Patient ID	Patient Name		Birth Date	Gender	Age
SA00144448	TESTING, PGXQP		1966-05-26	M	54
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MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292

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⚠ Pharmacogenomic Interactions

amitriptyline *Elavil*
amoxapine *Asendin*
amphetamine
aripiprazole *Abilify*
atomoxetine *Strattera*
atorvastatin *Lipitor*
avatrombopag *Doptelet*
brexpiprazole *Rexulti*
carvedilol *Coreg*
celecoxib *Celebrex*
cevimeline *Evoxac*
citalopram *Celexa*
clomipramine *Anafranil*
clozapine *Clozaril*
codeine
darifenacin *Enablex*
desipramine *Norpramin*
deutetrabenazine *Austedo*
dexlansoprazole *Dexilant*
donepezil *Aricept*
doxepin *Sinequan*
dronabinol *Marinol, THC*
elagolix *Orilissa*
eliglustat *Cerdelga*
erdafitinib *Balversa*
escitalopram *Lexapro*
fesoterodine *Toviaz*
flecainide *Tambocor*
fluoxetine *Prozac*
flurbiprofen *Ocufen*
fluvoxamine *Luvox*
fosphenytoin *Cerebyx*
galantamine *Razadyne*
gefitinib *Iressa*
haloperidol *Haldol*
ibuprofen
iloperidone *Fanapt*
imipramine *Tofranil*
lansoprazole *Prevacid*
lofexidine *Lucemyra*
meclizine
Medi-Meclizine, Bonine, Motion Sickness, Verticalm
meloxicam *Mobic*
metoclopramide *Reglan*
metoprolol *Toprol, Lopressor*
mirabegron *Myrbetriq*
nebivolol *Bystolic*
nortriptyline *Pamelor*
oliceridine *Olinvyk*
omeprazole
Prilosec, Zegerid, OmePPi
oxycodone
pantoprazole *Protonix*
paroxetine *Paxil*
perphenazine *Trilafon*
phenytoin *Phenytek, Dilantin*
pimozide *Orap*
piroxicam *Feldene*
propafenone *Rythmol*
propranolol *Inderal, Innopran*
protriptyline *Vivactil*
risperidone *Risperdal*
rosuvastatin *Crestor*
sertraline *Zoloft*
simvastatin *FloLipid, Zocor*
siponimod *Mayzent*
tacrolimus
Envarsus, Protopic, Astagraf
tamoxifen *Nolvadex, Soltamox*
tamsulosin *Flomax*
tenoxicam *Mobiflex*
tetrabenazine *Xenazine*
thioridazine *Mellaril*
tolterodine *Detrol*
tramadol *Ultram, ConZip*
trimipramine *Surmontil*
valbenazine *Ingrezza*
venlafaxine *Effexor*
voriconazole *Vfend*
vortioxetine *Trintellix*
warfarin *Coumadin, Jantoven*

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Standard Prescription Recommended

brivaracetam *Briviact*
carisoprodol *Soma*
clobazam *Onfi*
clopidogrel *Plavix*
diazepam *Valium*
esomeprazole *Nexium*
flibanserin *Addyi*
ondansetron *Zuplenz, Zofran*
tropisetron

Pharmacogenomic Interaction Details

Medication	Comment
amitriptyline *Elavil*	According to the FDA label, CYP2D6 poor metabolizers may have higher than expected plasma concentrations of tricyclic antidepressants (TCAs) when given usual doses. The Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for tricyclic antidepressants indicates that individuals with decreased CYP2D6 activity are expected to demonstrate decreased metabolism of amitriptyline, which may lead to increased plasma concentrations of the active medication and a higher probability of adverse effects; individuals with increased CYP2C19 metabolism are expected to convert tertiary amines to secondary amines at a greater rate, which may affect response or adverse effects. This individual is expected to demonstrate decreased CYP2D6 activity and increased CYP2C19 activity; therefore, consider selecting an alternate medication.
amoxapine *Asendin*	According to the FDA label, CYP2D6 poor metabolizers may have higher than expected plasma concentrations of amoxapine when administered a standard dose.
amphetamine	Increased potential for adverse events. According to the FDA label, a reduced starting dose or alternative agent should be considered for patients who are CYP2D6 poor metabolizers. Please see the FDA label for details.
aripiprazole *Abilify*	Increased potential for adverse events. According to the FDA label, patients who are CYP2D6 poor metabolizers should be administered a reduced dose. Please see the FDA label for details.
atomoxetine *Strattera*	The FDA label suggests initiating at a standard dose (0.5 mg/kg/day for children/adolescents up to 70 kg body weight or 40 mg/day for children/adolescents over 70 kg body weight and adults) and only titrating up to the usual target dose (1.2 mg/kg/day for children/adolescents up to 70 kg and 80 mg/day for children/adolescents over 70 kg and adults) if symptoms fail to improve after 4 weeks and the initial dose is well tolerated. If unacceptable adverse effects are noted as the dose is increased, consider a dose reduction.
atorvastatin *Lipitor*	Monitor for the presence of adverse events. According to the Dutch Pharmacogenetics Working Group guidelines, the risk of myopathy may be increased with this genotype.
avatrombopag *Doptelet*	According to the FDA label, individuals with reduced CYP2C9 metabolism may have higher than expected plasma concentrations of avatrombopag when administered a standard dose and may be at increased risk for adverse events.
brexpiprazole *Rexulti*	Increased potential for adverse events. According to the FDA label, patients who are CYP2D6 poor metabolizers should be administered a reduced dose. Please see the FDA label for details.
carvedilol *Coreg*	According to the FDA label, CYP2D6 poor metabolizers who are treated with carvedilol may have a higher rate of dizziness during dose titration.

