

RightMed[®] Oncology Medication Report

The RightMed Oncology Report is a specialty report. It contains a set of medications selected and classified by OneOme for use in the treatment of oncology patients and their supportive care needs.





Patient and report summary

Patient name: **Sample Patient**
 Patient date of birth: **1958-07-04**
 Original report date: **2024-09-06**








Ordering provider: **Sample Doctor**
 Ordering facility: **LIMSTITUTION**
 Product type: **Oncology Medication**
 Report type: **Original**

Major gene-drug interactions	3 Chemotherapeutic agents	3 Supportive care medications
Moderate gene-drug interactions	0 Chemotherapeutic agents	8 Supportive care medications

Report legend Based on this patient's genetic profile, medications are reported according to genotype-predicted interactions described below.

	Major gene-drug interaction	Major genotype-drug interaction identified that affects the metabolism of the medication and/or indicates an elevated risk of adverse reaction or loss of efficacy.
	Moderate gene-drug interaction	Moderate genotype-drug interaction identified that affects the metabolism of the medication and/or indicates an elevated risk of adverse reaction or loss of efficacy.
	Minimal gene-drug interaction	Minimal genotype-drug interaction identified that does not significantly affect medication metabolism or predict an elevated risk of adverse reaction or loss of efficacy.
	Limited pharmacogenetic impact	No pharmacogenetic variants demonstrate a significant impact on medication response. Other types of genetic tests that may guide prescribing (e.g., tumor marker testing, diagnostic, or indication-establishing testing) are not taken into account.

Icon legend Some medications are reported with icons to indicate that specific clinical annotations and/or dosing guidelines provided by FDA, CPIC, or other professional associations are available in Vantage.

	FDA evidence	This medication is listed on the FDA Table of Pharmacogenetic Associations. Not all genetic variants or genetic variant-inferred phenotypes may be accounted for. Further information can be found at: https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations .
	Increased exposure	Total exposure to active compound(s) may be increased. Monitor for adverse effects.
	Decreased exposure	Total exposure to active compound(s) may be decreased. Monitor for lack of therapeutic response.
	Difficult to predict	Total exposure to active compound(s) is difficult to predict. Monitor patient response.
	Reduced response	Response to medication may be lowered due to genetic changes impacting mechanisms other than exposure (e.g. receptor function).
	Additional testing	According to FDA labeling, additional laboratory testing may be indicated.
	Professional guideline	Medication has professional guidelines associated with this patient's genetic test results. Avoidance, dose adjustment, or heightened monitoring may be indicated.

Report and laboratory comments

Secondary findings

This patient is a carrier for one or more pathogenic or likely pathogenic variants in the following gene(s): DPYD. Please review the *Gene and phenotype summary* for additional information and consider genetic counseling as appropriate.

Genotype-predicted interactions for chemotherapeutic agents

Chemotherapy

⚠ Major gene-drug interaction

- Capecitabine * 📖 1, 5, 24, 26, 33, 62, 86 (Xeloda®)
- Fluorouracil * 📖 1, 5, 24, 26, 33, 62, 86 (Adrucil®)

⚠ Moderate gene-drug interaction

✅ Minimal gene-drug interaction

- Belinostat 1, 92, 97 (Beleodaq®)
- Docetaxel 1 (Docefrez®, Taxotere®)
- Irinotecan * 1, 2, 26, 28, 30, 53 (Camptosar®)
- Mercaptopurine 📖 1, 3, 26, 59, 74, 92 (Purixan®)
- Tamoxifen * 1, 2, 31 (Soltamox®)
- Thioguanine 📖 1, 3, 26, 59, 74, 92 (Tabloid®)

ℹ Limited pharmacogenetic impact

Kinase inhibitors (KIs) and monoclonal antibodies (mAbs)

⚠ Major gene-drug interaction

- Pazopanib * 📖 1 (Votrient®)

⚠ Moderate gene-drug interaction

✅ Minimal gene-drug interaction

- Dasatinib 📖 1 (Sprycel®)
- Gefitinib * 📖 1 (Iressa®)
- Lapatinib * 📖 1, 79 (Tykerb®)
- Nilotinib * 📖 1, 4 (Tasigna®)
- Ruxolitinib 1 (Jakafi®)
- Temsirolimus 1 (Torisel®)

