

Patient Case Study Report

Date of Birth: MM/DD/YYYY

Clinician: Case Study Clinician

Order Number: #####

Report Date: MM/DD/YYYYY

Reference:

Questions about report interpretation?

Contact our Medical Information team:

855.891.9415 | medinfo@genesight.com

Antidepressants



Non-Smokers

Smoking is defined as the daily inhalation of burning plant material (cigarettes, marijuana), and **excludes** vaping and e-cigarettes. This is used to determine medication results.

Use as Directed

desvenlafaxine (Pristiq®)
levomilnacipran (Fetzima®)

Moderate Gene-drug Interaction

vilazodone (Viibryd®) 1
trazodone (Desyrel®) 1,7

Significant Gene-drug Interaction

bupropion (Wellbutrin®) 1,6
fluoxetine (Prozac®) 1,6
selegiline (Emsam®) 1,6
venlafaxine (Effexor®) 1,6
citalopram (Celexa®) 1,4,6
escitalopram (Lexapro®) 1,4,6
sertraline (Zoloft®) 1,4,6
mirtazapine (Remeron®) 1,6,7
amitriptyline (Elavil®) 1,6,8
clomipramine (Anafranil®) 1,6,8
desipramine (Norpramin®) 1,6,8
doxepin (Sinequan®) 1,6,8
imipramine (Tofranil®) 1,6,8
nortriptyline (Pamelor®) 1,6,8
vortioxetine (Trintellix®) 1,6,8
paroxetine (Paxil®) 1,4,6,8
duloxetine (Cymbalta®) 1,6,7,8
fluvoxamine (Luvox®) 1,6,7,8

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.
- 7: Smoking status changes the results of this medication. **See next section labeled Smokers for smoking results.**
- 8: FDA label identifies a potential gene-drug interaction for this medication.

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Use as Directed

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levomilnacipran (Fetzima®)

Moderate Gene-drug Interaction

vilazodone (Viibryd®)	1
mirtazapine (Remeron®)	3
trazodone (Desyrel®)	3
duloxetine (Cymbalta®)	3,8
fluvoxamine (Luvox®)	3,8

Significant Gene-drug Interaction

bupropion (Wellbutrin®)	1,6
fluoxetine (Prozac®)	1,6
selegiline (Emsam®)	1,6
venlafaxine (Effexor®)	1,6
citalopram (Celexa®)	1,4,6
escitalopram (Lexapro®)	1,4,6
sertraline (Zoloft®)	1,4,6
amitriptyline (Elavil®)	1,6,8
clomipramine (Anafranil®)	1,6,8
desipramine (Norpramin®)	1,6,8
doxepin (Sinequan®)	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.
- 3: Difficult to predict dose adjustments due to conflicting variations in metabolism.
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Anxiolytics and Hypnotics



Non-Smokers

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Use as Directed

alprazolam (Xanax®)
 buspirone (BuSpar®)
 chlordiazepoxide (Librium®)
 clonazepam (Klonopin®)
 clorazepate (Tranxene®)
 eszopiclone (Lunesta®)
 lemborexant (Dayvigo®)
 lorazepam (Ativan®)
 oxazepam (Serax®)
 suvorexant (Belsomra®)
 temazepam (Restoril®)
 zolpidem (Ambien®)

Moderate Gene-drug Interaction

Significant Gene-drug Interaction

diazepam (Valium®)	1,6
propranolol (Inderal®)	1,6,7,8

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.
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 eszopiclone (Lunesta®)
 lemborexant (Dayvigo®)
 lorazepam (Ativan®)
 oxazepam (Serax®)
 suvorexant (Belsomra®)
 temazepam (Restoril®)
 zolpidem (Ambien®)

Moderate Gene-drug Interaction

propranolol (Inderal®) 3,8

Significant Gene-drug Interaction

diazepam (Valium®) 1,6

Clinical Considerations

- 1: Serum level may be too high, lower doses may be required.
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Antipsychotics