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Medication	Comment
celecoxib *Celebrex*	Increased potential for adverse events. According to the FDA label and the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C9 and NSAIDS, individuals with decreased CYP2C9 activity may have higher systemic concentrations of celecoxib and may require a reduced dosage. For poor metabolizers, the FDA label recommends reducing the starting dose to half of the lowest recommended dose. CPIC recommends initiating therapy at 25-50% of the lowest recommended starting dose, with dose titration upward to clinical effect or 25-50% of the maximum recommended dose with caution. Upward titration is not recommended until after steady-state is reached. Use of the lowest effective dosage for the shortest duration consistent with individual patient treatment goals is recommended. See the CPIC guideline for more details. The FDA label recommends consideration of alternate therapy in patients with juvenile rhematoid arthritis.
cevimeline *Evoxac*	According to the FDA label, patients who are CYP2D6 poor metabolizers may have an increased potential for adverse reactions. Please see the FDA label for details.
citalopram *Celexa*	According to the Clinical Pharmacogenetics Implementation Consortium guideline for selective serotonin reuptake inhibitors, there is a potential for lack of efficacy due to increased CYP2C19-mediated metabolism. Consider an alternate medication not predominantly metabolized by CYP2C19.
clomipramine *Anafranil*	The Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for tricyclic antidepressants indicates that individuals with decreased CYP2D6 activity are expected to demonstrate decreased metabolism of clomipramine, which may lead to increased plasma concentrations of the active medication and a higher probability of adverse effects; individuals with increased CYP2C19 metabolism are expected to convert tertiary amines to secondary amines at a greater rate, which may affect response or adverse effects. This individual is expected to demonstrate decreased CYP2D6 activity and increased CYP2C19 activity; therefore, consider selecting an alternate medication.
clozapine *Clozaril*	Increased potential for adverse events. According to the FDA label, patients who are CYP2D6 poor metabolizers have higher than expected systemic clozapine concentrations and may require a reduced dose. Please see the FDA label for details.
codeine	Potential for reduced efficacy. According to the FDA label and CPIC guideline for codeine, CYP2D6 poor metabolizers may have lower systemic concentrations of the active metabolite of codeine which may result in reduced efficacy. Consider an alternate medication (e.g. non-opioid analgesic) if response is suboptimal.
darifenacin *Enablex*	According to the FDA label, CYP2D6 poor metabolizers may have higher than expected plasma concentrations of darifenacin when administered a standard dose. Use with caution.

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Medication	Comment
desipramine *Norpramin*	According to the FDA label, CYP2D6 poor metabolizers may have higher than expected plasma concentrations of desipramine when given usual doses. The Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for tricyclic antidepressants indicates that individuals with decreased CYP2D6 activity are expected to demonstrate decreased metabolism of desipramine, which may lead to increased plasma concentrations of the active medication and a higher probability of adverse effects. This individual is expected to demonstrate decreased CYP2D6 activity. The CPIC guideline suggests considering selecting an alternate medication or if desipramine use is warranted considering a 50% reduction of the starting dose.
deutetrabenazine *Austedo*	According to the FDA label, individuals who are CYP2D6 poor metabolizers should not exceed 36 mg (maximum single dose of 18 mg) due to the potential for clinically relevant QT prolongation.
dexlansoprazole *Dexilant*	Increased risk for therapeutic failure. According to the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C19 and proton pump inhbitors (PPIs), individuals with ultrarapid CYP2C19 activity may have decreased systemic concentrations of PPIs and may be at risk for therapeutic failure and require a dose adjustment. CPIC recommends increasing the starting daily dose by 100%, which may be given in dividided doses, and monitoring for efficacy. See the CPIC guideline for more details.
donepezil *Aricept*	According to the FDA label, CYP2D6 poor metabolizers have reduced clearance of donepezil. Use with caution.
doxepin *Sinequan*	According to the FDA label, CYP2D6 poor metabolizers may have higher than expected plasma concentrations of doxepin when given usual doses. The Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for tricyclic antidepressants indicates that individuals with decreased CYP2D6 activity are expected to demonstrate decreased metabolism of doxepin, which may lead to increased plasma concentrations of the active medication and a higher probability of adverse effects; individuals with increased CYP2C19 metabolism are expected to convert tertiary amines to secondary amines at a greater rate, which may affect response or adverse effects. This individual is expected to demonstrate decreased CYP2D6 activity and increased CYP2C19 activity; therefore, consider selecting an alternate medication.
dronabinol *Marinol, THC*	Increased potential for adverse reactions. According to the FDA label, individuals with reduced CYP2C9 metabolism may have higher than expected plasma concentrations of dronabinol when administered a standard dose. Monitor for adverse reactions.
elagolix *Orilissa*	According to the FDA label, individuals with the SLCO1B1 521 C/C genotype are expected to have a 78% mean increase in eligolix concentration compared to individuals with normal transporter function; however, a dose adjustment is not required based on SLCO1B1 status.
eliglustat *Cerdelga*	Increased potential for adverse events. According to the FDA label, CYP2D6 reduced metabolizers may have higher systemic concentrations of eliglustat which may result in adverse reactions (QT prolongation). The recommended dosages are based on CYP2D6 metabolizer status. Coadministration with strong CYP3A inhibitors is contraindicated in intermediate and poor CYP2D6 metabolizers. Refer to FDA labeling for specific dosing recommendations.

