



Medication Response Genetic Test

PATIENT/CLIENT Charles Warden
 DOB: Apr 5, 1985 ID: 107261908
 Sex: Male

ORDERING PROVIDER

Carlos Ramos, MD
 NPI: 1447451323

SPECIMEN

Type: Saliva
 Barcode: 38-7218-0615-3623
 Collected: Jan 31, 2019
 Received: Feb 4, 2019

Report date: Feb 12, 2019

DETAILS

GENE	RESULT	PHENOTYPE	SUMMARY
<i>CYP2C19</i>	*1/*1	normal metabolizer	Certain medications may be metabolized at a normal rate.
<i>CYP2D6</i>	*4/*41	intermediate metabolizer	Certain medications may be metabolized at a reduced rate compared to normal metabolizers.

NOTES ABOUT YOUR RESULT

A possible drug-drug interaction was detected

A note from your ordering provider: Some of the medications you shared you are taking (indomethacin and citalopram) may have an increased risk of an interaction. Please do not make any changes to your medications before speaking to your provider. The benefits of taking these interacting medications at the same time can often outweigh the risks, and stopping a medication suddenly could be harmful. We recommend you speak with the healthcare provider who prescribed these medications to discuss if they are working as intended.

Your other medications may affect how your body processes medications

A note from your ordering provider: Some of the medications you shared you are taking (citalopram) may impact how your body may process other medications. Taking these medications at the same time may lead to a different response than the genetic results suggest. Please do not make any changes to your medications before speaking to your provider. The benefits of taking these interacting medications at the same time can often outweigh the risks, and stopping a medication suddenly could be harmful. We recommend you speak with the healthcare provider who prescribed these medications to discuss if they are working as intended.

GENES ANALYZED

The genes below were analyzed to understand how they may impact your body's processing of certain medications. Please see the test methodology and limitations section for additional information.

CYP2C19, *CYP2D6*



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**GENES
SEQUENCED**

Additional genes below have been sequenced and will soon be analyzed. This report will be updated with this information.

CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, DPYD, F5, IFNL3, NUDT15, SLCO1B1, TPMT, VKORC1



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Mental Health Medication Insights

Do not make any changes without talking to your doctor

Changing medications or dosage on your own could be harmful to your health. Also, genetics alone do not determine whether a medication is appropriate.

Color selected medications that may be processed by the genes analyzed by the Color test based on published guidelines from professional societies.¹ While the FDA labels^{2,3} for these medications acknowledge some role that genetics play in medications, the impact of genetic variations on the effectiveness of these drugs has not yet been definitively established. The guidelines from professional societies have not been approved by the FDA.

MENTAL HEALTH MEDICATIONS

More detailed medication-specific information is on the following pages

DRUGS

- Amitriptyline (Elavil®)
- Clomipramine (Anafranil®)
- Desipramine (Norpramin®)
- Doxepin (Silenor®, Zonalon®)
- Imipramine (Tofranil®)
- Nortriptyline (Pamelor®)
- Trimipramine (Surmontil®)
- Duloxetine (Cymbalta®)
- Citalopram (Celexa®)
- Escitalopram (Lexapro®)
- Fluvoxamine (Luvox®)
- Paroxetine (Paxil®)
- Sertraline (Zoloft®)

CURRENT PRESCRIPTIONS

PRESCRIPTION	LAST UPDATED
Citalopram (Celexa®)	Feb 12, 2019
Cyclosporine (Restasis®)	Feb 12, 2019
Indomethacin (Indocin®)	Feb 12, 2019

PATIENT/CLIENT	Charles Warden
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Sex: Male	

Amitriptyline (Elavil®)

Amitriptyline is typically used to treat depression by stabilizing mood.

Category: Mental Health



It's unclear how people with these genetic results will process Amitriptyline.

GENES ANALYZED

GENE	RESULT	PHENOTYPE
<i>CYP2C19</i>	*1/*1	normal metabolizer
<i>CYP2D6</i>	*4/*41	intermediate metabolizer

WHAT THIS MEANS

It is difficult to predict exactly how people with these results will process this medication because there are multiple genetic factors involved.