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Use as Directed

cariprazine (Vraylar®)	
lumateperone (Caplyta®)	
lurasidone (Latuda®)	
paliperidone (Invega®)	
ziprasidone (Geodon®)	
asenapine (Saphris®)	7
thiothixene (Navane®)	7

Moderate Gene-drug Interaction

fluphenazine (Prolixin®)	1
quetiapine (Seroquel®)	1
olanzapine (Zyprexa®)	1,7
clozapine (Clozaril®)	1,7,8
haloperidol (Haldol®)	1,7,8

Significant Gene-drug Interaction

chlorpromazine (Thorazine®)	1,6,7
aripiprazole (Abilify®)	1,6,8
brexpiprazole (Rexulti®)	1,6,8
iloperidone (Fanapt®)	1,6,8
risperidone (Risperdal®)	1,6,8
thioridazine (Mellaril®)	1,6,9
perphenazine (Trilafon®)	1,6,7,8

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.
- 7: Smoking status changes the results of this medication. **See next section labeled Smokers for smoking results.**
- 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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Use as Directed

cariprazine (Vraylar®)
lumateperone (Caplyta®)
lurasidone (Latuda®)
paliperidone (Invega®)
ziprasidone (Geodon®)

Moderate Gene-drug Interaction

fluphenazine (Prolixin®)	1
quetiapine (Seroquel®)	1
asenapine (Saphris®)	3
chlorpromazine (Thorazine®)	3
olanzapine (Zyprexa®)	3
perphenazine (Trilafon®)	1,8
clozapine (Clozaril®)	3,8
haloperidol (Haldol®)	3,8

Significant Gene-drug Interaction

thiothixene (Navane®)	2
aripiprazole (Abilify®)	1,6,8
brexpiprazole (Rexulti®)	1,6,8
iloperidone (Fanapt®)	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.
- 2: Serum level may be too low, higher 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.

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Mood Stabilizers

This section applies to smokers and non-smokers.
The presence of the highly inducible CYP1A2 variant is not predicted to influence these medications.

Use as Directed

carbamazepine (Tegretol®)
lamotrigine (Lamictal®)
oxcarbazepine (Trileptal®)
valproic acid/divalproex (Depakote®)

Moderate Gene-drug Interaction

Significant Gene-drug Interaction

No Proven Genetic Markers

gabapentin (Neurontin®)	10	lithium (Eskalith®)	10	topiramate (Topamax®)	10
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Clinical Considerations

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 applies to smokers and non-smokers.
The presence of the highly inducible CYP1A2 variant is not predicted to influence these medications.

Use as Directed

Moderate Gene-drug Interaction

Significant Gene-drug Interaction

dexamethylphenidate (Focalin®)	4
methylphenidate (Ritalin®, Concerta®)	4

No Proven Genetic Markers

amphetamine salts (Adderall®)	10	dextroamphetamine (Dexedrine®)	10	lisdexamfetamine (Vyvanse®)	10
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Non-Stimulants

Use as Directed

Moderate Gene-drug Interaction

Significant Gene-drug Interaction

viloxazine (Qelbree®)	1
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atomoxetine (Strattera®)	1,5,8
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No Proven Genetic Markers

clonidine (Kapvay®)	10
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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.
- 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



ADRA2A Moderately Reduced Response

C/C

This patient is homozygous for the C allele of the -1291G>C polymorphism in the adrenergic alpha-2A receptor gene. This genotype suggests a moderately reduced 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 Normal 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 normal risk of serious dermatologic reactions including toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS) when taking certain mood stabilizers.

HTR2A Normal Sensitivity

G/A

This individual is heterozygous for the G allele and A allele of the -1438G>A polymorphism for the Serotonin Receptor Type 2A. They have one copy of the G allele. This genotype is not predictive of adverse drug reactions with 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

**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 Non-smoker: Extensive (Normal) Metabolizer
Smoker: Ultrarapid Metabolizer

-163C>A - A/A

CYP1A2 -163C>A - A allele enzyme activity: Highly inducible

CYP1A2 -163C>A - A allele enzyme activity: Highly inducible

This genotype may be consistent with either the extensive (normal) metabolizer phenotype or the ultrarapid metabolizer phenotype. If the patient is a non-smoker (see pg. 1 for definition), the presence of the highly inducible 'A' allele and non-smoker status indicates an extensive (normal) metabolizer phenotype. If the patient is a smoker, the presence of the highly inducible 'A' allele and smoker status indicates an ultrarapid metabolizer phenotype.