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Medication	Comment
erdafitinib *Balversa*	Increased risk for adverse reactions. According to the FDA label, individuals with the CYP2C9 *3/*3 genotype may have higher than expected plasma concentrations of erdafitinib. Monitor for adverse reactions.
escitalopram *Lexapro*	According to the Clinical Pharmacogenetics Implementation Consortium guideline for selective serotonin reuptake inhibitors, there is a potential for lack of efficacy due to increased CYP2C19-mediated metabolism. Consider an alternate medication not predominantly metabolized by CYP2C19.
fesoterodine *Toviaz*	According to the FDA label, individuals who are CYP2D6 poor metabolizers may have higher than expected plasma concentrations of fesoterodine when administered a standard dose. Use with caution.
flecainide *Tambocor*	According to the Dutch Pharmacogenetics Working Group guidelines, CYP2D6 poor metabolizers may convert flecainide to inactive metabolites at an decreased rate, and thus may be at increased risk for adverse events (QT prolongation) at standard doses. Consider initiating therapy with a reduced dose, monitoring the plasma medication concentration, and obtaining an ECG.
fluoxetine *Prozac*	According to the Clinical Pharmacogenetics Implementation Consortium guideline for selective serotonin reuptake inhibitors, the relationship between CYP2D6 phenotype and outcomes of patients taking fluoxetine is unclear. However, it may be reasonable to consider an alternate medication not predominantly metabolized by CYP2D6 or to monitor carefully if fluoxetine is used.
flurbiprofen *Ocufen*	Increased potential for adverse events. According to the FDA label and the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C9 and NSAIDS, individuals with decreased CYP2C9 activity may have higher systemic concentrations of flurbiprofen and may require a reduced dosage. For poor metabolizers, the FDA label recommends reducing the starting dose to half of the lowest recommended dose. CPIC recommends initiating therapy at 25-50% of the lowest recommended starting dose, with dose titration upward to clinical effect or 25-50% of the maximum recommended dose with caution. Upward titration is not recommended until after steady-state is reached. Use of the lowest effective dosage for the shortest duration consistent with individual patient treatment goals is recommended. See the CPIC guideline for more details. The FDA label recommends consideration of alternate therapy in patients with juvenile rheumatoid arthritis.
fluvoxamine *Luvox*	According to the Clinical Pharmacogenetics Implementation Consortium guideline for selective serotonin reuptake inhibitors and FDA label, this individual may be at increased risk for adverse effects due to decreased CYP2D6-mediated metabolism. Consider reducing the starting dose and titrating to response or using an alternate medication not metabolized by CYP2D6.
fosphenytoin *Cerebyx*	Consider testing for HLA-B*15:02 prior to prescription. According to the CPIC guideline, a typical initial/loading dose is recommended, followed by a reduction (by approximately 50%) for subsequent doses. Subsequent doses should be adjusted according to therapeutic drug monitoring, response, and adverse effects.
galantamine *Razadyne*	According to the FDA label, patients who are CYP2D6 poor metabolizers may have higher systemic concentrations. The dose of the medication should be individually titrated to tolerability.

