# Genecept Assay® Report

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| **Hasta:** | Adı Soyadı | **Hasta No:** | 01 |
|---|---|---|---|
| **Doğum Tarihi:** | 12/28/2000 | **Protokol No:** | 1 |
| **İstemi Yapan Dr.:** | Doktor İsmi | **Numune Alma Tarihi:** | 12/26/2017 |
| **Numune Tipi:** | Buccal | **Lab Kabul Tarihi:** | 12/27/2017 |
| **İstenen Test:** | Genecept Assay 2.0 | **Sonuçlanma Tarihi:** | 1/12/2018 1:17 PM |

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**Literatür Bilgileri Gözlemcileri**
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## Bu Rapor Nasıl Okunmalı?

Bu raporda yer alan bilgiler, ortak genetik polimorfizmler ve bunların davranışa, psikiyatrik durumlara ve ilaç yanıtına olan etkileri ile ilgili araştırmalara dayanmaktadır. Sonuç yorumları sadece psikotrop terapilere odaklanır. Psikotropik olmayan terapilerle ilgili çıkarımlar değişebilir ve bu raporda dikkate alınmamıştır. Bu sonuçlar, spesifik tedavi önerilerini teşhis etmek veya yapmak için tasarlanmamıştır. Tüm görüntüler sadece bilgi amaçlıdır. Bu rapordaki ilaçlar ve tedaviler kapsamlı veya kuralcı değildir.

**Klinisyenler için Kişiselleştirilmiş Danışma**
Klinik Destek Ekibimiz, biyobelirteçlerin klinik yorumunu sağlamak ve genetik test sonuçlarını potansiyel tedavi stratejilerine çevirmek ve ayrıca raporla ilgili sorularınızı cevaplamak için mevcuttur. Bu ücretsiz hizmet tüm Genecept Testi testleri ile birlikte gelir. Klinik istişareler doğrudan Genomind Portalından programlanabilir.

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**Referanslar:**
Bu raporda yer alan alıntılar, Genomind Edebiyat Özeti'nde bulunan referanslara karşılık gelmektedir. Literatür Özeti **http://portal.genomind.com** adresinde bulunabilir veya customerservice@genomind.com veya 877-895-8658 numaralı telefonlardan bir kopyasını istemek için Genomind ile iletişime geçebilirsiniz.

# BULGULAR RAPORU: Farmakodinamik Gen Varyasyonları; İlaç Hedef Bölgeleri

İlgili tedavilerle dikkatli olun | Tedavi seçenekleri | Bilinen gen-ilaç etkileşimi yok