CYP2B6 Poor Metabolizer

*6/*6

CYP2B6*6 allele enzyme activity: Reduced

CYP2B6*6 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.

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 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 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 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.

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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 Smoking Dependent	CYP2B6 Poor	CYP2C19 Intermediate	CYP2C9 Normal	CYP2D6 Poor	CYP3A4 Normal	UGT1A4 Normal	UGT2B15 Normal
Antidepressants									
desvenlafaxine (Pristiq®)				●			○		
levomilnacipran (Fetzima®)				●		●	○		
Anxiolytics and Hypnotics									
alprazolam (Xanax®)							○		
buspirone (BuSpar®)						●	○		
chlordiazepoxide (Librium®)		Ⓛ					○		○
clonazepam (Klonopin®)							○		
clorazepate (Tranxene®)		Ⓛ					○		○
eszopiclone (Lunesta®)					○		○		
lemborexant (Dayvigo®)							○		
lorazepam (Ativan®)									○
oxazepam (Serax®)									○
suvorexant (Belsomra®)							○		
temazepam (Restoril®)			●		○		○		○
zolpidem (Ambien®)		Ⓛ		●	○	●	○		
Antipsychotics									
asenapine (Saphris®)		Ⓛ				●	○	○	
cariprazine (Vraylar®)						●	○		
lumateperone (Caplyta®)							○		
lurasidone (Latuda®)							○		
paliperidone (Invega®)						●	○		
thiothixene (Navane®)		Ⓛ							
ziprasidone (Geodon®)		Ⓛ					○		
Mood Stabilizers									
carbamazepine (Tegretol®)			●				○		
lamotrigine (Lamictal®)								○	
oxcarbazepine (Trileptal®)									
valproic acid/divalproex (Depakote®)			●		○			○	
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 phenotype may be ultrarapid due to smoking. Smoking status may change the medication category. Refer to sections labeled Smokers to see medication categories for individuals who smoke.

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

Patient Case Study Report

Date of Birth: MM/DD/YYYY

Clinician: Case Study Clinician

Order Number: #####

Report Date: MM/DD/YYYY

Reference:

Questions about report interpretation?

Contact our Medical Information team:

855.891.9415 | medinfo@genesight.com

Gene-drug Interactions

Moderate Gene-Drug Interaction

	CES1A1 Normal	CYP1A2 Smoking Dependent	CYP2B6 Poor	CYP2C19 Intermediate	CYP2C9 Normal	CYP2D6 Poor	CYP3A4 Normal	UGT1A4 Normal	UGT2B15 Normal
Antidepressants									
trazodone (Desyrel®)		⓪				●	○		
vilazodone (Viibryd®)				●		●	○		
Antipsychotics									
clozapine (Clozaril®)		⓪				●*	○	○	
fluphenazine (Prolixin®)		⓪		●	○	●	○		
haloperidol (Haldol®)		⓪				●	○	○	
olanzapine (Zyprexa®)		⓪				●	○	○	
quetiapine (Seroquel®)						●	○		
Stimulants									
dexmethylphenidate (Focalin®)	○								
methylphenidate (Ritalin®, Concerta®)	○								
Non-stimulants									
viloxazine (Qelbree®)						●			