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Medication	Comment
gefitinib *Iressa*	Increased risk for adverse reaction. According to the FDA label, individuals who are CYP2D6 poor metabolizers may have higher than expected plasma concentrations of gefitinib when administered a standard dose. No dose adjustments are recommened, but this individual should be monitored closely for adverse reactions.
haloperidol *Haldol*	According to the literature and the Dutch Pharmacogenetics Working Group, based on this individual's CYP2D6 status, there is a potential for decreased haloperidol metabolism; consider prescribing a reduced dose or an alternate medication.
ibuprofen	Increased potential for adverse events. According to the FDA label and the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C9 and NSAIDS, individuals with decreased CYP2C9 activity may have higher systemic concentrations of ibuprofen and may require a reduced dosage. For poor metabolizers, the FDA label recommends reducing the starting dose to half of the lowest recommended dose. CPIC recommends initiating therapy at 25-50% of the lowest recommended starting dose, with dose titration upward to clinical effect or 25-50% of the maximum recommended dose with caution. Upward titration is not recommended until after steady-state is reached. Use of the lowest effective dosage for the shortest duration consistent with individual patient treatment goals is recommended. See the CPIC guideline for more details. The FDA label recommends consideration of alternate therapy in patients with juvenile rhematoid arthritis.
iloperidone *Fanapt*	Increased risk for adverse reactions, including QT prolongation. According to the FDA label, individuals who are CYP2D6 poor metabolizers may have higher than expected plasma concentrations of iloperidone when administered a standard dose, and dosage should be reduced by 50%.
imipramine *Tofranil*	According to the FDA label, CYP2D6 poor metabolizers may have higher than expected plasma concentrations of tricyclic antidepressants (TCAs) when given usual doses. The Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for tricyclic antidepressants indicates that individuals with decreased CYP2D6 activity are expected to demonstrate decreased metabolism of imipramine, which may lead to increased plasma concentrations of the active medication and a higher probability of adverse effects; individuals with increased CYP2C19 metabolism are expected to convert tertiary amines to secondary amines at a greater rate, which may affect response or adverse effects. This individual is expected to demonstrate decreased CYP2D6 activity and increased CYP2C19 activity; therefore, consider selecting an alternate medication.
lansoprazole *Prevacid*	Increased risk for therapeutic failure. According to the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C19 and proton pump inhbitors (PPIs), individuals with ultrarapid CYP2C19 activity may have decreased systemic concentrations of PPIs and may be at risk for therapeutic failure and require a dose adjustment. CPIC recommends increasing the starting daily dose by 100%, which may be given in dividided doses, and monitoring for efficacy. See the CPIC guideline for more details.
lofexidine *Lucemyra*	According to the FDA label, individuals who are CYP2D6 poor metabolizers should be monitored for adverse events such as orthostatic hypotension and bradycardia.

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Medication	Comment
meclizine *Medi-Meclizine, Bonine, Motion Sickness, Verticalm*	Potential for adverse events. According to the FDA label, CYP2D6 poor metabolizers have reduced clearance of donepezil and should be monitored for adverse events.
meloxicam *Mobic*	According to the Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline for NSAIDs, individuals with reduced CYP2C9 metabolism may be at increased risk of toxicity when treated with standard doses. Consider selecting an alternate therapy not metabolized by CYP2C9 or an NSAID metabolized by CYP2C9 that has a shorter half-life.
metoclopramide *Reglan*	According to the FDA label, individuals who are CYP2D6 poor metabolizers may have higher than expected plasma concentrations of metoclopramide when administered a standard dose, and may be at risk for adverse reactions. A lower dose is recommended. Refer to the FDA label for indication-specific dosing recommendations.
metoprolol *Toprol, Lopressor*	According to the FDA label, CYP2D6 poor metabolizers have higher than expected systemic concentrations of metoprolol. Monitor carefully.
mirabegron *Myrbetriq*	According to the FDA label, CYP2D6 poor metabolizers have higher systemic concentrations of mirabegron.
nebivolol *Bystolic*	According to the FDA label, CYP2D6 poor metabolizers have higher than expected systemic concentrations of nebivolol. However, the FDA label suggests that no dose adjustments are necessary as the clinical effect and safety profile observed in poor metabolizers are similar to those of normal metabolizers.
nortriptyline *Pamelor*	According to the FDA label, CYP2D6 poor metabolizers may have higher than expected plasma concentrations of nortriptyline when given usual doses. The Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for tricyclic antidepressants indicates that individuals with decreased CYP2D6 activity are expected to demonstrate decreased metabolism of nortriptyline, which may lead to increased plasma concentrations of the active medication and a higher probability of adverse effects. This individual is expected to demonstrate decreased CYP2D6 activity. The CPIC guideline suggests considering selecting an alternate medication or if nortriptyline use is warranted considering a 50% reduction of the starting dose.
oliceridine *Olinvyk*	According to the FDA label, CYP2D6 poor metabolizers may require less frequent dosing. Closely monitor for respiratory depression and sedation at frequent intervals and base subsequent doses on the severity of pain and response to treatment.
omeprazole *Prilosec, Zegerid, OmePPi*	Increased risk for therapeutic failure. According to the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C19 and proton pump inhbitors (PPIs), individuals with ultrarapid CYP2C19 activity may have decreased systemic concentrations of PPIs and may be at risk for therapeutic failure and require a dose adjustment. CPIC recommends increasing the starting daily dose by 100%, which may be given in dividided doses, and monitoring for efficacy. See the CPIC guideline for more details.
oxycodone	Potential for insufficent analgesia. Data are conflicting on the association of CYP2D6 phenotype and oxycodone analgesic effect and toxicity. An alternate medication such as hydrocodone may be considered with monitoring for efficacy. Concomitant use of CYP3A4 inducers may also contribute to potential for insufficient analgesia.