| GENE RESULT | THERAPEUTIC IMPLICATIONS | INTERACTION | CLINICAL IMPACT |
|---|---|---|---|
| Serotonin Transporter (SLC6A4)<br>L(A)/S<br>[Orta risk] | *SLC6A4, serotonin geri alımından sorumlu bir presinaptik transmembran proteindir.*<br>• SSRI'lar, bu taşıyıcıyı terapötik bir yanıt üretmek için bloke ederek hareket ederler<br>• S veya L (G) allel taşıyıcılarında SSRI'lara karşı daha yüksek yan etki veya intolerans riski.<br>• SNRI veya non-SSRI antidepresanlar gibi tedavi seçenekleri klinik olarak endike is kullanılabilir. | | **Use caution** with SSRIs<br>**Therapeutic options: SNRIs** or **non-SSRI antidepressants** may be used if clinically indicated |
| Dopamine 2 Receptor (DRD2)<br>DEL/DEL<br>[Zayıf yanıt için yüksek risk] | *DRD2 beyinde dopamin tarafından etkilenen bir reseptördür*<br>• DRD2 antipsikotik ajanlar ile modüle edilir.<br>• Düşük ekspresyon ve reseptör yoğunluğuna bağlı olarak antipsikotiklerle zayıf yanıt ve kilo alma riski daha yüksektir<br>• DEL alleli olan hastalar daha yüksek opioid bağımlılığı riski altında olabilirler. | | **Use caution** with antipsychotics and opioids |
| Alpha-2A Adrenergic Receptor (ADRA2A)<br>C/G<br>[Geliştirilmiş yanıt] | *ADRA2A is a receptor which plays an important role in neurotransmitter release*<br>• Improved response to stimulants for symptoms of attention deficit/hyperactivity disorder as compared to patients with the C/C genotype | | **Therapeutic options: stimulants** may be used for attention deficit/hyperactivity disorder if clinically indicated |
| Methylenetetrahydro-folate Reductase (MTHFR)<br>C677T:<br>T/T<br>A1298C:<br>A/A<br>[Düşük Aktivite] | *MTHFR is an enzyme responsible for the conversion of folic acid to methylfolate which is a cofactor needed for serotonin, norepinephrine and dopamine synthesis*<br>• Risk for reduced MTHFR enzyme activity and reduced methylfolate production<br>• L-methylfolate supplementation of SSRIs and SNRIs show improved symptom reduction and medication adherence compared to SSRIs/SNRIs alone in Major Depressive Disorder<br>• L-methylfolate may be an effective monotherapy for patients with Major Depressive Disorder | | **Therapeutic options: L-methylfolate** may be used if clinically indicated |
| Brain-derived Neurotrophic Factor (BDNF)<br>Met/Met | *BDNF is a protein involved in neuronal development and neural plasticity*<br>• Potential risk for increased depression symptoms, impaired working memory, and altered stress response<br>• Studies have shown that Met carriers may have less satisfactory response to SSRIs in Caucasians, but not Asians, however larger studies need to be conducted to confirm these findings<br>• Exercise has been linked to improvements in cognition, and recent studies show that Met allele carriers may demonstrate enhanced effects of exercise on working memory compared to Val/Val patients | | **Therapeutic options:** increased levels of **physical activity/exercise** if clinically appropriate |
| Calcium Channel (CACNA1C)<br>G/G<br>[Normal] | *CACNA1C is a subunit of L-type voltage gated calcium channels which is involved in excitatory signaling in the brain*<br>• This genotype confers normal activity | | There are no known gene-drug interactions for this genotype |
| Sodium Channel (ANK3)<br>C/T<br>[Değişmiş nöronal sinyallemenin orta riski] | *ANK3 is a protein that plays a role in sodium ion channel function and is involved in excitatory signaling in the brain*<br>• A single T allele confers a modest increased risk for altered neuronal signaling, however this modest increased risk is unlikely to be clinically significant<br>• This genotype confers normal activity | | There are no known gene-drug interactions for this genotype |
| Serotonin Receptor 2C (5HT2C)<br>T/T<br>[Lower weight gain risk] | *5HT2C is a receptor involved in the regulation of satiety*<br>• The T allele confers a protective effect against risk of weight gain with atypical antipsychotics as compared to the C/C genotype | | There are no known gene-drug interactions for this genotype |
| Melanocortin 4 Receptor (MC4R)<br>C/C<br>[Normal] | *MC4R is a receptor that plays a central role in the control of food intake*<br>• MC4R is involved in antipsychotic-induced weight gain<br>• This genotype confers normal activity | | There are no known gene-drug interactions for this genotype |
| Catechol-O-Methyltransferase (COMT)<br>Val/Met<br>[Normal] | *COMT is an enzyme responsible for breakdown of dopamine in the frontal cortex of the brain*<br>• COMT is involved in response to stimulants<br>• This genotype confers normal activity | | There are no known gene-drug interactions for this genotype |

Use caution with related therapies | Therapeutic options | No known gene-drug interaction

| GENE RESULT | THERAPEUTIC IMPLICATIONS | INTERACTION | CLINICAL IMPACT |
|---|---|---|---|
| μ-Opioid Receptor (OPRM1)<br>A/A<br>[Normal response] | *OPRM1 is an opioid receptor which is affected by natural and synthetic compounds*<br>• OPRM1 is involved in response to opioids<br>• This genotype confers normal activity | ✓ | There are no known gene-drug interactions for this genotype |
| Glutamate Receptor Kainate 1 (GRIK1)<br>A/C<br>[Normal] | *GRIK1 is an excitatory neurotransmitter receptor*<br>• GRIK1 is involved in response to topiramate for alcohol abuse<br>• Patients of European descent with the A allele may be less likely to respond to topiramate for alcohol abuse | ✓ | There are no known gene-drug interactions for this genotype |

