19*17 allele enzyme activity: Increased

This genotype is most consistent with the extensive (normal) metabolizer phenotype.

CYP2C9 **Extensive (Normal) Metabolizer**

*1/*1

CYP2C9*1 allele enzyme activity: Normal
CYP2C9*1 allele enzyme activity: Normal

This genotype is most consistent with the extensive (normal) metabolizer phenotype.

CYP2D6 **Poor Metabolizer**

*4/*41

CYP2D6*4 allele enzyme activity: None
CYP2D6*41 allele enzyme activity: Reduced

This genotype is most consistent with the poor metabolizer phenotype. This patient may have reduced enzyme activity as compared to individuals with the normal phenotype.

CYP3A4 **Extensive (Normal) Metabolizer**

*1/*1

CYP3A4*1 allele enzyme activity: Normal
CYP3A4*1 allele enzyme activity: Normal

This genotype is most consistent with the extensive (normal) metabolizer phenotype.

UGT1A4 **Ultrarapid Metabolizer**

*1/*3

UGT1A4*1 allele enzyme activity: Normal
UGT1A4*3 allele enzyme activity: Increased

This genotype is most consistent with the ultrarapid metabolizer phenotype. This patient may have increased enzyme activity as compared to individuals with the normal phenotype.

UGT2B15 **Extensive (Normal) Metabolizer**

*1/*2

UGT2B15*1 allele enzyme activity: Normal
UGT2B15*2 allele enzyme activity: Reduced

This genotype is most consistent with the extensive (normal) metabolizer phenotype. The patient is expected to have normal enzyme activity.

Questions? Call 855.891.9415 or
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GENE-DRUG INTERACTIONS

USE AS DIRECTED								
	CYP1A2	CYP2B6	CYP2C19	CYP2C9	CYP3A4	CYP2D6	UGT1A4	UGT2B15
ANTIDEPRESSANTS								
desvenlafaxine (Pristiq®)			○		○			
levomilnacipran (Fetzima®)			○		○	●		
sertraline (Zoloft®)		●	○	○	○	●		
vilazodone (Viibryd®)			○		○	●		
ANXIOLYTICS AND HYPNOTICS								
alprazolam (Xanax®)					○			
buspirone (BuSpar®)					○	●		
chlordiazepoxide (Librium®)	○				○			○
clonazepam (Klonopin®)					○			
clorazepate (Tranxene®)	○				○			○
diazepam (Valium®)	○	●	○	○	○			○
eszopiclone (Lunesta®)				○	○			
lorazepam (Ativan®)								○
oxazepam (Serax®)								○
temazepam (Restoril®)		●		○	○			○
zolpidem (Ambien®)	○		○	○	○	●		
ANTIPSYCHOTICS								
asenapine (Saphris®)	○				○	●	●	
cariprazine (Vraylar®)					○	●		
lurasidone (Latuda®)					○			
paliperidone (Invega®)					○	●		
thiothixene (Navane®)	○							
ziprasidone (Geodon®)	○				○			
MOOD STABILIZERS								
carbamazepine (Tegretol®)		●			○			
oxcarbazepine (Trileptal®)								
valproic acid/divalproex (Depakote®)		●		○			●	

MODERATE GENE-DRUG INTERACTION								
	CYP1A2	CYP2B6	CYP2C19	CYP2C9	CYP3A4	CYP2D6	UGT1A4	UGT2B15
ANTIDEPRESSANTS								
citalopram (Celexa®)			○		○	●		
escitalopram (Lexapro®)			○		○	●		
selegiline (Emsam®)	○	●	○		○			
trazodone (Desyrel®)	○				○	●		
ANTIPSYCHOTICS								
clozapine (Clozaril®)	○				○	●	●	

● - Variation was found in patient genotype that may impact medication response. ○ - This gene is associated with medication response, but patient genotype is normal.