Based on the genes analyzed and the available guidelines,^{4,5,6} the dose of Amitriptyline may need to be different than the standard dose to work effectively and limit side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing a different starting dose, monitoring your response, and making adjustments as needed^{4,5,6}



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These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- Individuals with these *CYP2D6* results may be at an increased risk of a sub-optimal response. Consider a 25% reduction of the recommended starting dose and utilize therapeutic drug monitoring to guide dose adjustments.^{4,5,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

PATIENT/CLIENT	Charles Warden
DOB: Apr 5, 1985	ID: 107261908
Sex: Male	

Citalopram (Celexa®)

Citalopram is typically used to treat depression by stabilizing mood.

Category: Mental Health



These genetic results have been associated with being a normal metabolizer of Citalopram.

GENES ANALYZED

GENE	RESULT	PHENOTYPE
CYP2C19	*1/*1	normal metabolizer

WHAT THIS MEANS

People who are normal metabolizers may process (metabolize) this medication as expected. Because of this, this medication may remain in the body at typical levels.

The genetic results do not suggest that Citalopram will be less effective at the standard dose or have an increased risk of side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

Since you're currently taking this medication, your healthcare provider may consider:

- Prescribing the recommended starting dose and making adjustments as needed^{8,6}

These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- For individuals with these results, consider initiating therapy with the recommended starting dose.^{8,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

PATIENT/CLIENT	Charles Warden
DOB: Apr 5, 1985	ID: 107261908
Sex: Male	

Clomipramine (Anafranil®)

Clomipramine is typically used to treat obsessive-compulsive disorder (OCD).

Category: Mental Health



It's unclear how people with these genetic results will process Clomipramine.

GENES ANALYZED	GENE	RESULT	PHENOTYPE
	<i>CYP2C19</i>	*1/*1	normal metabolizer
	<i>CYP2D6</i>	*4/*41	intermediate metabolizer

WHAT THIS MEANS

It is difficult to predict exactly how people with these results will process this medication because there are multiple genetic factors involved.

Based on the genes analyzed and the available guidelines,^{4,5,6} the dose of Clomipramine may need to be different than the standard dose to work effectively and limit side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing a different starting dose, monitoring your response, and making adjustments as needed^{4,5,6}



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These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- Individuals with these *CYP2D6* results may be at an increased risk of a sub-optimal response. Consider a 25% reduction of the recommended starting dose and utilize therapeutic drug monitoring to guide dose adjustments.^{4,5,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

PATIENT/CLIENT	Charles Warden
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Sex: Male	

Desipramine (Norpramin®)

Desipramine is typically used to treat depression by stabilizing mood.

Category: Mental Health



These genetic results have been associated with being an intermediate metabolizer of Desipramine.

GENES ANALYZED	GENE	RESULT	PHENOTYPE
	CYP2D6	*4/*41	intermediate metabolizer

WHAT THIS MEANS

People who are intermediate metabolizers may process (metabolize) this medication slower than expected. Because of this, this medication may remain at higher levels in the body for longer than expected.

Based on the genes analyzed and the available guidelines,^{4,5,6} the dose of Desipramine may need to be different than the standard dose to work effectively and limit side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing a different starting dose, monitoring your response, and making adjustments as needed^{4,5,6}



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These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- Individuals with these results may be at risk for an adverse or poor response to medications that are metabolized by *CYP2D6*. A 25% reduction of the recommended starting dose may be considered. Utilize therapeutic drug monitoring to guide dose adjustments.^{4,5,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

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Sex: Male	

Doxepin (Silenor®, Zonalon®)

Doxepin is typically used to treat depression and anxiety. It can also be used to treat insomnia or itchy skin.

Category: Mental Health



It's unclear how people with these genetic results will process Doxepin.

GENES ANALYZED	GENE	RESULT	PHENOTYPE
	<i>CYP2C19</i>	*1/*1	normal metabolizer
	<i>CYP2D6</i>	*4/*41	intermediate metabolizer

WHAT THIS MEANS

It is difficult to predict exactly how people with these results will process this medication because there are multiple genetic factors involved.

Based on the genes analyzed and the available guidelines,^{4,5,6} the dose of Doxepin may need to be different than the standard dose to work effectively and limit side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing a different starting dose, monitoring your response, and making adjustments as needed^{4,5,6}



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These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- Individuals with these *CYP2D6* results may be at an increased risk of a sub-optimal response. Consider a 25% reduction of the recommended starting dose and utilize therapeutic drug monitoring to guide dose adjustments.^{4,5,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

PATIENT/CLIENT	Charles Warden
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Sex: Male	

Duloxetine (Cymbalta®)

Duloxetine is typically used to treat depression, anxiety, and some forms of chronic pain.

