

PHARMACOGENETIC TEST REQUEST FORM

#TRF031914

Patient Information: Please make sure that the patient's name is included on this form and that all other information is included here or on an attachment.

Name:	Gender: <input type="checkbox"/> Female <input type="checkbox"/> Male
Address:	Race: <input type="checkbox"/> Caucasian <input type="checkbox"/> African American
City:	<input type="checkbox"/> Hispanic <input type="checkbox"/> Asian
State:	<input type="checkbox"/> Other
Zip Code:	Date of Birth:
Phone:	Social Security Number:
	Do you use denture adhesive? <input type="checkbox"/> Yes <input type="checkbox"/> No

Insurance Information: Please include a copy of both sides of the insurance card(s).

Primary Insurance	Secondary Insurance
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Testing Panel: Please check the desired testing panel(s) or circle desired test(s). Genes Tested

☐ Full Panel (All Tests in the Cardiac, Pain and Psychotropic Panels)

☐ Cardiac Drug Metabolism and Risk Factor Profile

Warfarin	Statin induced myopathy	Metoprolol	CYP2D6	CYP2C19	Factor II
NSAID	Antiplatelet	CVD Risk	CYP2C9	SLCO1B1	Factor V
ARB	Antiarrhythmic	Thrombosis Risk	CYP3A4	APOE	MTHFR
			CYP3A5		VKORC1

☐ Pain Management Drug Metabolism Profile

Opiate	Tricyclic Antidepressants	CYP2C19	CYP3A4	SLCO1B1
NSAID	Methotrexate	CYP2D6	CYP3A5	CYP2C9

☐ Surgery Drug Metabolism Profile

Opiate	NSAID	Antiplatelet	CYP2C19	CYP3A4	Factor II
		Thrombosis Risk	CYP2D6	CYP3A5	Factor V
				CYP2C9	MTHFR

☐ Psychotropic Drug Metabolism Profile

Select SSRI/SNRI	Tricyclic Antidepressants	Select psychotropic	CYP2C19	CYP3A4	CYP2C9
	Hyperhomocysteinemia		CYP2D6	CYP3A5	MTHFR

Diagnosis Information: You must include at least one ICD-9 code showing the patient's medical condition for each panel chosen above, indicating the reasons for ordering this test.

ICD-9 Diagnosis Code	Additional Information

Authorizations: All information is required

Ordering Provider Name:	
Ordering Provider Signature:	
Specimen Collector Name and Date:	
Practice Name:	

Genetic Testing and Billing Informed Consent

Purpose of the Test—The purpose of the GeneTrait Laboratories' (GTL) cardiac, pain, psychotropic and surgery test panels is to determine whether you (the patient) have a genetic makeup that causes your body to process certain medications differently than the "average" person. Many people do. If you are taking the cardiac test panel, then the test will also identify whether you have specific genetic characteristics that indicate an increased or decreased likelihood of you developing certain cardiac conditions in the future.

Medical Implications, Alternatives and Limitations—There is no alternative test or procedure that provides the exact same benefits as genetic testing. The medical implications of the test results are that your doctor may treat your condition with greater accuracy if the results show that your genes contain DNA variants from the average population, as further described below. If your test does not show that you possess relevant genetic variants, then the result does not affect your treatment, but you could still possess relevant genetic variations that the test is not designed to identify.

Possible Risks--This is a non-invasive test performed on DNA samples obtained by rubbing your cheek with a swab. There are no known medical risks from this genetic testing.

Possible Benefits--The benefits are that your doctor will obtain information about your unique genetic makeup. If the test shows variants in your DNA that cause your body to process medications or certain medical conditions differently than the average person, then your doctor will be able to make adjustments to medication that will allow you to manage or recover from your medical condition more quickly. In some cases it will also allow you to avoid, or greatly lessen the impact of, adverse drug reactions or interactions and the chances of receiving ineffective medication.

With the cardiac panel, if the test shows that you are more prone to developing certain cardiac conditions, then your doctor or medical advisor may be able to suggest changes in diet, exercise or other lifestyle factors that allow you to have a better chance of avoiding or lessening those conditions. Knowing that you have a greater risk of developing certain conditions may give you more motivation to go ahead and make desirable changes in diet, exercise, etc.

