GeneSight® Psychotropic

Pharmacogenomic Test

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

Antidepressants

This section shows the results for non-smokers and smokers due to the absence of the highly inducible CYP1A2 variant.

Use as Directed

desvenlafaxine (Pristiq®)
levomilnacipran (Fetzima®)

Moderate Gene-drug Interaction

selegiline (Emsam®)	1
trazodone (Desyrel®)	1
vilazodone (Viibryd®)	1
sertraline (Zoloft®)	1,4
bupropion (Wellbutrin®)	1,6

Significant Gene-drug Interaction

fluoxetine (Prozac®)	1,6
mirtazapine (Remeron®)	1,6
venlafaxine (Effexor®)	1,6
citalopram (Celexa®)	1,4,6
escitalopram (Lexapro®)	1,4,6
amitriptyline (Elavil®)	1,6,8
clomipramine (Anafranil®)	1,6,8
desipramine (Norpramin®)	1,6,8
doxepin (Sinequan®)	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 moderately 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. Medications should not be changed based solely on the test results. The results of this test are intended to supplement other clinical information considered by a healthcare provider within the context of a comprehensive medical evaluation.
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, the characteristics of the drug prescribed, and the risk and safety information provided in the drug's labeling. Propranolol and oxcarbazepine prescribed for neuropsychiatric disorders might be considered off-label. Please consult their respective FDA drug labels for specific guidelines regarding their use.

The GeneSight Psychotropic test interpretations are based on a thorough review of published peer-reviewed literature, internal research, and FDA label information when applicable. The clinical validity and utility of the GeneSight Psychotropic test have been evaluated for patients with major depressive disorder who failed at least one psychotropic medication in multiple clinical studies.

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Anxiolytics and Hypnotics

This section shows the results for non-smokers and smokers due to the absence of the highly inducible CYP1A2 variant.

Use as Directed

- **alprazolam** (Xanax®)
- **buspirone** (BuSpar®)
- **clonazepam** (Klonopin®)
- **eszopiclone** (Lunesta®)
- **lemborexant** (Dayvigo®)
- **suvorexant** (Belsomra®)
- **temazepam** (Restoril®)

Moderate Gene-drug Interaction

chlordiazepoxide (Librium®)	1
clorazepate (Tranxene®)	1
diazepam (Valium®)	1
lorazepam (Ativan®)	1
oxazepam (Serax®)	1
zolpidem (Ambien®)	1

Significant Gene-drug Interaction

propranolol (Inderal®)	1,6,8

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.

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Antipsychotics

This section shows the results for non-smokers and smokers due to the absence of the highly inducible CYP1A2 variant.

Use as Directed

- **asenapine** (Saphris®)
- **cariprazine** (Vraylar®)
- **lumateperone** (Caplyta®)
- **lurasidone** (Latuda®)
- **paliperidone** (Invega®)
- **thiothixene** (Navane®)
- **ziprasidone** (Geodon®)

Moderate Gene-drug Interaction

fluphenazine (Prolixin®)	1
olanzapine (Zyprexa®)	1
quetiapine (Seroquel®)	1
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.
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.

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Mood Stabilizers

This section shows the results for non-smokers and smokers because CYP1A2 is not predicted to influence these medications.

Use as Directed

valproic acid/divalproex (Depakote®)

Moderate Gene-drug Interaction

Significant Gene-drug Interaction

lamotrigine (Lamictal®) 6
oxcarbazepine (Trileptal®) 6,8
carbamazepine (Tegretol®) 6,9

No Proven Genetic Markers

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

Clinical Considerations

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.
10: While this medication does not have clinically proven genetic markers that allow it to be categorized, it may be an effective choice based on other clinical factors.

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Stimulants

This section shows the results for non-smokers and smokers because CYP1A2 is not predicted to influence these medications.

Use as Directed	Moderate Gene-drug Interaction	Significant Gene-drug Interaction
dexmethylphenidate (Focalin®) **methylphenidate** (Ritalin®, Concerta®)		

No Proven Genetic Markers

amphetamine salts (Adderall®)	10	**dextroamphetamine** (Dexedrine®)	10	**lisdexamfetamine** (Vyvanse®)	10

Non-Stimulants

Use as Directed	Moderate Gene-drug Interaction	Significant Gene-drug Interaction
guanfacine (Intuniv®)	**viloxazine** (Qelbree®) 1	**atomoxetine** (Strattera®) 1,5,8

No Proven Genetic Markers

clonidine (Kapvay®)	10

Clinical Considerations

1: Serum level may be too high, lower doses may be required.
5: CYP2D6 genotype indicates that this patient may experience increased frequency of side effects but also greater symptom improvement in those who find the treatment tolerable.
8: FDA label identifies a potential gene-drug interaction for this medication.
10: While this medication does not have clinically proven genetic markers that allow it to be categorized, it may be an effective choice based on other clinical factors.