## RESULTS REPORT: Pharmacokinetic Gene Variations; CYP450 Drug Metabolism

| GENE RESULT | THERAPEUTIC IMPLICATIONS | INTERACTION | CLINICAL IMPACT |
|---|---|---|---|
| CYP2C19<br>PM<br>*2/*2<br>[Low activity] | ***Poor metabolizer:*** *↑ risk of elevated serum levels and drug interactions*<br>• A dose adjustment or alternate therapy may be necessary | ⚠ | **Use caution** with medications metabolized by CYP2C19<br>*See Drug Interaction Summary for details* |
| CYP1A2<br>EM<br>*1A/*1F<br>[Normal activity and risk for induction **in the presence of inducers**] | *Variations in the CYP1A2 liver enzyme can result in altered drug metabolism and unexpected drug serum levels*<br>• This genotype confers normal activity<br>• This patient, however, **in the presence of inducers**, is *at risk for induction of CYP1A2* which may increase metabolism due to the presence of the *1F allele (see the Genecept Assay Report Interpretation Guide for full list of inducers) | ✓ | There are no known gene-drug interactions for this genotype |
| CYP2B6<br>EM<br>*1/*1<br>[Normal activity] | *Variations in the CYP2B6 liver enzyme can result in altered drug metabolism and unexpected drug serum levels*<br>• This genotype confers normal activity | ✓ | There are no known gene-drug interactions for this genotype |
| CYP2C9<br>EM<br>*1/*1<br>[Normal activity] | *Variations in the CYP2C9 liver enzyme can result in altered drug metabolism and unexpected drug serum levels*<br>• This genotype confers normal activity | ✓ | There are no known gene-drug interactions for this genotype |
| CYP2D6<br>EM<br>*1/*4<br>[Normal activity] | *Variations in the CYP2D6 liver enzyme can result in altered drug metabolism and unexpected drug serum levels*<br>• This genotype confers normal activity | ✓ | There are no known gene-drug interactions for this genotype |
| CYP3A4<br>*1/*1<br>CYP3A5<br>*3/*3<br>[Normal activity] | *Variations in the CYP3A4/5 liver enzymes can result in altered drug metabolism and unexpected drug serum levels*<br>• This genotype confers normal activity<br>• CYP3A activity is determined by the sum activity of the CYP3A family of genes; in adults the most influential are CYP3A4 and 3A5 | ✓ | There are no known gene-drug interactions for this genotype |

This is based upon a review of the literature that is suggestive of treatments which may be appropriate and those that may be used with caution or avoided. Clinicians should review the full prescribing information of treatments being considered and should make their own treatment decisions based upon their knowledge as it relates to the patient. The selection of any therapeutic option is at the sole discretion of the prescriber. The physician is a learned intermediary and should be making all decisions based on experience and knowledge as related to the patient. The prescriber is expected to be well versed in the adverse effects and monitoring parameters of any medications prescribed or recommended to patients. Medications in this report are listed in alphabetical order; listing of medications is not meant to imply comparable efficacy or safety. Brand names are listed for exemplary purposes only; additional brand names exist and Genomind does not endorse or support any particular product. All registered trademarks are the property of their respective owners.

## Drug Interaction Summary:

This summary provides a listing of implications for psychotropic and pain medications specific to your patient's genetic profile