Category: Mental Health



These genetic results have been associated with being an intermediate metabolizer of Duloxetine.

GENES ANALYZED

GENE	RESULT	PHENOTYPE
<i>CYP2D6</i>	*4/*41	intermediate metabolizer

WHAT THIS MEANS

People who are intermediate metabolizers may process (metabolize) this medication slower than expected. Because of this, this medication may remain at higher levels in the body for longer than expected.

Based on the genes analyzed, the response to Duloxetine may be affected, but the impact is currently unclear.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing the recommended starting dose and making adjustments as needed because there are no established guidelines for this result type.^{9,6}

These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- Data are lacking describing the effect of *CYP2D6* intermediate metabolism on duloxetine therapy; therefore standard dosing recommendations may be considered.^{9,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

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Sex: Male	

Escitalopram (Lexapro®)

Escitalopram is typically used to treat depression and anxiety by stabilizing mood and promoting relaxation.

Category: Mental Health



These genetic results have been associated with being a normal metabolizer of Escitalopram.

GENES ANALYZED

GENE	RESULT	PHENOTYPE
<i>CYP2C19</i>	*1/*1	normal metabolizer

WHAT THIS MEANS

People who are normal metabolizers may process (metabolize) this medication as expected. Because of this, this medication may remain in the body at typical levels.

The genetic results do not suggest that Escitalopram will be less effective at the standard dose or have an increased risk of side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing the recommended starting dose and making adjustments as needed^{8,6}

These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- For individuals with these results, consider initiating therapy with the recommended starting dose.^{8,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

PATIENT/CLIENT	Charles Warden
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Sex: Male	

Fluvoxamine (Luvox®)

Fluvoxamine is typically used to treat obsessive-compulsive disorder (OCD).

Category: Mental Health



These genetic results have been associated with being an intermediate metabolizer of Fluvoxamine.

GENES ANALYZED

GENE	RESULT	PHENOTYPE
CYP2D6	*4/*41	intermediate metabolizer

WHAT THIS MEANS

People who are intermediate metabolizers may process (metabolize) this medication slower than expected. Because of this, this medication may remain at higher levels in the body for longer than expected.

The genetic results do not suggest that Fluvoxamine will be less effective at the standard dose or have an increased risk of side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing the recommended starting dose and making adjustments as needed^{8,6}

These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- For individuals with these results, consider initiating therapy with the recommended starting dose.^{8,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

PATIENT/CLIENT	Charles Warden
DOB: Apr 5, 1985	ID: 107261908
Sex: Male	

Imipramine (Tofranil®)

Imipramine is typically used to treat depression by stabilizing mood.

Category: Mental Health



It's unclear how people with these genetic results will process Imipramine.

GENES ANALYZED	GENE	RESULT	PHENOTYPE
	<i>CYP2C19</i>	*1/*1	normal metabolizer
	<i>CYP2D6</i>	*4/*41	intermediate metabolizer

WHAT THIS MEANS

It is difficult to predict exactly how people with these results will process this medication because there are multiple genetic factors involved.

Based on the genes analyzed and the available guidelines,^{4,5,6} the dose of Imipramine may need to be different than the standard dose to work effectively and limit side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing a different starting dose, monitoring your response, and making adjustments as needed^{4,5,6}



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These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- Individuals with these *CYP2D6* results may be at an increased risk of a sub-optimal response. Consider a 25% reduction of the recommended starting dose and utilize therapeutic drug monitoring to guide dose adjustments.^{4,5,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

PATIENT/CLIENT	Charles Warden
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Sex: Male	

Nortriptyline (Pamelor®)

Nortriptyline is typically used to treat depression by stabilizing mood.

Category: Mental Health



These genetic results have been associated with being an intermediate metabolizer of Nortriptyline.

GENES ANALYZED

GENE	RESULT	PHENOTYPE
<i>CYP2D6</i>	*4/*41	intermediate metabolizer

WHAT THIS MEANS

People who are intermediate metabolizers may process (metabolize) this medication slower than expected. Because of this, this medication may remain at higher levels in the body for longer than expected.