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Patient Genotypes and Phenotypes

Pharmacodynamic Genes

PD

ADRA2A — **Normal Response**
C/G

This patient is heterozygous for the -1291G>C polymorphism in the adrenergic alpha-2A receptor gene. They have one copy of the C allele and one copy of the G allele. This genotype suggests a normal response to certain ADHD medications.

HLA-A*3101 — **Normal 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 normal 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.

HLA-B*1502 — **Higher Risk**
Present

This patient carries either the HLA-B*1502 allele or a closely related *15 allele. Presence of HLA-B*1502 or some of the closely related *15 alleles suggests higher risk of serious dermatologic reactions including toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS) when taking certain mood stabilizers.

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.

SLC6A4 — **Intermediate Response**
L/S

This patient is heterozygous for the short/long promoter polymorphism of the serotonin transporter gene. The short promoter allele is reported to decrease expression of the serotonin transporter compared to the homozygous long promoter allele. The patient may have a moderately decreased likelihood of response to certain selective serotonin reuptake inhibitors due to the presence of the short form of the gene.

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Patient Genotypes and Phenotypes

Pharmacokinetic Genes

PK

CES1A1 — **Extensive (Normal) Metabolizer**
GLY/GLY

CES1A1 - Gly allele enzyme activity: Normal
CES1A1 - Gly allele enzyme activity: Normal

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

CYP1A2 — **Extensive (Normal) Metabolizer**
-163C>A - C/C

CYP1A2 -163C>A - C allele enzyme activity: Normal
CYP1A2 -163C>A - C allele enzyme activity: Normal

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

CYP2B6 — **Extensive (Normal) Metabolizer**
*1/*1

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

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

CYP2C19 — **Intermediate Metabolizer**
*1/*2

CYP2C19*1 allele enzyme activity: Normal
CYP2C19*2 allele enzyme activity: None

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.

CYP2C9 — **Intermediate Metabolizer**
*1/*2

CYP2C9*1 allele enzyme activity: Normal
CYP2C9*2 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.

CYP2D6 — **Poor Metabolizer**
*3/*41

CYP2D6*3 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 — **Extensive (Normal) Metabolizer**
*1/*1

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

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

UGT2B15 — **Intermediate Metabolizer**
*2/*2

UGT2B15*2 allele enzyme activity: Reduced
UGT2B15*2 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.

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Additional Genotypes

Not Included in Categorizing Medications

Genotypes reported in this section have not been shown to be reliable markers of medication outcomes

COMT
VAL/VAL

This patient is homozygous for the Val allele of the Val158Met polymorphism in the catechol-o-methyltransferase gene.

A summary of the studies that have assessed the potential effect of COMT genotype on response to psychotropic medications can be found here: https://genesight.com/comt.

To categorize medications on this pharmacogenomic test, a gene must have a variant that has been shown to have a significant impact on medication outcomes, as demonstrated in multiple well-designed studies. Studies assessing the gene in this section have not shown that it is a reliable marker of medication outcomes. Therefore, this gene does not currently meet the criteria for categorizing medications. The patient's genotype is provided for informational purposes only.

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Gene-drug Interactions

Use as Directed

	CES1A1 Normal	CYP1A2 Normal	CYP2B6 Normal	CYP2C19 Intermediate	CYP2C9 Intermediate	CYP2D6 Poor	CYP3A4 Normal	UGT1A4 Normal	UGT2B15 Intermediate
Antidepressants									
desvenlafaxine (Pristiq®)				●			○		
levomilnacipran (Fetzima®)				●		●	○		
Anxiolytics and Hypnotics									
alprazolam (Xanax®)							○		
buspirone (BuSpar®)						●	○		
clonazepam (Klonopin®)							○		
eszopiclone (Lunesta®)					●		○		
lemborexant (Dayvigo®)							○		
suvorexant (Belsomra®)							○		
temazepam (Restoril®)			○		●		○		●
Antipsychotics									
asenapine (Saphris®)		○				●	○	○	
cariprazine (Vraylar®)						●	○		
lumateperone (Caplyta®)							○		
lurasidone (Latuda®)							○		
paliperidone (Invega®)						●	○		
thiothixene (Navane®)		○							
ziprasidone (Geodon®)		○					○		
Mood Stabilizers									
valproic acid/divalproex (Depakote®)			○		●			○	
Stimulants									
dexmethylphenidate (Focalin®)	○								
methylphenidate (Ritalin®, Concerta®)	○								
Non-stimulants									
guanfacine (Intuniv®)							○		

● Variation was found in patient genotype that may impact medication metabolism.

○ This gene is associated with medication metabolism, but the predicted patient phenotype is normal.

* This gene-drug interaction is recognized by the FDA or CPIC.