Reliability of Positive Result as a Predictor of Future Medical Conditions—If you test positive for certain DNA variants that make you more likely to develop certain cardiac conditions, that does not necessarily mean that you will develop those conditions. It just increases your chances. Whether you develop them or not, and to what extent, will continue to depend on many factors, including your past and future lifestyle choices.

Privacy and Confidentiality—Your specimens will be used only for this test, and any portion of your DNA specimens that are not consumed during this test will be destroyed by GeneTrait Laboratories (GTL) within sixty days following specimen collection, or the specimen holding period required by CLIA for proficiency testing, if longer. Your genetic information is completely confidential. GTL will keep your genetic records for years, but will not release them to anyone except your doctor's office, unless we receive a court order or other legal process to release them, or we receive a properly completed Medical Report Request Form from you (you may obtain that form on our web site, www.genetrait.com). Keep in mind that if you give anyone, such as an insurance company or employer, permission to access your medical records, the records they obtain from your doctor's office will include the results of this genetic testing.

Genetic Counseling—Your doctor can discuss any questions you have regarding genetic testing. You may also consult genetic counselors, trained specifically in this area of medicine, either before you sign this Consent or later. Your doctor's office can give you the name and contact information for genetic counselors.

Billing—I understand that I am responsible for payment for the requested genetic testing. I hereby authorize GeneTrait Laboratories to bill my insurance companies, and to take all necessary steps on my behalf to secure payment from my insurers. I authorize any holder of medical information about me to release it to GTL and to my insurers, as needed for insurance billing. I also authorize GTL to retain any insurance payments for these tests.

Consent--I have reviewed, understand and have been given a copy of this Consent form. I have no further questions at this time, and I voluntarily consent to taking and paying for the requested genetic tests.

PATIENT OR GUARDIAN SIGNATURE

PRINT PATIENT NAME

DATE

PHYSICIAN SIGNATURE (NY Only)

PRINT PHYSICIAN NAME

DATE

SPECIMEN COLLECTION PROCEDURE

If you have any questions, please call (609) 235-1600

#SCP080614

1. Completing the Test Request Form

Please fill out the Test Request Form completely. If filling out by hand, please print, and ensure that the following are completed:

- Select the desired testing panel
- Provide at least one Diagnosis Code that supports the requested testing
- Copy the patient's insurance card
- Signature of Ordering Medical Professional
- Sample Collector's name

2. Completing the Informed Consent Form

Provide one copy of the Informed Consent Form to the patient, and give the patient the opportunity to look it over and ask any questions.

The patient must sign, date and print their name on a copy of the Informed Consent Form to be provided with the submitted samples.

3. Collect Buccal Swabs

Open swab kit and remove the specimen envelope for the patient whose sample you are obtaining.

Remove the specimen envelope from its plastic wrapper, leaving the desiccant packet in the specimen envelope (it keeps the swabs dry).

Print the patient's name and date of birth on the specimen envelope, along with the date of collection, and the collector's initials.

Firmly rub each of the 4 swabs provided up and down, while rotating the swab against the inside of the patient's cheek. Try to avoid swabbing the gums or teeth, as denture adhesive and similar dental products can interfere with the DNA extraction process.

At the collector's discretion, an adult or older child may swab his or her own cheek (ask them to please rub as hard as possible without hurting themselves—they will usually rub harder than the collector would).

Place each swab directly into the specimen envelope immediately when it comes out of the patient's mouth. Make sure that the desiccant packets are in the specimen envelope with the specimens.

Close the self adhesive flap of the envelope and place the specimen envelope in the longer pouch at the top of the clear plastic biohazard bag, and seal the biohazard bag.

4. Completing Case Processing

Fold the Test Request Form, copies of insurance cards and the Informed Consent Form, and place them in the open front pouch of the biohazard bag, along with any other paperwork.