ℹ Limited pharmacogenetic impact

Genotype-predicted interactions for supportive care medications

Gastrointestinal management (nausea/vomiting, appetite, gastritis, GERD)

⚠ Major gene-drug interaction

⚠ Moderate gene-drug interaction

- Dexlansoprazole 📖 1, 56, 92 (Dexilant®)
- Lansoprazole 📖 1, 26, 56, 92 (Prevacid®)
- Omeprazole 📖 1, 26, 29, 56, 63, 92 (Prilosec®)
- Pantoprazole 📖 1, 26, 56, 92 (Protonix®)

✅ Minimal gene-drug interaction

- Chlorpromazine 1, 70, 88 (Thorazine®)
- Dronabinol 1, 92 (Marinol®, Syndros®)
- Fosaprepitant 1, 65 (Emend Injection®)
- Haloperidol 1, 2, 69, 87, 95 (Haldol®)
- Metoclopramide 📖 1, 8, 92 (Reglan®)

ℹ Limited pharmacogenetic impact

Gastrointestinal management (nausea/vomiting, appetite, gastritis, GERD) (cont.)

⚠ Major gene-drug interaction

⚠ Moderate gene-drug interaction

✔ Minimal gene-drug interaction

ℹ Limited pharmacogenetic impact

- Ondansetron 1, 10, 45, 93 (Zofran®)

Pain management (opioid therapy)

⚠ Major gene-drug interaction

⚠ Moderate gene-drug interaction

✔ Minimal gene-drug interaction

ℹ Limited pharmacogenetic impact

- Codeine 📖 1, 21, 26, 57, 61, 92
- Hydrocodone 1, 19, 20 (Hysingla®, Zohydro®)
- Methadone 1, 21, 27 (Dolophine®, Methadose®)
- Tramadol 📖 1, 21, 26, 61, 92 (Ultram®)

Neuropathy and non-opioid pain management

⚠ Major gene-drug interaction

⚠ Moderate gene-drug interaction

✔ Minimal gene-drug interaction

ℹ Limited pharmacogenetic impact

- Amitriptyline * 1, 2, 26, 35, 36, 98 (Elavil®)
- Celecoxib 📖 1, 89, 92 (Celebrex®)
- Clomipramine 📖 1, 26, 35, 92 (Anafranil®)
- Desipramine 📖 1, 35, 92 (Norpramin®)
- Doxepin * 📖 1, 35 (Silenor®)
- Flurbiprofen 📖 1, 89, 92 (Ansaid®)
- Ibuprofen * 📖 1, 48, 89 (Advil®, Motrin®)
- Imipramine * 📖 1, 26, 35, 80, 81 (Tofranil®)
- Meloxicam 📖 1, 89, 92 (Mobic®)
- Nortriptyline 📖 1, 26, 35, 92 (Pamelor®)
- Piroxicam * 📖 1, 71, 72, 89 (Feldene®)
- Trimipramine * 📖 1, 35, 51, 52 (Surmontil®)
- Gabapentin (Neurontin®)
- Pregabalin (Lyrica®)

Mental health (antidepressants, anxiolytics)

⚠ Major gene-drug interaction

⚠ Moderate gene-drug interaction


✔ Minimal gene-drug interaction


ℹ Limited pharmacogenetic impact


- Bupropion 1, 90, 100 (Wellbutrin®)
- Citalopram 📖 1, 11, 12, 26, 92 (Celexa®)
- Diazepam * 1, 40 (Valium®)


Mental health (antidepressants, anxiolytics) (cont.)

 Major gene-drug interaction

 Moderate gene-drug interaction


 Minimal gene-drug interaction


 Limited pharmacogenetic impact


- Escitalopram  1, 11, 12, 26, 92 (Lexapro[®])
- Fluoxetine  1, 11, 12, 58 (Prozac[®])
- Fluvoxamine  1, 11, 12, 26, 92
- Nefazodone 1, 75, 96 (Serzone[®])
- Paroxetine  1, 11, 12, 26, 92 (Paxil[®])
- Sertraline  1, 11, 12 (Zoloft[®])
- Venlafaxine  1, 11, 26, 67, 82, 85, 92 (Effexor[®])
- Vortioxetine  1, 11, 92 (Trintellix[®])




Neuropsychiatry (anticonvulsants, smoking cessation, sleep medication)