| | Medication | Primary metabolizing enzyme(s) | Use as Directed: No known gene-drug interactions | Therapeutic Options: Options which may be used if clinically indicated | Use with Caution: CYP450: Serum levels may be ↑ [reduced dose may be required] | Use with Caution: CYP450: Serum levels may be ↓ [increased dose may be required] | Use with Caution: Increased risk for adverse events or poor response |
|---|---|---|---|---|---|---|---|
| | **Antidepressants** | | | SLC6A4 | | | SLC6A4 |
| SSRIs | Citalopram (Celexa®) ℞ | 2C19 | | | ✓ | | ✓ |
| SSRIs | Escitalopram (Lexapro® ) | 2C19 | | | ✓ | | ✓ |
| SSRIs | Fluoxetine (Prozac®) | 2D6, 2C9 | | | | | ✓ |
| SSRIs | Fluvoxamine (Luvox®) | 2D6, 1A2 | | | | | ✓ |
| SSRIs | Paroxetine (Paxil®) | 2D6 | | | | | ✓ |
| SSRIs | Sertraline (Zoloft®) | 2C19, 2B6 | | | ✓ | | ✓ |
| SNRIs | Desvenlafaxine (Pristiq®) | -- | ✓ | ✓ | | | |
| SNRIs | Duloxetine (Cymbalta®) | 1A2, 2D6 | ✓ [6] | ✓ | | | |
| SNRIs | Levomilnacipran (Fetzima®) | 3A4/5 | ✓ | ✓ | | | |
| SNRIs | Milnacipran (Savella®) | -- | ✓ | ✓ | | | |
| SNRIs | Venlafaxine (Effexor®) [1] | 2D6, 2C19, 3A4/5 | | ✓ | ✓ | | |
| Other | Bupropion (Wellbutrin®) [1] | 2B6 | ✓ | ✓ | | | |
| Other | Mirtazapine (Remeron®) | 2D6, 3A4/5, 1A2 | ✓ [6] | ✓ | | | |
| Other | Nefazodone | 3A4/5 | ✓ | ✓ | | | |
| Other | Trazodone (Desyrel®, Oleptro®) | 3A4/5, 2D6 | ✓ | ✓ | | | |
| Other | Vilazodone (Viibryd®) | 3A4/5 | ✓ | ✓ | | | |
| Other | Vortioxetine (Trintellix®) ℞ | 2D6, 3A4/5 | ✓ | ✓ | | | |
| TCAs | Amitriptyline (Elavil®) | 2D6, 2C19 | | | ✓ | | |
| TCAs | Amoxapine (Asendin®) | 2D6 | ✓ | | | | |
| TCAs | Clomipramine (Anafranil®) | 2D6, 2C19, 1A2 | | | ✓ | | |
| TCAs | Desipramine (Norpramin®) | 2D6 | ✓ | | | | |
| TCAs | Doxepin (Sinequan®) | 2D6, 2C19 | | | ✓ | | |
| TCAs | Imipramine (Tofranil®) | 2D6, 2C19 | | | ✓ | | |
| TCAs | Nortriptyline (Pamelor®) | 2D6 | ✓ | | | | |
| TCAs | Protriptyline (Vivactil®) | 2D6 | ✓ | | | | |
| TCAs | Trimipramine (Surmontil®) | 2D6, 2C19 | | | ✓ | | |
| MAOIs | Phenelzine (Nardil®) | -- | ✓ | | | | |
| MAOIs | Selegiline (Eldepryl®, Emsam®) | 2B6 | ✓ | | | | |
| MAOIs | Tranylcypromine (Parnate®) | -- | ✓ | | | | |
| | **Mood Stabilizers/Anticonvulsants** | | | | | | |
| | Carbamazepine (Tegretol®) | 3A4/5 | ✓ | | | | |
| | Gabapentin (Neurontin®, Gralise®) | -- | ✓ | | | | |
| | Lamotrigine (Lamictal®) | -- | ✓ | | | | |
| | Lithium (Lithobid®, Eskalith®) | -- | ✓ | | | | |
| | Oxcarbazepine (Trileptal®) | -- | ✓ | | | | |
| | Pregabalin (Lyrica®) | -- | ✓ | | | | |
| | Topiramate (Topamax®) | -- | ✓ | | | | |
| | Valproate (Depakote®, Depakene®) | 2C9 | ✓ | | | | |