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GENE-DRUG INTERACTIONS

MODERATE GENE-DRUG INTERACTION								
	CYP1A2	CYP2B6	CYP2C19	CYP2C9	CYP3A4	CYP2D6	UGT1A4	UGT2B15
ANTIPSYCHOTICS								
fluphenazine (Prolixin®)	○		○	○	○	●		
haloperidol (Haldol®)	○				○	●	●	
olanzapine (Zyprexa®)	○				○	●	●	
quetiapine (Seroquel®)					○	●		

SIGNIFICANT GENE-DRUG INTERACTION								
	CYP1A2	CYP2B6	CYP2C19	CYP2C9	CYP3A4	CYP2D6	UGT1A4	UGT2B15
ANTIDEPRESSANTS								
amitriptyline (Elavil®)	○		○	○	○	●	●	
bupropion (Wellbutrin®)		●			○	●		
clomipramine (Anafranil®)	○		○		○	●		
desipramine (Norpramin®)						●		
doxepin (Sinequan®)	○		○	○	○	●	●	
duloxetine (Cymbalta®)	○					●		
fluoxetine (Prozac®)			○	○	○	●		
fluvoxamine (Luvox®)	○					●		
imipramine (Tofranil®)	○		○		○	●		
mirtazapine (Remeron®)	○			○	○	●		
nortriptyline (Pamelor®)						●		
paroxetine (Paxil®)					○	●		
venlafaxine (Effexor®)			○	○	○	●		
vortioxetine (Trintellix®)		●	○	○	○	●		
ANXIOLYTICS AND HYPNOTICS								
propranolol (Inderal®)	○					●		
ANTIPSYCHOTICS								
aripiprazole (Abilify®)					○	●		
brexpiprazole (Rexulti®)					○	●		
chlorpromazine (Thorazine®)	○				○	●		
iloperidone (Fanapt®)					○	●		
perphenazine (Trilafon®)	○		○		○	●		
risperidone (Risperdal®)					○	●		
thioridazine (Mellaril®)	○		○		○	●		
MOOD STABILIZERS								
lamotrigine (Lamictal®)							●	

● - Variation was found in patient genotype that may impact medication response. ○ - This gene is associated with medication response, but patient genotype is normal.