 Major gene-drug interaction

 Moderate gene-drug interaction


 Minimal gene-drug interaction


 Limited pharmacogenetic impact


- Brivaracetam 1, 92 (Briviact[®])
- Carbamazepine   1, 6, 26, 73, 92 (Carbatrol[®], Tegretol[®])
- Clobazam 1, 92, 99 (Onfi[®])
- Eslicarbazepine 1, 6, 47, 73 (Aptiom[®])
- Fosphenytoin 1, 2, 6, 13, 16, 60, 68 (Cerebyx[®])
- Lamotrigine 1, 6, 60, 73 (Lamictal[®])
- Nicotine 17, 22, 44, 66 (Nicoderm C-Q[®], Nicorette[®], Nicotrol[®])
- Oxcarbazepine  1, 6, 73 (Trileptal[®])
- Phenytoin 1, 2, 6, 13, 16, 60, 68 (Dilantin[®])
- Quetiapine 1, 9, 50, 91, 94 (Seroquel[®])
- Trazodone 1 (Desyrel[®])
- Levetiracetam (Keppra[®])
- Temazepam (Restoril[®])
- Varenicline (Chantix[®])

Antimicrobial (antibiotics, antifungals)

 Major gene-drug interaction

 Moderate gene-drug interaction

 Minimal gene-drug interaction

 Limited pharmacogenetic impact

- Isavuconazole 1 (Cresemba[®])
- Itraconazole 1 (Onmel[®], Sporanox[®])
- Voriconazole  1, 15, 26, 64, 92 (Vfend[®])
- Fluconazole (Diflucan[®])
- Levofloxacin (Levaquin[®])
- Moxifloxacin (Avelox[®])

Antithrombosis and cardiovascular management (hypertension, hyperlipidemia)

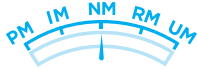
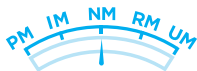
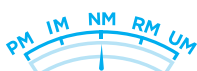


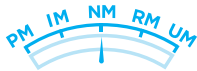
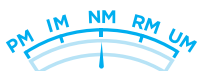

⚠ Major gene-drug interaction	⚠ Moderate gene-drug interaction	✔ Minimal gene-drug interaction	ℹ Limited pharmacogenetic impact
<ul style="list-style-type: none"> ■ Lovastatin + 📖 1, 18 (Mevacor®) ■ Pitavastatin + 📖 1, 18 (Livalo®) ■ Simvastatin * + 📖 1, 18, 26, 55, 92 (Zocor®) 	<ul style="list-style-type: none"> ■ Atorvastatin + 📖 1, 18, 26, 92 (Lipitor®) ■ Fluvastatin + 📖 1, 18, 26 (Lescol®) ■ Pravastatin + 📖 1, 18 (Pravachol®) ■ Rosuvastatin + 📖 1, 18, 92 (Crestor®) 	<ul style="list-style-type: none"> ■ Carvedilol * 1 (Coreg®) ■ Cilostazol 1, 91 (Pletal®) ■ Clopidogrel * 1, 2, 26, 83, 84 (Plavix®) ■ Losartan 1, 7, 25, 54, 78 (Cozaar®) ■ Metoprolol * 1, 2, 26 (Lopressor®, Toprol XL®) ■ Ticagrelor 1 (Brilinta®) ■ Warfarin * 1, 14, 42, 43 (Coumadin®, Jantoven®) 	<ul style="list-style-type: none"> ■ Lisinopril (Prinivil®, Zestril®) ■ Prasugrel (Effient®) ■ Spironolactone (Aldactone®)

Other









⚠ Major gene-drug interaction	⚠ Moderate gene-drug interaction	✔ Minimal gene-drug interaction	ℹ Limited pharmacogenetic impact
		<ul style="list-style-type: none"> ■ Allopurinol * 23, 34, 38, 49, 76 (Aloprim®, Zyloprim®) ■ Ethinyl estradiol 1, 2 ■ Fesoterodine * 1 (Toviaz®) ■ Tamsulosin * 1 (Flomax®) 	<ul style="list-style-type: none"> ■ Risedronate (Actonel®, Atelvia®)

Genotype-derived classification of medications is provided as a service by OneOme and is intended solely for use by a medical professional who has reviewed and understands all sections within this report, including possible limitations of the services provided by OneOme. The relationships between the drugs and pharmacogenes annotated in this report are supported by scientific evidence that meets OneOme's criteria for inclusion. The order in which drugs are listed does not have any clinical or medical implications. Commonly used trade names for medications are listed for reference only. The list may not be inclusive of all trade names available and does not indicate preference or recommendation by OneOme of one medication product over another. For more information on these medications, for a list of additional medications curated but not annotated by OneOme, or to evaluate possible drug-to-drug interactions, please consult Vantage, which is accessible through the provider portal at portal.oneome.com.