Based on the genes analyzed and the available guidelines,^{4,5,6} the dose of Nortriptyline may need to be different than the standard dose to work effectively and limit side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing a different starting dose, monitoring your response, and making adjustments as needed^{4,5,6}



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Sex: Male	

These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- Individuals with these results may have higher than expected plasma concentrations of nortriptyline resulting in an increased probability of adverse reactions. Consider a 25% reduction of recommended starting dose. Utilize therapeutic drug monitoring to guide dose adjustments.^{4,5,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

PATIENT/CLIENT	Charles Warden
DOB: Apr 5, 1985	ID: 107261908
Sex: Male	

Paroxetine (Paxil®)

Paroxetine is typically used to treat depression, obsessive-compulsive disorder (OCD), and other related issues.

Category: Mental Health



These genetic results have been associated with being an intermediate metabolizer of Paroxetine.

GENES ANALYZED

GENE	RESULT	PHENOTYPE
CYP2D6	*4/*41	intermediate metabolizer

WHAT THIS MEANS

People who are intermediate metabolizers may process (metabolize) this medication slower than expected. Because of this, this medication may remain at higher levels in the body for longer than expected.

The genetic results do not suggest that Paroxetine will be less effective at the standard dose or have an increased risk of side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing the recommended starting dose and making adjustments as needed^{8,6}

These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- For individuals with these results, consider initiating therapy with the recommended starting dose.^{8,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

PATIENT/CLIENT	Charles Warden
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Sex: Male	

Sertraline (Zoloft®)

Sertraline is typically used to treat depression, obsessive-compulsive disorder (OCD), and other related issues.

Category: Mental Health



These genetic results have been associated with being a normal metabolizer of Sertraline.

GENES ANALYZED	GENE	RESULT	PHENOTYPE
	CYP2C19	*1/*1	normal metabolizer

WHAT THIS MEANS

People who are normal metabolizers may process (metabolize) this medication as expected. Because of this, this medication may remain in the body at typical levels.

The genetic results do not suggest that Sertraline will be less effective at the standard dose or have an increased risk of side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing the recommended starting dose and making adjustments as needed^{8,6}

These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- For individuals with these results, consider initiating therapy with the recommended starting dose.^{8,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>

PATIENT/CLIENT	Charles Warden
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Sex: Male	

Trimipramine (Surmontil®)

Trimipramine is typically used to treat depression by stabilizing mood.

Category: Mental Health



It's unclear how people with these genetic results will process Trimipramine.

GENES ANALYZED

GENE	RESULT	PHENOTYPE
<i>CYP2C19</i>	*1/*1	normal metabolizer
<i>CYP2D6</i>	*4/*41	intermediate metabolizer

WHAT THIS MEANS

It is difficult to predict exactly how people with these results will process this medication because there are multiple genetic factors involved.

Based on the genes analyzed and the available guidelines,^{4,5,6} the dose of Trimipramine may need to be different than the standard dose to work effectively and limit side effects.⁷

NEXT STEPS

Next steps

These results can't tell if you will or will not experience side effects or need to change medications. Your doctor will consider many factors when choosing the right medication and dosage for you, but your genetic results can help. Some other factors your doctor may consider include health history, body weight, lifestyle, and other medications you're taking.

If you are prescribed this medication in the future, this information may be useful for you. Your healthcare provider may consider:

- Prescribing a different starting dose, monitoring your response, and making adjustments as needed^{4,5,6}



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These are more detailed recommendations for your healthcare provider. They may consider these guidelines, along with other information they have about you, to inform your personalized medication plan:

- Individuals with these *CYP2D6* results may be at an increased risk of a sub-optimal response. Consider a 25% reduction of the recommended starting dose and utilize therapeutic drug monitoring to guide dose adjustments.^{4,5,6}
- Please consult a clinical pharmacist for more information.
- Refer to FDA drug label for additional information at <https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm>



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TEST METHODOLOGY AND LIMITATIONS

Methodology

Genomic DNA is extracted from the submitted sample, enriched for select regions using a hybridization protocol, and sequenced using Illumina Next Generation Sequencing. Sequence data is aligned to a reference genome, and variants are identified using a suite of bioinformatic tools designed to detect single nucleotide variants, small insertions/deletions, copy number variants, insertions and inversions, and to infer diplotypes. Reported variants may be confirmed by alternate technologies, including Sanger sequencing, MLPA, aCGH or probe-based genotyping. Analysis, variant calling and reporting focus on the complete coding sequence and adjacent intronic sequence of the primary transcript(s), unless otherwise indicated.