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Medication	Comment
pantoprazole *Protonix*	Increased risk for therapeutic failure. According to the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C19 and proton pump inhbitors (PPIs), individuals with ultrarapid CYP2C19 activity may have decreased systemic concentrations of PPIs and may be at risk for therapeutic failure and require a dose adjustment. CPIC recommends increasing the starting daily dose by 100%, which may be given in dividided doses, and monitoring for efficacy. See the CPIC guideline for more details.
paroxetine *Paxil*	According to the Clinical Pharmacogenetics Implementation Consortium guideline for selective serotonin reuptake inhibitors, there is a potential for adverse events due to reduced CYP2D6-mediated metabolism. Consider selecting an alternate medication not predominantly metabolized by CYP2D6 or if the use of paroxetine is warranted, consider a reduced starting dose with titration to response.
perphenazine *Trilafon*	Increased potential for adverse events. According to the FDA label, patients who are CYP2D6 poor metabolizers should be administered a reduced dose. Please see the FDA label for details.
phenytoin *Phenytek, Dilantin*	Consider testing for HLA-B*15:02 prior to prescription. According to the CPIC guideline, a typical initial/loading dose is recommended, followed by a reduction (by approximately 50%) for subsequent doses. Subsequent doses should be adjusted according to therapeutic drug monitoring, response, and adverse effects.
pimozide *Orap*	According to the FDA label, CYP2D6 poor metabolizers may require a different dosing strategy and may take longer to achieve steady state when used at doses >4mg/day for adults or >0.05mg/kg/day for children. See FDA drug label for details regarding medication dosing.
piroxicam *Feldene*	According to the FDA label and the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C9 and NSAIDS, individuals with decreased CYP2C9 activity may have higher systemic concentrations of piroxicam and may be at increased risk of adverse reactions. CPIC recommends selection of an alternate therapy not metabolized by CYP2C9 or metabolized by CYP2C9 but with a shorter half-life. The FDA label suggests consideration of a reduced dose. See the CPIC guideline and FDA label for more details.
propafenone *Rythmol*	Increased risk for adverse events. According to the FDA label, CYP2D6 poor metabolizers have higher than expected systemic concentrations of propafenone and are at increased risk for adverse reactions (e.g. arrhythmias). Propafenone should not be administered in CYP2D6 poor metabolizers who are taking a CYP3A4 inhibitor.
propranolol *Inderal, Innopran*	According to the FDA label, CYP2D6 poor metabolizers have higher than expected systemic concentrations of propranolol. Monitor carefully.
protriptyline *Vivactil*	According to the FDA label, CYP2D6 poor metabolizers may have higher than expected plasma concentrations of tricyclic antidepressants when given usual doses. Due to the potential for adverse events, consider an alternate medication or reduction of the starting dose with use of therapeutic drug monitoring to further titrate the dose.

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Medication	Comment
risperidone *Risperdal*	Decreased CYP2D6-mediated metabolism may result in higher risperidone and lower 9-hydroxyrisperidone concentrations. Some literature suggests that dosage adjustment or use of an alternate therapy may be advised, while other studies and the FDA label indicate that there is limited evidence of a clinical impact of these differences in medication/metabolite concentrations and that a standard dose may be appropriate.
rosuvastatin *Crestor*	According to the FDA label, individuals with this SLCO1B1 genotype have higher than expected systemic concentrations of rosuvastatin. Increased rosuvastatin levels have been reported with this genotype, but have not definitively been associated with myopathy or reduced efficacy.
sertraline *Zoloft*	According to the Clinical Pharmacogenetics Implementation Consortium guideline for selective serotonin reuptake inhibitors, there is a potential for lack of efficacy due to increased CYP2C19-mediated metabolism. Initiate with standard dose; if patient does not respond as expected, consider an alternate medication not predominantly metabolized by CYP2C19.
simvastatin *FloLipid, Zocor*	According to the FDA label and Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for simvastatin, individuals with this SLCO1B1 genotype have higher than expected systemic concentrations of simvastatin and may be at risk for adverse reactions (myopathy). The risk of adverse reaction (myopathy) is higher for patients on 80 mg than for those on lower doses. CPIC recommends considering a lower dose or an alternate medication.
siponimod *Mayzent*	According to the FDA label, siponimod is contraindicated in patients with this CYP2C9 genotype.
tacrolimus *Envarsus, Protopic, Astagraf*	Increased doses may be required. According to the FDA label and the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP3A5 and tacrolimus dosing, individuals with intermediate CYP3A5 activity have lower systemic tacrolimus concentrations and a lower probability of achieving target tacrolimus concentrations when taking a standard dose. Therapeutic drug monitoring should be used to guide dose adjustments. See the FDA label and CPIC guideline for more information.
tamoxifen *Nolvadex, Soltamox*	According to the FDA label and CPIC guideline for tamoxifen, this individual may have a lower than expected concentration of the active metabolite, endoxifen, and a poor response to tamoxifen. CPIC recommends considering alternative hormonal therapy such as an aromatase inhibitor for postmenopausal women or aromatase inhibitor along with ovarian function suppression in premenopausal women. Note, higher dose tamoxifen (40 mg/day) increases but does not normalize endoxifen concentrations in CYP2D6 poor metabolizers.
tamsulosin *Flomax*	According to the FDA label, CYP2D6 poor metabolizers have higher than expected systemic concentrations of tamsulosin. Use with caution, particularly at doses higher than 0.4 mg.
tenoxicam *Mobiflex*	According to the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C9 and NSAIDS, individuals with decreased CYP2C9 activity may have higher systemic concentrations of tenoxicam and may be at increased risk of adverse reactions. CPIC recommends selection of an alternate therapy not metabolized by CYP2C9 or metabolized by CYP2C9 but with a shorter half-life. See the CPIC guideline for more details.