Gene and phenotype summary

Gene	Genotype		Phenotype summary / Metabolic status
CYP1A2	*1A/*1A		Normal metabolizer Fully functional enzyme activity is likely based on the genotype results. Normal metabolism of the medication affected by this gene is predicted.
CYP2B6	*1/*1		Normal metabolizer Fully functional enzyme activity is likely based on the genotype results. Normal metabolism of the medication affected by this gene is predicted.
CYP2C9	*1/*1		Normal metabolizer Fully functional enzyme activity is likely based on the genotype results. Normal metabolism of the medication affected by this gene is predicted.
CYP2C19	*1/*1		Normal metabolizer Fully functional enzyme activity is likely based on the genotype results. Normal metabolism of the medication affected by this gene is predicted.
CYP2C Cluster	rs12777823 GG		Normal CYP2C rs12777823 homozygous wild-type genotype consistent with normal clearance of a certain medication, independent of the impact of CYP2C9*2 and *3. CYP2C rs12777823, together with CYP4F2, CYP2C9, and VKORC1, may affect treatment management of a certain medication.
CYP2D6	*1/*1		Normal metabolizer Fully functional enzyme activity is likely based on the genotype results. Normal metabolism of the medication affected by this gene is predicted.
CYP3A4	*1/*1		Normal metabolizer Fully functional enzyme activity is likely based on the genotype results. Normal metabolism of the medication affected by this gene is predicted.
CYP3A5	*3/*3		Poor metabolizer This CYP3A5 genotype is associated with the phenotype most prevalent in studies used to define standard dosing guidelines.

Gene and phenotype summary (cont.)

CYP4F2	*1/*1		<p>Normal activity</p> <p>Genotype consistent with normal activity of the CYP4F2 enzyme, which catalyzes the metabolism of vitamin K, in counterpoint to the activity of VKORC1. CYP4F2, together with CYP2C9, VKORC1, and a variant in CYP2C Cluster, may affect treatment management of a certain medication.</p>
COMT	rs4680 AA		<p>Low activity</p> <p>The AA (Met/Met) genotype is associated with lower COMT activity than the GG (Val/Val) or GA (Val/Met) genotypes.</p>
DPYD	*1/*13		<p>Intermediate metabolizer</p> <p>DPD activity score= 1. This genotype and activity score is consistent with an intermediate metabolizer phenotype. Decreased DPD enzyme activity is associated with an increased risk for severe or fatal drug toxicity when treated with fluoropyrimidine drugs.</p>
F2	rs1799963 GG		<p>Normal risk</p> <p>Normal risk of thrombosis associated with Factor II (prothrombin). Other genetic and clinical factors contribute to the risk for thrombosis.</p>
F5	rs6025 GG		<p>Normal risk</p> <p>Normal risk of thrombosis associated with Factor V. Other genetic and clinical factors contribute to the risk for thrombosis.</p>
GRIK4	rs1954787 TT		<p>Altered receptor function</p> <p>Homozygous variant glutamate ionotropic receptor kainate type subunit 4 (GRIK4) genotype is consistent with altered receptor function.</p>
HLA-A	Negative		<p>Normal risk</p> <p>Negative for the presence of the HLA-A*31:01 allele. Normal risk of hypersensitivity induced by certain medications, and possibly others of structural similarity. Hypersensitivity and severe cutaneous reactions may occur regardless of the presence of the HLA-A*31:01 allele, in particular the presence of the HLA-B*15:02 allele is associated with severe cutaneous reactions induced by certain medications.</p>
HLA-B	Positive for *57:01		<p>Increased risk: HLA-B*57:01 positive</p> <p>Positive for presence of the HLA-B*57:01 allele. Negative for presence of the HLA-B*15:02 and HLA-B*58:01 alleles. Increased risk of hypersensitivity and severe hepatotoxicity induced by certain medications. Hypersensitivity, severe cutaneous reactions, and severe hepatotoxicity may occur regardless of the presence of HLA-B*15:02, HLA-B*57:01, or HLA-B*58:01 alleles. In particular, the presence of the HLA-A*31:01 allele is associated with hypersensitivity reactions induced by a certain medication, and possibly other medications of structural similarity.</p>

Gene and phenotype summary (cont.)