Questions? Call 855.891.9415 or
email medinfo@assurexhealth.com

TEST INFORMATION

The buccal swab sample was collected on 2/13/2020 and received in the laboratory on 2/14/2020. Genomic DNA was isolated and the relevant genomic regions were amplified by polymerase chain reaction (PCR). Analysis of CYP2D6 deletion and duplication, HLA-B*1502 and SLC6A4 was completed by electrophoresis of PCR products. Analysis of rs1061235 (indicating presence of the HLA-A*3101 allele or certain HLA-A*33 alleles), CYP1A2, CYP2B6, CYP2C19, CYP2C9, CYP2D6, CYP3A4, HTR2A, UGT1A4 and UGT2B15 was completed by using iPLEX MassARRAY® technology (Agena Bioscience). The following genetic variants may be detected in the assay: CYP1A2 -3860G>A (NG_008431.1:g.28338G>A), -2467T>delT (NM_000761.4:c.-1635delT), -739T>G (NM_000761.4:c.-10+103T>G), -729C>T (NM_000761.4:c.-10+113C>T), -163C>A (NM_000761.4:c.-9-154C>A), 125C>G (NM_000761.4:c.125C>G), 558C>A (NM_000761.4:c.558C>A), 2116G>A (NM_000761.4:c.1042G>A), 2473G>A (NM_000761.4:c.1130G>A), 2499A>T (NM_000761.4:c.1156A>T), 3497G>A (NM_000761.4:c.1217G>A), 3533G>A (NM_000761.4:c.1253+1G>A), 5090C>T (NM_000761.4:c.1291C>T), 5166G>A (NM_000761.4:c.1367G>A), 5347C>T (NM_000761.4:c.1548C>T); CYP2B6 *1, *4 (NM_000767.4:c.785A>G), *6 (NM_000767.4:c.516G>T; c.785A>G), *9 (NM_000767.4:c.516G>T); CYP2C19 *1, *2 (NM_000769.2:c.681G>A), *3 (NM_000769.2:c.636G>A), *4 (NM_000769.2:c.1A>G), *5 (NM_000769.2:c.1297C>T),*6 (NM_000769.2:c.395G>A), *7 (NM_000769.2:c.819+2T>A), *8 (NM_000769.2:c.358T>C), *17 (NM_000769.2:c.-806C>T); CYP2C9 *1, *2 (NM_000771.3:c.430C>T), *3 (NM_000771.3:c.1075A>C), *4 (NM_000771.3:c.1076T>C), *5 (NM_000771.3:c.1080C>G), *6 (NM_000771.3:c.817delA); CYP2D6 *1, *2 (NM_000106.5:c.886C>T; c.1457G>C), *2A (NM_000106.5:c.-1584C>G; c.886C>T; c.1457G>C), *3 (NM_000106.5:c.775delA), *4 (NM_000106.5:c.506-1G>A; c.100C>T; c.1457G>C), *5 (CYP2D6 Deletion), *6 (NM_000106.5:c.454delT), *7 (NM_000106.5:c.971A>C), *8 (NM_000106.5:c.505G>T; c.886C>T; c.1457G>C), *9 (NM_000106.5:c.841_843delAAG), *10 (NM_000106.5:c.100C>T; c.1457G>C), *11, *12 (NM_000106.5:c.124G>A; c.886C>T; c.1457G>C), *14 (NM_000106.5:c.505G>A; c.886C>T; c.1457G>C), *15, *17 (NM_000106.5:c.320C>T; c.886C>T; c.1457G>C), *41 (NM_000106.5:c.985+39G>A; c.886C>T; c.1457G>C), gene duplication; CYP3A4 *1, *13 (NM_017460.5:c.1247C>T), *15A (NM_017460.5:c.485G>A), *22 (NM_017460.5:c.522-191C>T); HLA-B*1502; rs1061235 (NM_002116.7:c.*66A>T); HTR2A -1438G>A (NM_000621.4:c.-998G>A); SLC6A4 L, S; UGT1A4 *1, *3 (NM_007120.2:c.142T>G); UGT2B15 *1, *2 (NM_001076.3:c.253G>T). The following rare genetic variants have not been observed by the Assurex Health, Inc. laboratory: CYP1A2 125C>G, 558C>A; CYP2C19 *7.

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 2/18/2020 by:

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.

GeneSight Psychotropic is covered by U.S. Patent No. 9,111,028

Genetic testing was completed by a CLIA and CAP accredited laboratory in the United States located at:

6000 Mason-Montgomery Road
Mason, OH 45040

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

GeneSight Psychotropic Test Version: 3.0.2

GeneSight® Order Medical Necessity Documentation

Patient Name _____ Patient Date of Birth _____ Order Number _____

GeneSight Psychotropic

ICD-10 Code(s)

F41.9	Anxiety disorder, unspecified
F43.9	Reaction to severe stress, unspecified
F33.1	Major depressive disorder, recurrent, moderate

Diagnosis

According to DSM-5 criteria, does the patient suffer from Major Depressive Disorder (MDD)?

☑ Yes ☐ No

☑ Depressed mood
☐ Diminished interest in activities
☑ Significant weight gain/loss
☑ Insomnia or hypersomnia
☐ Psychomotor agitation/retardation
☑ Fatigue
☐ Feelings of worthlessness or guilt
☑ Diminished concentration
☐ Recurrent thought of death

According to DSM-5 criteria, are the patient's depressive symptoms:

☐ Mild: few, if any, symptoms in excess of the five required to make the diagnoses and the symptoms result in only minor functional impairment

☑ Moderate: symptoms or functional impairment are between 'mild' and 'severe'

☐ Severe: most symptoms and the symptoms markedly interfere with functioning; can occur with or without psychotic symptoms

Medical Necessity

Are you contemplating an alteration* in a neuropsychiatric medication treatment?