5. Shipping

Ship sealed swab kit(s) to GeneTrait Laboratories using the provided FedEx Airbills and Envelopes or Bags (envelopes should be used whenever possible). Please combine specimen kits into as few shipments as possible.

Sample Diagnostic Codes

The following ICD-9 diagnostic codes are offered solely as examples of ICD-9 codes that are sometimes used to indicate the reasons for ordering GTL's DNA test. It is essential that the practitioner enter one or more ICD-9 codes on the front of the Test Request Form that indicate the medical condition of the patient for which this test will help with treatment (whether such codes are shown below or not). At least one ICD-9 code should be entered for each general medical condition/test panel selected on the Test Request Form.

The sample codes below are organized according to the general medical conditions to which they relate.

CODE	DESCRIPTION	CODE	DESCRIPTION
Diagnosis Codes Relevant to all Test Panels			
V58.69	long term use of other medications	995.20	Unspec Adverse Effect, Drug Unspec
Diagnosis Codes Relevant to Cardiac Panel			
272.0	elevated cholesterol	413.0	angina (chest pain)
401.0	essential hypertension	414.00	coronary atherosclerosis of unspec type
410.70	subendocardial infarction episode unspecified	416.0	primary pulmonary hypertension
411.1	intermediate coronary syndrome	425.9	secondary cardiomyopathy unspec
272.4	hyperlipidemia (metabolic disease)		
Diagnosis Codes Relevant to Pain Panel			
338.4	chronic pain syndrome	722.52	lumbosacral intervertebral disk
338.11	acute pain due to trauma	723.1	pain cervical / neck
338.19	other acute pain	724.1	pain thoracic
338.29	other chronic pain	724.2	pain lumbar
346.11	intractable migraine	724.3	sciatica
714.0	rheumatoid arthritis	724.5	back ache, unspecified
715.0	osteoarthrosis, generalized	724.8	other syndromes referable to back
719.40	pain in unspecified joint	726.10	disorders of bursae + tendons in shoulder region
719.45	pain in joint, pelvic region and thigh	729.1	myalgia and myositis unspecified
719.96	unspecified disorder of joint, lower leg	780.96	generalized pain
722.0	displ of cervical + intervertebral disk	836.2	other tear of cartilage or meniscus of knee
Diagnosis Codes Relevant to Surgery Panel			
Use ICD-9 code that supports the reason that surgery is being performed			
Diagnosis Codes Relevant to Antidepressant Panel			
295.70	schizoaffective disorder, unspecified	300.9	unspecified nonpsychotic mental disorder
296.20	major depressive affective disorder, 1 episode	301.4	obsessive-compulsive personality disorder
296.30	major depressive affective disorder, recur epis	309.81	posttraumatic stress disorder
296.90	unspecified episodic mood disorder	311	depressive disorder, not elsewhere classified
300.00	anxiety state, unspecified		

Common Metabolic Substrates

CYP2C9

Beta Blockers

carvedilol (Coreg)
 metoprolol (Lopressor, Toprol)
 propranolol (Inderal, Innopran XL)
 timolol

NSAIDs

celecoxib (Celebrex)
 diclofenac potassium (Cataflam)
 diclofenac sodium (Voltaren)
 flurbiprofen (Ansaid)
 ibuprofen (Advil Motrin)
 indomethacin (Indocine)
 meloxicam (Mobic)
 naproxen (Naprosyn)
 naproxen sodium (Aleve, Anaprox)
 piroxicam (Feldene)

Anti-diabetic

glibenclamide
 glyburide (DiaBeta)
 glimepiride (Amaryl)
 glipizide (Glucotrol)
 tolbutamide

Angiotensin II Blockers (hypertension)

losartan (Cozaar)
 irbesartan (Avapro)

Antidepressants

amitriptyline (Elavil)
 doxepin (Silenor, Sinequan)
 fluoxetine (Prozac)

Statins

fluvastatin (Lescol)

Other

nateglinide (Starlix)
 rosiglitazone (Avandia)
 tamoxifen (Nolvadex, Soltamox)
 toremide (Demadex)

CYP2C9/VKORC₁

Anticoagulant

warfarin (Coumain)