HTR2A	rs7997012 TT		<p>Variant absent</p> <p>The TT genotype is the wildtype genotype associated with intron 2 of the HTR2A gene.</p>
NUDT15	*1/*1		<p>Normal metabolizer</p> <p>NUDT15 genotype is consistent with normal enzyme activity and is not associated with an increased risk of thiopurine-induced toxicities. Toxicities with thiopurines can occur due to impaired TPMT activity independently from the NUDT15 activity.</p>
OPRM1	rs1799971 AA		<p>Variant absent</p> <p>The AA genotype (or Asn/Asn isoform) is the wildtype genotype associated with the mu-1 opioid receptor.</p>
SLC6A4	L/L (La/La)		<p>Typical to increased expression</p> <p>Genotype consistent with a typical to increased expression of the SLC6A4 transporter compared to other genotypes. This genotype was shown to exhibit different phenotypes in East Asian populations, as opposite outcomes were observed for this genotype in East Asian populations when compared to Caucasian populations.</p>
SLCO1B1	*1/*5		<p>Decreased function</p> <p>SLCO1B1 genotype consistent with decreased function of the OATP1B1 transporter.</p>
TPMT	*1/*1		<p>Normal metabolizer</p> <p>TPMT genotype is consistent with a normal metabolizer phenotype and is not associated with an increased risk of thiopurine-induced toxicities. Toxicities with thiopurines can occur due to impaired NUDT15 activity independently from the TPMT activity.</p>
UGT1A1	*1/*1		<p>Normal metabolizer</p> <p>Genotype consistent with fully functional UGT1A1 enzyme activity, or a normal metabolizer phenotype.</p>
VKORC1	rs9923231 GG		<p>Normal activity</p> <p>Genotype consistent with normal activity of the vitamin K epoxide reductase enzyme, associated with c.-1639GG (rs9923231). VKORC1, together with CYP2C9, CYP4F2, and a variant in CYP2C Cluster, may affect treatment management of a certain medication.</p>

CYP phenotype abbreviations

PM	Poor metabolizer
IM	Intermediate metabolizer
NM	Normal metabolizer
RM	Rapid metabolizer
UM	Ultrarapid metabolizer

Test information

Specimen ID: 8871789060668	Clinical testing performed by: OneOme	Reported by: Ellie Jhun in None
Specimen type: Buccal swab	807 Broadway St. NE Suite 100	CLIA: 24D2109855
Collection date: 2024-09-01	Minneapolis, MN 55412, United States	CAP: 9432670
Receive date: 2024-09-06		NY PFI: 9226

Test results

The following analytical results were interpreted by OneOme to produce the pharmacogenomic interpretations and annotations described in the *Gene and phenotype summary*. Method-specific analytical limitations or inferred haplotypes may limit the ability to produce a definitive phenotype interpretation. See *Methodology and limitations* and/or the *Report and laboratory comments* sections for additional information.