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MAYO CLINIC LABORATORIES

Patient ID	Patient Name		Birth Date	Gender	Age
SA00144448	TESTING, PGXQP		1966-05-26	M	54
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
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Medication	Comment
tetrabenazine *Xenazine*	Increased risk for adverse events. According to the FDA label, CYP2D6 poor metabolizers have higher than expected systemic concentrations of tetrabenazine. The maximum recommended single dose for CYP2D6 poor metabolizers is 25 mg and the maximum recommended total daily dose is 50 mg.
thioridazine *Mellaril*	According to the FDA label, thioridazine is contraindicated in individuals with significantly reduced CYP2D6 activity due to increased risk for QT interval prolongation, Torsades de pointes, and sudden death. Use of an alternate medication is recommended.
tolterodine *Detrol*	Increased risk for adverse events, such as QT prolongation. According to the FDA label, CYP2D6 poor metabolizers have higher than expected systemic concentrations of tolterodine and are at risk for adverse events. Monitor carefully.
tramadol *Ultram, ConZip*	Potential for reduced efficacy. According to the CPIC guideline (titled for codeine), CYP2D6 poor metabolizers may have lower systemic concentrations of the active metabolite, which may result in reduced efficacy. Consider an alternate medication (e.g. non-opioid analgesic) if response is suboptimal.
trimipramine *Surmontil*	According to the FDA label, CYP2D6 poor metabolizers may have higher than expected plasma concentrations of tricyclic antidepressants (TCAs) when given usual doses. The Clinical Pharmacogenetics Implementation Consortium guideline for tricyclic antidepressants indicates that individuals with decreased CYP2D6 activity are expected to demonstrate decreased metabolism of trimipramine, which may lead to increased plasma concentrations of the active medication and a higher probability of adverse effects; individuals with increased CYP2C19 metabolism are expected to convert tertiary amines to secondary amines at a greater rate, which may affect response or adverse effects. This individual is expected to demonstrate decreased CYP2D6 activity and increased CYP2C19 activity; therefore, consider selecting an alternate medication.
valbenazine *Ingrezza*	Increased risk for adverse reaction. According to the FDA label, a dose reduction may be considered based on tolerability and potential QT prolongation in CYP2D6 poor metabolizers.
venlafaxine *Effexor*	Increased risk for adverse reaction. According to the FDA label, CYP2D6 poor metabolizers may have higher than expected systemic parent drug and metabolite concentrations. Additionally, the Dutch Pharmacogenetics Working Group guidelines suggest that there is a potential for increased venlafaxine and decreased O-desmethylvenlafaxine concentrations due to decreased CYP2D6-mediated metabolism. Consider a dose reduction, alternate medication not predominantly metabolized by CYP2D6, or using therapeutic drug monitoring to aid in titrating the dose to clinical response.
voriconazole *Vfend*	According to the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C19 and voriconazole therapy, individuals who are CYP2C19 ultrarapid metabolizers have a decreased probability of attaining therapeutic concentrations with standard dosing. Therefore, consider an alternate medication (e.g. isavuconazole, liposomal amphotericin B, posaconazole).
vortioxetine *Trintellix*	According to the FDA label, the maximum recommended dose for CYP2D6 poor metabolizers (such as this individual) is 10 mg/day. Consider reduction of the starting dose with careful monitoring or an alternate medication.

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Medication	Comment
warfarin *Coumadin, Jantoven*	This patient's CYP2C9 and VKORC1 genotype suggests that a significant warfarin dose decrease may be required to maintain optimal INR. Initial warfarin dosing recommendations based on the CYP2C9/VKORC1 genotype are available in the drug label. Furthermore, the rs12777823 A allele was detected. For patients who self-identify as being of African ancestry, the presence of the rs12777823 A allele suggests that this patient may require a decreased warfarin dose than that predicted by CYP2C9/VKORC1 alone. Currently, there is no evidence to support a role of this variant on warfarin dosing in patients of non-African ancestry.

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Genotype Findings

Analyte	Result	Performing Site
CYP1A2 Genotype	*1F/*1F	MCR
CYP1A2 Phenotype	Rapid metabolizer This individual is expected to metabolize CYP1A2 substrates at a normal rate, or at a higher than normal rate if CYP1A2 is induced such as when exposed to tobacco smoke or other substances known to induce CYP1A2. If CYP1A2 inducers are stopped or started, a change in phenotype is possible. Note: This is the most common phenotype among Caucasian individuals.	MCR
CYP2C19 Genotype	*17/*17	MCR
CYP2C19 Phenotype	Ultrarapid metabolizer For prodrugs that are activated by CYP2C19, increased drug activation is expected and may result in increased risk for adverse reactions; for drugs that are inactivated by CYP2C19, increased drug inactivation is expected which may result in lower blood levels of the parent drug and poorer response.	MCR
CYP2C9 Genotype	*3/*3	MCR
CYP2C9 Phenotype	Poor metabolizer This patient has a genotype associated with minimal to no CYP2C9 enzyme activity. Caution should be exercised when treating with drugs metabolized by CYP2C9. Dose reduction or use of an alternate medication metabolized through a different pathway may be considered.	MCR
CYP2C9 Activity Score	0.00	MCR
CYP2D6 Genotype	*4/*4	MCR
CYP2D6 Phenotype	Poor metabolizer Prodrugs are converted to their active metabolite at a greatly reduced rate, if at all, which may lead to decreased efficacy for some drugs. Alternatively, drugs that are inactivated by CYP2D6 are metabolized at a greatly reduced rate, if at all, which is expected to result in an increased risk of adverse effects.	MCR
CYP2D6 Activity Score	0.00	MCR
CYP3A4 Genotype	*1/*1	MCR
CYP3A4 Phenotype	Normal (extensive) metabolizer Normal metabolism of drugs that are inactivated or activated by CYP3A4 is expected.	MCR
CYP3A5 Genotype	*1/*3	MCR