☑ Yes ☐ No

Has the patient failed or are they currently failing at least one neuropsychiatric medication?

☑ Yes ☐ No

Medication that the patient has failed or is currently failing:
Prozac® (fluoxetine)

Additional Information (optional)

None provided.

* Alterations include medication elimination, switching, augmentation, and/or dose adjustments

The undersigned attests that he/she is licensed to order the selected test(s). I acknowledge that the patient has been provided with information regarding the selected genetic test(s) and obtained consent for genetic testing from the patient or his/her legal authorized representative. I attest that the selected genetic test(s) are medically necessary and that these results will be used in the medical management and treatment decisions for the above referenced patient and agree to provide any additional information or documentation to support medical necessity, upon request.

Insurers require that you maintain documentation supporting the medical necessity for GeneSight tests in the patient's medical record. Please verify that the order information above is correct and include in your patient's medical record. In addition to the information provided for this order, please ensure that the patient's medical record is up-to-date with DSM-5-based diagnostic information.

Healthcare Provider Information

Name _____

Signature _____ Date _____

Customer Service 866.757.9204 • Fax 888.894.4344

GeneSight® Order Medical Necessity Documentation

Patient Name _____ Patient Date of Birth _____ Order Number _____

GeneSight Analgesic

ICD-10 Code(s)

Medical Necessity

- ☐ Patient has failed or is currently failing at least one analgesic medication and I am contemplating an alteration in an analgesic medication treatment.
- ☐ Patient is on multiple medications for his/her condition which increases the risk for adverse drug events.
- ☐ Patient suspected of abuse and/or diversion with current medication regimen.
- ☐ Initial onset of condition in patient with no prior pharmacological treatment history for condition.
- ☐ Other

GeneSight ADHD

ICD-10 Code(s)

Medical Necessity

- ☐ Patient has failed or is currently failing at least one neuropsychiatric medication and I am contemplating an alteration in a neuropsychiatric medication treatment.
- ☐ Patient is on multiple medications for his/her condition which increases the risk for adverse drug events.
- ☐ Patient suspected of abuse and/or diversion with current medication regimen.
- ☐ Initial onset of condition in patient with no prior pharmacological treatment history for condition.
- ☐ Other

GeneSight MTHFR

ICD-10 Code(s)

F41.9 Anxiety disorder, unspecified

F43.9 Reaction to severe stress, unspecified

Medical Necessity

- ☐ I am considering folate supplementation for patient.
- ☐ Patient has low serum folate levels.
- ☑ Other

TBD

Ordered by:

Customer Service 866.757.9204 • Fax 888.894.4344

Questions? Call 855.891.9415 or
email medinfo@assurexhealth.com

NORMAL FOLIC ACID CONVERSION	REDUCED FOLIC ACID CONVERSION	SIGNIFICANTLY REDUCED FOLIC ACID CONVERSION
	✓	

Note: Serum levels of folate may be too low. Folate supplementation or higher daily intake of folic acid may be required.

PATIENT GENOTYPE AND PHENOTYPE

MTHFR	Intermediate Activity	C/T

This individual is heterozygous for the C677T polymorphism in the MTHFR gene. This genotype is associated with reduced folic acid metabolism, moderately decreased serum folate levels, and moderately increased homocysteine levels.

TEST INFORMATION

The buccal swab sample was collected on 2/13/2020 and received in the laboratory on 2/14/2020. 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 2/18/2020 by:

Genetic testing was completed by a CLIA and CAP accredited laboratory in the United States located at:

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Mason, OH 45040

Customer Service
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GeneSight MTHFR Test Version: 1.0