CYP2C19

Anti-Depressants

citalopram (Celexa)
 escitalopram (Lexapro)
 imipramine (Tofranil)
 sertraline (Zoloft, Lustral)

Anti-Platelets

clopidogrel (Plavix)
 prasugrel (Effient)

Beta-Blockers

propranolol (Inderal)

Synthetic Opioid

methadone (Symoron, Dolophine, Amidone, Methadose, Physeptone, Heptadon)

Proton Pump Inhibitors

lansoprazole (Prevacid)
 omeprazole (Prilosec)
 pantoprazole (Protonix)
 rabeprazole (Aciphex)

NSAIDs

indomethacin (Indocin)

Other

carisoprodol (Soma)
 primidone (Mysoline)

CYP2D6

Anti-arrhythmics

propafenone (Rythmol SR, Rytmonorm)

Antidepressants

amitriptyline (Elavil)
 bupropion (Amelintin, Wellbutrin)
 clomipramine (Anafranil)
 desipramine (Norpramin)

Doxepin (Sinequan)

duloxetine (Cymbalta)

Fluoxetine (Prozac)

fluvoxamine (Luvox)

Imipramine (Tofranil)

mirtazapine (Remeron, Remeron SolTab)

Nortriptyline (Pamelor)

paroxetine (Paxil, Pexava)

Sertraline (Zoloft)

trazodone (Desyrel, Olepro)

Venlafaxine (Effexor)

Anti-Psychotics

aripiprazole (Abilify)
 haloperidol (Haldol)

Olanzapine (Zyprexa, Zydys)

pimozide (Orap)

Risperidone (Risperdal, Risperdal M-Tab)

ziprasidone (Geodon)

Beta Blockers

carvedilol (Coreg)
 S-metoprolol (Lopressor)
 nebivolol (Bystolic)
 propranolol (Inderal)
 timolol (Betimol)

Hypertension

labetalol (Normodyne, Trandate)

Pain Management

codeine
 hydrocodone
 oxycodone
 tramadol (Ultram, Ultracet)

CYP3A4/3A5

Antiplatelet/Anticoag

ticagrelor (Brilinta)

Statins

atorvastatin (Lipitor)
 lovastatin (Mevacor)
 simvastatin (Zocor)

Pain Management

fentanyl

Macrolide Antibiotics

clarithromycin
 telithromycin

Benzodiazepines

alprazolam
 diazepam-30H
 midazolam
 triazolam

Immune Modulators:

cyclosporine
 tacrolimus (FK506)

HIV Antivirals

indinavir
 nelfinavir
 ritonavir
 saquinavir

Prokinetics

cisapride

Antihistamines

astemizole
 chlorpheniramine
 terfenadine

Calcium Channel Blockers

amlodipine
 diltiazem
 felodipine
 lercanidipine
 nifedipine2
 nisoldipine
 nitrendipine
 verapamil

HMG CoA Reductase

Inhibitors:

atorvastatin
 cerivastatin
 lovastatin
 simvastatin

Steroids

hydrocortisone
 progesterone
 testosterone1

Other

alfentanil
 aprepitant
 aripiprazole

boceprevir
 buspirone
 cafergot
 cilostazol
 codeine-N-demethylation
 dapsone
 dexamethasone
 dextromethorphan2
 docetaxel
 domperidone
 eplerenone
 finasteride
 gleeevec
 haloperidol
 irinotecan
 LAAM
 lidocaine
 methadone
 nateglinide
 ondansetron
 pimozide
 propranolol
 quetiapine
 quinine
 risperidone
 romidepsin
 salmeterol
 sildenafil
 sirolimus
 sorafenib
 sunitinib
 tamoxifen
 taxol
 telaprevir
 terfenadine
 torisel
 trazodone
 vemurafenib
 vincristine
 zaleplon
 ziprasidone
 zolpidem

Inducers and Inhibitors

CYP2C9

Strong Inhibitors

Diflucan (fluconazole)

Moderate Inhibitors

Cordarone
 (amiodarone)
 Luvox (fluvoxamine)
 Prozac (fluoxetine)