Significant Gene-Drug Interaction

	CES1A1 Normal	CYP1A2 Smoking Dependent	CYP2B6 Poor	CYP2C19 Intermediate	CYP2C9 Normal	CYP2D6 Poor	CYP3A4 Normal	UGT1A4 Normal	UGT2B15 Normal
Antidepressants									
amitriptyline (Elavil®)				●*		●*			
bupropion (Wellbutrin®)			●			●	○		
citalopram (Celexa®)				●*		●	○		
clomipramine (Anafranil®)		⓪		●*		●*	○		
desipramine (Norpramin®)						●*			
doxepin (Sinequan®)		⓪		●*	○	●*	○	○	
duloxetine (Cymbalta®)		⓪				●			
escitalopram (Lexapro®)				●*		●	○		
fluoxetine (Prozac®)				●	○	●	○		
fluvoxamine (Luvox®)		⓪				●*			
imipramine (Tofranil®)		⓪		●*		●*	○		
mirtazapine (Remeron®)		⓪			○	●	○		

● 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.

⓪ This phenotype may be ultrarapid due to smoking. Smoking status may change the medication category. Refer to sections labeled Smokers to see medication categories for individuals who smoke.

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

Patient Case Study Report

Date of Birth: MM/DD/YYYY

Clinician: Case Study Clinician

Order Number: #####

Report Date: MM/DD/YYYY

Reference:

Questions about report interpretation?

Contact our Medical Information team:

855.891.9415 | medinfo@genesight.com

Gene-drug Interactions

Significant Gene-Drug Interaction (Continued)

	CES1A1 Normal	CYP1A2 Smoking Dependent	CYP2B6 Poor	CYP2C19 Intermediate	CYP2C9 Normal	CYP2D6 Poor	CYP3A4 Normal	UGT1A4 Normal	UGT2B15 Normal
Antidepressants									
nortriptyline (Pamelor®)						●*			
paroxetine (Paxil®)						●*	○		
selegiline (Emsam®)		Ⓛ	●	●			○		
sertraline (Zoloft®)			●*	●*			○		
venlafaxine (Effexor®)				●	○	●*	○		
vortioxetine (Trintellix®)			●	●	○	●*	○		
Anxiolytics and Hypnotics									
diazepam (Valium®)		Ⓛ	●	●	○		○		○
propranolol (Inderal®)		Ⓛ				●			
Antipsychotics									
aripiprazole (Abilify®)						●*	○		
brexpiprazole (Rexulti®)						●*	○		
chlorpromazine (Thorazine®)		Ⓛ				●	○		
iloperidone (Fanapt®)						●*	○		
perphenazine (Trilafon®)		Ⓛ		●		●*	○		
risperidone (Risperdal®)						●*	○		
thioridazine (Mellaril®)		Ⓛ		●		●*	○		
Non-stimulants									
atomoxetine (Strattera®)						●*			

No Proven Genetic Markers

	CES1A1 Normal	CYP1A2 Smoking Dependent	CYP2B6 Poor	CYP2C19 Intermediate	CYP2C9 Normal	CYP2D6 Poor	CYP3A4 Normal	UGT1A4 Normal	UGT2B15 Normal
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.

Ⓛ This phenotype may be ultrarapid due to smoking. Smoking status may change the medication category. Refer to sections labeled Smokers to see medication categories for individuals who smoke.

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

Patient, Sample

Date of Birth: MM/DD/YYYY

Clinician: Sample Clinician

Order Number: #####

Report Date: MM/DD/YYYY

Reference:

Questions about report interpretation?

Contact our Medical Information team:

855.891.9415 | medinfo@genesight.com

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:



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

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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.

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

Laboratory Director: Nina King, PhD

Customer Service

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

GeneSight Psychotropic Test Version: 4.2 Case Study

CONFIDENTIAL HEALTHCARE INFORMATION

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Patient Name

Page 15 of 15

Patient Case Study Report

DOB: MM/DD/YYYY
Order Number: #####
Report Date: MM/DD/YYYY
Clinician: Case Study Clinician
Reference:

Questions about report interpretation?

Contact our Medical Information team

855.891.9415

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 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, PhD, HCLD(ABB), CC(NRCC), CQ(NYSDOH)

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

6000 Mason-Montgomery Road
Mason, OH 45040

Laboratory Director: Nina King, PhD

Customer Service

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GeneSight MTHFR Test Version: 1.0