*See last page for drug interaction summary footnotes

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|---|---|---|---|---|---|---|
| **Atypical Antipsychotic** | | | | | | DRD2 |
| Aripiprazole (Abilify®) | 2D6, 3A4/5 | | | | | ✓ [4] |
| Asenapine (Saphris®) | 1A2 | | | | | ✓ [4] |
| Brexpiprazole (Rexulti®) | 2D6, 3A4/5 | | | | | ✓ [4] |
| Cariprazine (Vraylar®) | 3A4/5 | | | | | ✓ [4] |
| Clozapine (Clozaril®) | 1A2, 3A4/5 | | | | | ✓ [4] |
| Iloperidone (Fanapt®) | 2D6, 3A4/5 | | | | | ✓ [4] |
| Lurasidone (Latuda®) | 3A4/5 | | | | | ✓ [4] |
| Olanzapine (Zyprexa®) | 1A2 | | | | | ✓ [4] |
| Paliperidone (Invega®) | -- | | | | | ✓ [4] |
| Quetiapine (Seroquel®) | 3A4/5 | | | | | ✓ [4] |
| Risperidone (Risperdal®) | 2D6, 3A4/5 | | | | | ✓ [4] |
| Ziprasidone (Geodon®) | -- | | | | | ✓ [4] |
| **Typical Antipsychotic** | | | | | | DRD2 |
| Chlorpromazine (Largactil®, Thorazine®) | 2D6 | | | | | ✓ [4] |
| Fluphenazine (Prolixin®) | 2D6 | | | | | ✓ [4] |
| Haloperidol (Haldol®) | 2D6, 3A4/5 | | | | | ✓ [4] |
| Loxapine (Loxitane®) | 3A4/5, 1A2 | | | | | ✓ [4] |
| Perphenazine (Trilafon®) | 2D6 | | | | | ✓ [4] |
| Pimozide (Orap®) | 2D6, 3A4/5 | | | | | ✓ [4] |
| Promethazine (Phenergan®) | 2D6 | | | | | ✓ [4] |
| Thioridazine (Mellaril®) | 2D6 | | | | | ✓ [4] |
| Thiothixene (Navane®) | 1A2 | | | | | ✓ [4] |
| Trifluoperazine (Stelazine®) | 1A2 | | | | | ✓ [4] |
| **Anxiolytic** | | | | | | |
| Alprazolam (Xanax®) | 3A4/5 | ✓ | | | | |
| Buspirone (Buspar®) | 3A4/5 | ✓ | | | | |
| Chlordiazepoxide (Librium®) | 3A4/5 | ✓ | | | | |
| Clonazepam (Klonopin®) | 3A4/5 | ✓ | | | | |
| Clorazepate (Tranxene®) | -- | ✓ | | | | |
| Diazepam (Valium®) | 2C19, 3A4/5 | | | ✓ | | |
| Hydroxyzine (Vistaril®) | -- | ✓ | | | | |
| Lorazepam (Ativan®) | -- | ✓ | | | | |
| Oxazepam (Serax®) | -- | ✓ | | | | |
| Propranolol (Inderal®) | 2D6, 1A2, 2C19 | | | ✓ | | |
| Temazepam (Restoril®) | -- | ✓ | | | | |
| **Dopaminergic Stimulants Agents** | | | ADRA2A | | | |
| Amphetamine-Dextroamphetamine (Adderall®, Evekeo®, Dyanavel®, Adzenys®) | 2D6 | ✓ | ✓ | | | |
| Dexmethylphenidate (Focalin®) | -- | ✓ | ✓ | | | |
| Dextroamphetamine (Dexedrine®, Procentra®, Zenzedi®) | -- | ✓ | ✓ | | | |
| Lisdexamfetamine (Vyvanse®) | -- | ✓ | ✓ | | | |
| Methamphetamine (Desoxyn®) | 2D6 | ✓ | ✓ | | | |
| Methylphenidate (Ritalin®, Concerta®, Daytrana®, Metadate®) | -- | ✓ | ✓ | | | |