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Gene-drug Interactions

Moderate Gene-Drug Interaction

	CES1A1 Normal	CYP1A2 Normal	CYP2B6 Normal	CYP2C19 Intermediate	CYP2C9 Intermediate	CYP2D6 Poor	CYP3A4 Normal	UGT1A4 Normal	UGT2B15 Intermediate
Antidepressants									
bupropion (Wellbutrin®)			○			●	○		
selegiline (Emsam®)		○	○	●			○		
sertraline (Zoloft®)			○	● *			○		
trazodone (Desyrel®)		○				●	○		
vilazodone (Viibryd®)				●		●	○		
Anxiolytics and Hypnotics									
chlordiazepoxide (Librium®)		○					○		●
clorazepate (Tranxene®)		○					○		●
diazepam (Valium®)		○	○	●	●		○		●
lorazepam (Ativan®)									●
oxazepam (Serax®)									●
zolpidem (Ambien®)		○		●	●	●	○		
Antipsychotics									
clozapine (Clozaril®)		○				● *	○	○	
fluphenazine (Prolixin®)		○		●	●	●	○		
haloperidol (Haldol®)		○				●	○	○	
olanzapine (Zyprexa®)		○				●	○	○	
quetiapine (Seroquel®)						●	○		
Non-stimulants									
viloxazine (Qelbree®)						●			

Significant Gene-Drug Interaction

	CES1A1 Normal	CYP1A2 Normal	CYP2B6 Normal	CYP2C19 Intermediate	CYP2C9 Intermediate	CYP2D6 Poor	CYP3A4 Normal	UGT1A4 Normal	UGT2B15 Intermediate
Antidepressants									
amitriptyline (Elavil®)				● *		● *			
citalopram (Celexa®)				● *		●	○		
clomipramine (Anafranil®)		○		● *		● *	○		
desipramine (Norpramin®)						● *			
doxepin (Sinequan®)		○		● *	●	● *	○	○	
duloxetine (Cymbalta®)		○				●			

● Variation was found in patient genotype that may impact medication metabolism.

○ This gene is associated with medication metabolism, but the predicted patient phenotype is normal.

* This gene-drug interaction is recognized by the FDA or CPIC.

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Gene-drug Interactions

Significant Gene-Drug Interaction (Continued)

	CES1A1 Normal	CYP1A2 Normal	CYP2B6 Normal	CYP2C19 Intermediate	CYP2C9 Intermediate	CYP2D6 Poor	CYP3A4 Normal	UGT1A4 Normal	UGT2B15 Intermediate
Antidepressants									
escitalopram (Lexapro®)				● *		●	○		
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									
carbamazepine (Tegretol®)			○				○		
lamotrigine (Lamictal®)								○	
oxcarbazepine (Trileptal®)									
Non-stimulants									
atomoxetine (Strattera®)						● *			

No Proven Genetic Markers

	CES1A1 Normal	CYP1A2 Normal	CYP2B6 Normal	CYP2C19 Intermediate	CYP2C9 Intermediate	CYP2D6 Poor	CYP3A4 Normal	UGT1A4 Normal	UGT2B15 Intermediate
Stimulants									
amphetamine salts (Adderall®)						*			

● Variation was found in patient genotype that may impact medication metabolism.

○ This gene is associated with medication metabolism, but the predicted patient phenotype is normal.

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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 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), ADRA2A, CES1A1, COMT, 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: ADRA2A -1291G>C (NM_000681.3:c.-1252G>C); CES1A1 Gly143Glu (NM_001025194.1:c.428G>A); COMT Val158Met (NM_007310.2:c.322G>A); CYP1A2 -163C>A (NM_000761.4:c.-9-154C>A); CYP2B6 *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 *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), *8 (NM_000769.2:c.358T>C), *17 (NM_000769.2:c.-806C>T); CYP2C9 *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 *2 (NM_000106.5: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 (NM_000106.6:c.181-1G>C; NM_000106.5:c.886C>T; c.1457G>C), *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 (NM_000106.6:c.137dup), *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), *114 (NM_000106.5: c.100C>T; c.505G>A; c.886C>T; c.1457G>C). gene duplication; CYP3A4 *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 *3 (NM_007120.2:c.142T>G); UGT2B15 *2 (NM_001076.3:c.253G>T). *1 is the reference allele and is reported by default if the other tested alleles are not detected. Interactions with smoking describe the gene-drug-environment interaction of CYP1A2 -163C>A, smoking status, and CYP1A2 substrates. Other drug-smoking interactions may exist. Interactions between marijuana smoking and the metabolism of CYP1A2 substrates have been observed and are expected to be mechanistically similar to the interactions between tobacco smoking, CYP1A2 substrates, and the CYP1A2 -163C>A variant.

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. References used to inform medication categorizations can be found here: https://genesight.com/references.

Report content approved on MM/DD/YYYY by:

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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:
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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 Psychotropic Test Version: 4.3 Sample