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Analyte	Result	Performing Site
CYP3A5 Phenotype	Intermediate metabolizer This patient is a CYP3A5 expresser and is expected to have increased CYP3A5 metabolism compared to individuals with the common CYP3A5*3/*3 genotype. Higher doses of some medications metabolized by CYP3A5 may be required because original dosing recommendations for some CYP3A5-metabolized medications were determined based on populations primarily comprised of CYP3A5 poor metabolizers (i.e. CYP3A5*3/*3). Therapeutic drug monitoring is recommended for applicable medications.	MCR
SLCO1B1 Genotype	*5/*5	MCR
SLCO1B1 Phenotype	Poor function SLCO1B1 encodes the organic anion-transporting polypeptide 1B1 (OATP1B1) influx transporter located on the basolateral membrane of hepatocytes. OATP1B1 facilitates the hepatic uptake of statins as well as other endogenous compounds (e.g. bilirubin). This individual is expected to have decreased transport of some substrates; however, there may be a variable impact of this genetic variation among substrates. This individual is positive for the c.521T>C variant that is commonly studied and associated with simvastatin-associated myopathy.	MCR
Warfarin *CYP2C9* Genotype	*3/*3	MCR
Warfarin *VKORC1* Resistance Genotype	No resistance variants detected	MCR
Warfarin *VKORC1* Promoter Genotype	G/G	MCR
Warfarin CYP2C9 and VKORC1 Promoter Phenotype	High warfarin sensitivity CYP2C9 is the primary enzyme responsible for metabolism of S-warfarin, while VKORC1 encodes the vitamin K epoxide reductase protein, which is the target of warfarin. Initial warfarin dosing recommendations based on the CYP2C9/VKORC1 genotype are available in the drug label.	MCR
Warfarin *CYP4F2* *3 Genotype	*1/*1 CYP4F2 is a vitamin K oxidase that limits excessive accumulation of vitamin K. For patients who self-identify as being of non-African ancestry, the CYP4F2*3 allele has been demonstrated to affect enzyme activity and to be associated with a modest influence on warfarin dose requirements. Currently, there is no evidence to support a role of this variant on warfarin dosing in patients of African ancestry.	MCR

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Analyte	Result	Performing Site
Warfarin rs12777823 Genotype	G/A The rs12777823 variant is located within the CYP2C cluster, and is associated with significant alterations in warfarin clearance in individuals of African American ancestry. Although this variant is identified in other populations, the association with warfarin dose requirements has only been identified among African Americans.	MCR

Additional Information

MCR

Initial warfarin dosing recommendations based on the CYP2C9/VKORC1 genotype are available in the drug label located online at: www.accessdata.fda.gov/drugsatfda_docs/label/2010/009218s108lbl.pdf
For additional information related to CYP4F2*3 (rs2108622) and rs12777823, please see the Clinical Pharmacogenomics Implementation Consortium Guideline for Pharmacogenetics-Guided Warfarin Dosing: 2017 Update (Clin Pharmacol Ther. 2017 Feb 15. doi: 10.1002/cpt.668). Medications and recommendations included in this report are based on the Clinical Pharmacogenetics Implementation Consortium Guidelines www.cpicpgx.org/guidelines/,
information publicly available in PharmGKB www.pharmgkb.org,
Dutch Pharmacogenetics Working Group Recommendations www.pharmgkb.org,
FDA medication labels, and available literature. For additional information regarding pharmacogenomic genes and their associated drugs, please see the Pharmacogenomic Associations Tables on the Mayo Clinic Laboratories webpage,https://www.mayocliniclabs.com/it-mmfiles/Pharmacogenomic_Associations_Tables.pdf.
This resource also includes information regarding enzyme inhibitors and inducers, as well as potential alternate drug choices. Please note that the information at this link is educational material intended for health care professionals and may not be comprehensive. This educational material is not intended to supersede the care provider's experience and knowledge of her/his patient to establish a diagnosis or a treatment plan. All medications require careful clinical monitoring. Please contact the laboratory at 1–800–533–1710 for further information about pharmacogenomic testing. For additional information on star allele nomenclature for the Cytochrome P450 enzymes, see the Pharmacogene Variation Consortium website www.pharmvar.org.