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|---|---|---|---|---|---|---|---|
| | **Miscellaneous Stimulants; NRIs; α2-Agonists** | | | | | | |
| | Armodafinil (Nuvigil®) | 3A4/5 | ✓ | | | | |
| | Atomoxetine (Strattera®) | 2D6 | ✓ | | | | |
| | Clonidine (Kapvay®) | 2D6 | ✓ | | | | |
| | Guanfacine (Intuniv®) | 3A4/5 | ✓ | | | | |
| | Modafinil (Provigil®) | 3A4/5 | ✓ | | | | |
| | **Alternative/Complementary** | | | MTHFR | | | |
| | L-methylfolate (EnLyte®, Deplin®) | -- | ✓ | ✓ | | | |
| | Omega-3-Fatty Acids | -- | ✓ | | | | |
| | **Sleep Modulator** | | | | | | |
| | Eszopiclone (Lunesta®) | 3A4/5 | ✓ | | | | |
| | Ramelteon (Rozerem®) | 1A2 | ✓ [6] | | | | |
| | Suvorexant (Belsomra®) | 3A4/5, 2C19 | | | ✓ | | |
| | Zaleplon (Sonata®) | 3A4/5 | ✓ | | | | |
| | Zolpidem (Ambien®) | 3A4/5 | ✓ | | | | |
| | **Pain** | | | | | | DRD2 |
| Non-opioid analgesics | Acetaminophen (Tylenol®) | -- | ✓ | | | | |
| Non-opioid analgesics | Celecoxib (Celebrex®) | 2C9 | ✓ | | | | |
| Non-opioid analgesics | Diclofenac (Voltaren®, Cataflam®) | 2C9 | ✓ | | | | |
| Non-opioid analgesics | Flurbiprofen (Ansaid®) | 2C9 | ✓ | | | | |
| Non-opioid analgesics | Ibuprofen (Advil®, Motrin®) | 2C9 | ✓ | | | | |
| Non-opioid analgesics | Ketorolac (Toradol®) | -- | ✓ | | | | |
| Non-opioid analgesics | Meloxicam (Mobic®) | 2C9 | ✓ | | | | |
| Non-opioid analgesics | Naproxen (Aleve®, Naprosyn®) | 1A2, 2C9 | ✓ [6] | | | | |
| Non-opioid analgesics | Piroxicam (Feldene®) | 2C9 | ✓ | | | | |
| Opioids | Alfentanil (Alfenta®) | 3A4/5 | | | | | ✓ [12] |
| Opioids | Codeine [1] | 2D6 | | | | | ✓ [12] |
| Opioids | Fentanyl (Duragesic®) | 3A4/5 | | | | | ✓ [12] |
| Opioids | Hydrocodone [1] | 2D6 | | | | | ✓ [12] |
| Opioids | Hydromorphone (Dilaudid®) | -- | | | | | ✓ [12] |
| Opioids | Meperidine (Demerol®) | 2B6, 3A4/5 | | | | | ✓ [12] |
| Opioids | Methadone (Dolophine®, Methadose®) | 3A4/5, 2B6 | | | | | ✓ [12] |
| Opioids | Morphine (MS Contin®, Kadian®) | -- | | | | | ✓ [12] |
| Opioids | Oxycodone (Oxycontin®) | 2D6, 3A4/5 | | | | | ✓ [12] |
| Opioids | Oxymorphone (Opana®) | -- | | | | | ✓ [12] |
| Opioids | Tapentadol (Nucynta®) | -- | | | | | ✓ [12] |
| Opioids | Tramadol (Ultram®) | 2D6, 3A4/5 | | | | | ✓ [12] |

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|---|---|---|---|---|---|---|
| **Miscellaneous** | | | | | | |
| Baclofen (Lioresal®) | -- | ✓ | | | | |
| Buprenorphine (Butrans®) | 3A4/5 | ✓ | | | | |
| Buprenorphine/Naloxone (Suboxone®) | 3A4/5 | ✓ | | | | |
| Carisoprodol (Soma®) | 2C19 | | | ✓ | | |
| Cyclobenzaprine (Flexeril®) | 1A2 | ✓ [6] | | | | |
| Gabapentin enacarbil (Horizant®) | -- | ✓ | | | | |
| Lorcaserin (Belviq®) | MultiCYP [11] | ✓ | | | | |
| Metaxalone (Skelaxin®) | MultiCYP [11] | ✓ | | | | |
| Metformin (Glucophage®) | -- | ✓ | | | | |
| Methocarbamol (Robaxin®) | -- | ✓ | | | | |
| Naltrexone (Revia®, Vivitrol®) | -- | ✓ | | | | |
| Tizanidine (Zanaflex®) | 1A2 | ✓ [6] | | | | |
| Tolcapone (Tasmar®) | -- | ✓ | | | | |

*See last page for drug interaction summary footnotes

## DRUG INTERACTION SUMMARY FOOTNOTES

[1] Prodrug or highly active metabolite - requiring activation by the liver; CYP450 IMs/PMs may experience lower efficacy due to reduced conversion to the active metabolite and higher levels of the parent drug; CYP450 UMs may experience increased conversion of the parent drug, and higher levels of the active metabolite

[4] This medication is listed to use with caution due to a DRD2 variation which may lead to side effects and non-response with antipsychotics

[6] This patient has a variation in CYP1A2 which may lead to increased metabolism of this drug **in the presence of CYP1A2 inducers**, use caution; see the Genecept Assay Report Interpretation Guide for information related to CYP1A2 inducers