This test was developed and its performance characteristics determined by Color Genomics, Inc. ("Color"), a clinical laboratory accredited by the College of American Pathologists (CAP) and certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing (CAP #8975161 - CLIA #05D2081492). This laboratory developed test has not been cleared or approved by the United States Food and Drug Administration (FDA). The FDA does not require this laboratory developed test to go through premarket FDA review. This test is used for clinical purposes. It should not be regarded as investigational or for research.

Variants, alleles and diplotypes are classified and described using recommended star-allele and metabolizer-effect nomenclature, where appropriate (PMID: 26479518).

Genes & Transcripts

CYP2C19, *CYP2D6*

Limitations

This analysis aims to detect the presence or absence of any of the following alleles, or genotypes at the specified positions:

CYP2D6: *2, *3, *4, *5, *6, *7, *8, *9, *10, *11, *12, *14A, *14B, *15, *17, *19, *29, *35, *41, *xN

CYP2C19: *2, *3, *4A, *4B, *10, *17

This analysis does not detect all possible variations in the tested genes; in some cases the reported result may be refined as new alleles are added to the analysis. When *1 is reported, it indicates that none of the alleles listed above were identified; it does not rule out the presence of an allele not analyzed by this test, and does not rule out the possibility that a non-normal allele is present. In some cases, observed data can be consistent with more than one possible diplotype, and in these cases the diplotype may be reported as "indeterminate". *CYP2D6* copy number is inferred from read depth at representative regions, but does not allow differentiation between partial and whole gene deletions and/or multiplications. Hybrid alleles in *CYP2D6* are not detected.

This test is not designed to detect chromosomal aneuploidy or complex rearrangements such as translocations. It also does not reliably detect mosaicism. The sensitivity to detect deletions and duplications in the range of 40-250bp, as well as those which deletion/duplication do not overlap more than 250bp of contiguous coding sequence, may be reduced. The presence of a large insertion may interfere with the chemistry used to target the genes of interest, which could decrease the detection sensitivity. In addition, the sequence and identity of a large insertion may not be completely resolved. Inversions including at least one coding exon will be detected only if the breakpoints are covered by the Color test. The sensitivity to detect variants may be reduced in regions of low/high GC content, and in the vicinity of homopolymers and simple sequence repeats.

Color only reports findings within the genes that are on the panel. It is important to understand that there may be variation in those genes that current technology is not able to detect, and that there may be additional relevant genes that are not included in this test. In the unlikely event a variant is detected that is not associated with the intended use of this test, this information will not be included in the report. Genetic counseling, clinical pharmacist, and/or physician consultation may be warranted to ensure complete understanding of your test results.

In very rare cases, such as allogeneic bone marrow transplant, or recent blood transfusion (within 7 days of testing), the results of germline DNA analysis may be complicated by donor mutations. DNA quality may be affected if a participant has received chemotherapy within the last 120 days. In addition, certain organ transplants or diseases (liver, kidney, heart) may limit the relevance of the results.



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PATIENT/CLIENT	Charles Warden
DOB: Apr 5, 1985	ID: 107261908
Sex: Male	

Disclaimers

Color implements several safeguards to avoid technical errors, such as automated sample handling and barcode scanning at several steps throughout the sequencing process. Color is not responsible for errors in specimen collection, transportation, and activation or other errors made prior to receipt at our laboratory. Due to the complexity of genetic testing, diagnostic errors, although rare, may occur due to sample mix-up, DNA contamination, or other laboratory operational errors (including, without limitation, equipment or reagent failure, or upstream supplier errors). In addition, poor sample DNA quality and certain characteristics inherent to specific regions of an individual's genomic DNA may limit the accuracy of results in those regions.

All classifications are based on review, interpretation, and/or analysis of evidence available at the time of reporting, including without limitation medical literature and scientific databases, and may change as new evidence becomes available.

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