Method

MCR

Genotyping is performed using a PCR-based 5'-nuclease assay. Fluorescently labeled detection probes anneal to the target DNA. PCR is used to amplify the segment of DNA that contains the polymorphism. If the detection probe is an exact match to the target DNA, the 5'-nuclease polymerase degrades the probe, the reporter dye is released from the effects of the quencher dye, and a fluorescent signal is detected. Genotypes are assigned based on the allele-specific fluorescent signals that are detected. (TaqMan SNP Genotyping Assays User Guide, Applied Biosystems)

Disclaimer

1 MCR

Targeted variant analysis performed by a polymerase chain reaction (PCR)-based 5'-nuclease assay using fluorescently labeled detection probes was used to test for the presence or absence of specific variants in the following genes. Pharmacogenomic data for these specific variants are reviewed and reported (if present): CYP1A2 (NM_000761.4) *1F, *1K, *6, and *7 CYP2C9 (NM_000771.3) *2, *3, *4, *5, *6, *8, *9, *11, *12, *13, *14, *15, *16, *17, *18, *25, *26, *28, *30, *33, and *35 CYP2C19 (NM_000769.1) *2, *3, *4, *5, *6, *7, *8, *9, *10, *17, and *35 CYP2D6 (NM_000106.4) *2A, *2, *3, *4, *4N, *5, *6, *7, *8, *9, *10, *11, *12, *13, *14,*15, *17, *29, *35, *36, *41, *68, *114, and CYP2D6 gene duplication Additional CYP2D6 variants may be detected through the cascade testing process. CYP3A4 (NM_017460.5) *8, *11, *12, *13, *16, *17, *18, *22, and *26
CYP3A5 (NM_000777.4) *3, *5, *6, *7, *8, and *9
CYP4F2 (NM_001082.4) *3
rs12777823G>A
SLCO1B1 (NM_006446.4) rs4149056 variant found in the *5, *15 and *17 alleles, and rs4149015 found in the *17 and *21 alleles VKORC1 (NM_024006.5) c.–1639G>A, c.85G>T,

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c.106G>T, c.121G>T, c.134T>C, c.172A>G, c.196G>A, c.358C>T, and c.383T>G

A two-tiered testing approach was used to identify CYP2D6 variants (including copy number variants). Tier 1 (always performed) consists of targeted variant analysis and a test for copy number variation (CNV) using CYP2D6-specific probes for the promoter, intron 6 and exon 9. Detectable CNVs include duplications, multiplications and deletions (*5) of CYP2D6, as well as CYP2D6–2D7 (i.e. *4N, *36, *68) and CYP2D7–2D6 (i.e. *13) hybrid genes. Tier 2, which is only performed when the phenotype in Tier 1 is ambiguous, consists of comprehensive Sanger sequencing of the CYP2D6 gene and/or CYP2D7–2D6 and CYP2D6–2D7 hybrid genes. For additional clinical information, see Cytochrome P450 2D6 (CYP2D6) Comprehensive Cascade (test ID 2D6Q).

For additional information on star allele nomenclature, please see the Pharmcogene Variation Consortium website www.pharmvar.org. Please contact the laboratory at 1–800–533–1710 for further information about pharmacogenomic testing.

CAUTIONS:

CLINICAL CORRELATIONS

This test is not designed to provide specific dosing recommendations and is to be used only as an aid to clinical decision making. Drug-label guidance should be used when dosing patients with medications, regardless of the predicted phenotype. Test results should be interpreted in the context of clinical findings, family history, and other laboratory data.

TECHNICAL LIMITATIONS

Pharmacological phenotype prediction and interpretation is based on the limited dataset of the specific variants/alleles interrogated. This test will not detect all variants that may cause abnormal drug metabolism or drug response. Rare variants may be present that could lead to false negative or positive results. If results obtained do not match the clinical findings (phenotype), additional testing should be considered. Assignment of a *1 allele indicates that none of the alleles of interest were detected, but does not rule out the presence of other variants in the gene. For additional information regarding the standard Human Genome Variation Society (HGVS) nomenclature associated with these variants, please see the Mayo Clinic Laboratories test catalog for this test.

The methods used to genotype may not identify the precise configuration of variants or alleles (in the case of CYP2D6) on a patient's chromosomes; therefore, this lab will report the most likely diplotype based upon reported or observed frequencies. Note that this ambiguity can be clarified by family studies, if desired. Samples may contain donor DNA if obtained from patients who received non-leukoreduced blood transfusions or allogeneic hematopoietic stem cell transplantation. Results from samples obtained under these circumstances may not accurately reflect the recipient's genotype. For individuals who have received blood transfusions, the genotype usually reverts to that of the recipient within 6 weeks. For individuals who have received allogeneic hematopoietic stem cell transplantation, a pre-transplant DNA specimen is recommended for testing. Pharmacogenetic test results in patients who have undergone liver transplantation may not accurately reflect the patient's drug metabolism status.

Reviewed by MCR

Mary Karow

Received: 06 May 2021 10:29 **Reported:** 06 May 2021 11:13

Laboratory Notes

1 This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

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