[11] MultiCYP - This drug is metabolized by multiple CYP450 enzymes, each having a minor effect on the drug's overall metabolism; abnormal activity in any one CYP450 enzyme is unlikely to be clinically significant for this drug

[12] Opioids are not contraindicated, although, patients with a DRD2 variation may be more likely to develop opioid dependence; use with caution

Medication has manufacturer dose-administration FDA labeling; see the Genecept Assay Report Interpretation Guide

*References for the drug interaction summary are available upon request

## TEST METHODOLOGY

This test was developed and performance characteristics were validated in the Genomind clinical laboratory. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). FDA does not require review of this test because it is a Lab-Developed Test (LDT). This test is used for clinical purposes and should not be regarded as investigational or for research use. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. Genomind performed the testing using standard and custom TaqMan reagents for all variants. The test results are intended to be used as prognostic and not diagnostic and are not intended as the sole means for patient management decisions.

**Test Methodology Limitations:** Factors influencing the amount and quality of DNA extracted include but are not limited to the amount of buccal cells extracted, patient oral hygiene, collection technique, and the presence of dietary or microbial sources of nucleic acids and nucleases. DNA quality and quantity are subject to matrix dependent influences. PCR inhibitors, extraneous DNA and nucleic acid degrading enzymes are all factors which may affect the evaluation of assay results. Some SNP assays are problematic due to multiple base repeats and other sequence aberrations which may hinder proper amplification and analysis. DNA purity can influence the assay. SLC6A4 contains many polymorphisms and the assay was developed and validated according to the current available scientific information. For pharmacogenetics tests like Genecept, undetected genetic and/or non-genetic factors such as drug-drug interactions may impact the phenotype. The Genecept report is based on a current understanding of the clinical relevance of the variant identified, penetrance, phenotype predictions, and recurrence risks.

Variants tested include SLC6A4 rs25531 and 5-HTTLPR; CACNA1C rs1006737; ANK3 rs10994336; 5HT2C rs3813929; MC4R rs489693; DRD2 rs1799732; COMT rs4680; ADRA2A rs1800544; MTHFR C677T and A1298C; BDNF rs6265; OPRM1 rs1799971; GRIK1 rs2832407; CYP1A2 *1C, *1D, *1E, *1F and *11; CYP2B6 *5, *6, and *7; CYP2C9 *2, *3, *4, *5, *6, *8, *11, *13, and *27; CYP2C19 *2, *3, *4, *5, *6, *7, *8, *9, *10, and *17; CYP2D6 *2, *3, *4, gene deletion (*5), gene duplication, *6, *7, *8, *9, *10, *11, *12, *14, *15, *17, *29 and *41; CYP3A5 *3, *6, *7; and CYP3A4 *22. Other known variants that are not listed are not detected and will not be included in the test report.

## LITERATURE REFERENCES

**THE LITERATURE INFORMATION UPON WHICH THIS REPORT RELIES WAS AGGREGATED AND REVIEWED BY GENOMIND, INC. SUMMARIES OF THESE NUMBERED REFERENCES BELOW ARE AVAILABLE UPON REQUEST OF GENOMIND'S COMPREHENSIVE LITERATURE SUMMARY [v2017-05].**

| Gene | References |
|---|---|
| **SLC6A4** | 1-24 |
| **CACNA1C** | 25-55 |
| **ANK3** | 26,28,30,35,37,46-49,56-64 |
| **5HT2C** | 7,65-75 |
| **MC4R** | 74,76-82 |
| **DRD2** | 83-87 |
| **COMT** | 88-117 |
| **ADRA2A** | 118-125 |
| **MTHFR** | 126-138 |

| Gene | References |
|---|---|
| **BDNF** | 139-161 |
| **OPRM1** | 162-172 |
| **GRIK1** | 173-177 |
| **CYP1A2** | 72,178-206 |
| **CYP2B6** | 178-182,199,203,207-220 |
| **CYP2C9** | 178-182,186,203,207,221-232 |
| **CYP2C19** | 7,178-182,199,203,207,216,222-224,231-244 |
| **CYP2D6** | 7,72,178-183,186,199-200,203,207,222-224,231-232,235,245-266 |
| **CYP3A4/5** | 7,72,178-183,186,199-200,203,207,216,267-269 |