CYP1A2 *1A/*1A	rs5030656	NM_000106.5:c.841_843delAAG	AAGAAG	
rs762551	NM_000761.4:c.-9-154C>A	rs35742686	NM_000106.5:c.775delA	AA
rs2069514	NG_008431.2:g.28338G>A	rs72549353	NM_000106.5:c.765_768delAACT	AACTAACT
rs2069526	NM_000761.4:c.-10+103T>G	rs5030655	NM_000106.5:c.454delT	TT
rs12720461	NM_000761.4:c.-10+113C>T	rs774671100	NM_000106.5:c.137_138insT	--
rs35694136	NM_000761.4:c.-1635delT	rs1080985	NM_000106.5:c.-1584C>G	CC
		rs59421388	NM_000106.5:c.1012G>A	GG
		rs28371725	NM_000106.5:c.985+39G>A	GG
		rs72549346	NM_000106.5:c.1088_1089insGT	--
		rs5030865	NM_000106.5:c.505G>[A,T]	GG
CYP2B6 *1/*1		CYP3A4 *1/*1		
rs3745274	NM_000767.4:c.516G>T	rs2740574	NM_017460.5:c.-392G>A	AA
rs2279343	NM_000767.4:c.785A>G	rs35599367	NM_017460.5:c.522-191C>T	CC
rs34223104	NM_000767.5:c.-82T>C			
rs3211371	NM_000767.4:c.1459C>T			
rs36079186	NM_000767.5:c.593T>C			
rs28399499	NM_000767.4:c.983T>C			
CYP2C9 *1/*1		CYP3A5 *3/*3		
rs7900194	NM_000771.3:c.449G>A	rs776746	NM_000777.4:c.219-237G>A	GG
rs1799853	NM_000771.3:c.430C>T	rs10264272	NM_000777.4:c.624G>A	GG
rs1057910	NM_000771.3:c.1075A>C	rs41303343	NM_000777.4:c.1035_1036insT	--
rs28371686	NM_000771.3:c.1080C>G			
rs56165452	NM_000771.3:c.1076T>C			
rs28371685	NM_000771.3:c.1003C>T			
rs9332131	NM_000771.3:c.817delA			
CYP2C19 *1/*1		CYP4F2 *1/*1		
rs12248560	NM_000769.2:c.-806C>T	rs2108622	NM_001082.4:c.1297G>A	GG
rs4244285	NM_000769.2:c.681G>A			
rs4986893	NM_000769.2:c.636G>A			
rs6413438	NM_000769.2:c.680C>T			
rs28399504	NM_000769.2:c.1A>G			
CYP2C Cluster rs12777823 GG		COMT rs4680 AA		
rs12777823	NC_000010.10:g.96405502G>A	rs4680	NM_000754.3:c.472G>A	AA
CYP2D6 *1/*1		DPYD *1/*13		
rs28371706	NM_000106.5:c.320C>T	rs75017182	NM_000110.4:c.1129-5923C>G	CC
rs267608319	NM_000106.5:c.1319G>A	rs55886062	NM_000110.3:c.1679T>G	TG
rs16947	NM_000106.5:c.886C>T	rs67376798	NM_000110.3:c.2846A>T	AA
rs79292917	NM_000106.5:c.975G>A	rs3918290	NM_000110.3:c.1905+1G>A	GG
rs1065852	NM_000106.5:c.100C>T	rs115232898	NM_000110.4:c.557A>G	AA
rs1135840	NM_000106.5:c.1457G>C			
rs3892097	NM_000106.5:c.506-1G>A			
rs769258	NM_000106.5:c.31G>A			
rs5030862	NM_000106.5:c.124G>A			
rs201377835	NM_000106.5:c.181-1G>C			
rs5030867	NM_000106.5:c.971A>C			
rs765776661	NM_000106.5:c.1411_1412insTGCCCACTG			
		F2 rs1799963 GG		
		rs1799963	NM_000506.4:c.*97G>A	GG
		F5 rs6025 GG		
		rs6025	NM_000130.4:c.1601G>A	GG
		GRIK4 rs1954787 TT		
		rs1954787	NM_001282470.2:c.83-10039T>C	TT
		HLA-A Negative		
		HLA00097	NM_002116 (interrogated at exon 2)	Negative
		HLA-B Positive for *57:01		

Test results (cont.)

rs144012689	NM_005514.7:c.1012+104A>T	TT
HLA00386	NM_005514 (interrogated at exon 2 and intron 2)	Negative
HLA00381	NM_005514 (interrogated at exon 3)	Negative

HTR2A rs7997012 TT

rs7997012	NM_000621.4:c.614-221T>C	TT
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NUDT15 *1/*1

rs116855232	NM_018283.3:c.415C>T	CC
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OPRM1 rs1799971 AA

rs1799971	NM_000914.4:c.118A>G	AA
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SLC6A4 L/L (La/La)

rs25531	NM_001045.5:c.-1936A>G	AA
rs774676466	NM_001045.5:c.-1917_-1875del43	LL

SLCO1B1 *1/*5

rs2306283	NM_006446.4:c.388A>G	Not tested
rs4149056	NM_006446.4:c.521T>C	TC
rs4149015	NM_006446.4:c.-910G>A	Not tested

TPMT *1/*1

rs1142345	NM_000367.3:c.719A>G	AA
rs1800584	NM_000367.3:c.626-1G>A	CC
rs1800462	NM_000367.3:c.238G>C	GG
rs1800460	NM_000367.3:c.460G>A	GG

UGT1A1 *1/*1

rs4148323	NM_001072.3:c.862-6536G>A	GG
rs1976391	NM_001072.3:c.862-9697A>G	AA

VKORC1 rs9923231 GG

rs7200749	NM_024006.5:c.358C>T	GG
rs9923231	NM_001311311.1:c.-1639G>A	GG

Electronically signed by:

 Ellie Jhun in None
 2024-09-06

Methodology and limitations

This test was developed, and its performance characteristics determined by OneOme, LLC, a clinical laboratory located at 807 Broadway Street NE Suite 100, Minneapolis, MN 55413. These tests have not been cleared or approved by the U.S. Food and Drug Administration. The FDA does not require this test to go through premarket FDA review. OneOme is certified under CLIA-88 and accredited by the College of American Pathologists as qualified to perform high-complexity testing. This test is approved for clinical use by the New York State Department of Health. This test should not be regarded as investigational or for research.

Genomic DNA was analyzed by PCR using Thermo Fisher TaqMan® and/or LGC Biosearch BHQ® probe-based methods to interrogate the variant locations listed in the Test results table above. For tests that include CYP2D6, the CYP2D6 copy number status was assessed at sites within the promoter, intron 2, intron 6, and exon 9. The test detects CYP2D6 deletions, duplications/multiplications, and hybrid alleles, but cannot differentiate duplications in the presence of a deletion.

Legacy nomenclature for applicable genes and alleles is used to remain consistent with industry language.

The test does not detect all known and unknown variations in the gene(s) tested, nor does absence of a detectable variant (designated as *1 for genes encoding drug metabolizing enzymes) rule out the presence of other, non-detected variants.

As with other common SNP genotyping techniques, these assays cannot differentiate between the maternal and paternal chromosomes. In cases where observed variants are associated with more than one haplotype, OneOme infers and reports the most likely diplotype based on published allele frequency and/or ethnicity data. Inferences with potential clinical impact are reported in the Report and laboratory comments section.

PCR may be subject to general interference by factors such as reaction inhibitors and low quality or quantity of extracted DNA. When present, these interferents typically yield no result rather than an inaccurate one. Very infrequent variants or polymorphisms occurring in primer- or probe-binding regions may affect testing and could produce an erroneous result or assay failure. Variant locations tested by the assay but not assigned a genotype call are reported as "No Call."

The variant detection methods validated by OneOme provide >99.9% accuracy for the adult population; however, clinical interpretation may be inaccurate for patients who have undergone or are receiving non-autologous blood transfusions, tissue, and/or organ transplant therapies. Although extremely rare, results could also be impacted by other factors not addressed above, such as laboratory error.

Pharmacogenetic correlation is largely based on studies of adult populations. Gene-drug guidance may not be informative in pediatric patients. For patients that may carry a probabilistic risk of disease, patients and providers should consider the benefits of consulting with a trained genetic counseling professional, physician, or pharmacogenomic specialist. For additional support, contact OneOme through the website or by calling 844-663-6635.

OneOme liability disclaimer

The interpretations and clinical annotations provided by OneOme are intended solely for use by a medical professional in the treatment of adult patients and do not constitute medical advice by OneOme. The treating provider remains ultimately responsible for all diagnosis and treatment decisions for the patient. OneOme disclaims liability for any errors, omissions or ambiguities in any translation or interpretation of a report by a third party, including without limitation direct, indirect, incidental, special, consequential or exemplary damages, whether such damages arise in contract, negligence, tort, under statute, in equity, at law or otherwise. Information included in this report is based upon scientific literature, including information from and guidelines published by professional associations (e.g., CPIC, FDA, DPWG), and does not take into account other genetic variants and environmental or social factors that may affect a patient's response. Other factors not included in this report include, but are not limited to, environmental factors (e.g., smoking), health factors (e.g., diet), social and familial factors, various medical conditions, and drug-to-drug interactions. Administration of any medication, including the ones listed in the OneOme reports, requires careful therapeutic monitoring regardless of the phenotype or genotype-predicted interaction reported. As a matter of practice, OneOme will routinely update its pharmacogenomic database as new information becomes available to the scientific community. Genotype-predicted interactions and annotations found on the patient's RightMed Comprehensive Test Report, Vantage Reports, or RightMed specialty reports are therefore dependent on the date of generation and/or the database version used to generate that report. Providers may access these reports with updated annotations using OneOme's latest released version through the provider portal at portal.oneome.com.

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