Other Inhibitors

Paxil (paroxetine)
 Tubuzid (isoniazid)
 Zoloft (sertraline)

Inducers

Rifadin (rifampin)
 Seconal (secobarbital)

CYP2C19

Strong Inhibitors

Luvox (fluvoxamine)
 Nexium (esomeprazole)
 Prevacid (lansoprazole)
 Prilosec (omeprazole)
 Ticlid (ticlopidine)

Moderate Inhibitors

Prozac (fluoxetine)

Weak/Mild Inhibitors

fenofibrate/fenofibric acid
 Paxil (paroxetine)
 Topamax (topinmate)
 Zoloft (sertraline)

Other Inhibitors

Aciphex (rabeprazole)
 Protonix (pantoprazole)

Inducers

Dilantin (phenytoin)
 Rifadin (rifampin)
 Tegretol (carbamazepine)

CYP2D6

Strong Inhibitors

Benadryl
 (diphenhydramine)
 Cardioquin (quinidine)
 Paxil (paroxetine)
 Prozac (fluoxetine)
 Sensipar (cinacalcet)
 Wellbutrin (bupropion)

Moderate Inhibitors

Cymbalta (duloxetine)
 Lamisil (terbinafine)
 Lexapro (escitalopram)
 Zoloft (sertraline)

Weak/Mild Inhibitors

Celebrex (celecoxib)
 Clexa (citalopram)
 Cordarone (amiodarone)
 Effexor (venlafaxine)
 Luvox (fluvoxamine)
 Remeron (mirtazapine)
 Serzone (nefazodone)
 Tagamet (cimetidine)

Other Inhibitors

Sinequan (doxepin)
 Zantac (ranitidine)
 Haldol (haloperidol)
 methadone
 nortriptyline
 chlorpheniramine
 clomipramine

CYP3A4/3A5

Strong Inhibitors

Biaxin (clarithromycin)
 indinivir
 nelfinavir
 Nizoral (ketoconazole)
 ritonavir
 saquinavir
 Serzone (nefazodone)
 Sporonox (itraconazole)
 telithromycin

Moderate Inhibitors

Calan (verapamil)
 Cardizem (diltiazem)
 Diflucan (fluconazole)
 Emend (aprepitant)
 erthromycin
 grapefruit juice

Weak/Mild Inhibitors

Tagamet (cimetidine)
 Other Inhibitors
 Cipro (ciprofloxacin)
 Cordarone (amiodarone)
 Effexor (venlafaxine)
 Luvox (fluvoxamine)
 Paxil (paroxetine)
 Prozac (fluoxetine)
 Zoloft (sertraline)

Inducers

Dailantin (phenytoin)
 Mycobutin (rifabutin)
 phenobarbital
 Rifadin (rifampin)
 St. Johns Wort
 Tegretol
 (carbamazepine)

- P450 Drug Interaction Table, Indiana University School of Medicine, Division of Clinical Pharmacology, found online at <http://medicine.iupui.edu/clinpharm/ddis/main-table/>.
- Table of Pharmacogenomic Biomarkers in Drug Labeling, United States Food and Drug Administration, found online at <http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm>.

	FDA Blackbox Warning Drugs			
<u>Analgesic</u>	<u>Gastroenterology</u>	<u>Metabolic Disorders</u>	<u>Oncology</u>	<u>Psychiatry</u>
Tramadol147	Dexlansoprazole (2)46	Carglumic Acid20	Denileukin Diftitox43	Amitriptyline6
<u>Anesthesiology</u>	Esomeprazole55	<u>Neurology</u>	Erlotinib (2)54	Aripiprazole8
Codeine36	Lansoprazole80	Carbamazepine (2)19	Everolimus (1)56	Atomoxetine10
<u>Antidotal Therapy</u>	Omeprazole103	Clobazam32	Everolimus (2)57	Citalopram (1)30
Sodium Nitrite132	Pantoprazole106	Dextromethorphan and Quinidine47	Exemestane58	Clomipramine33
<u>Cardiology</u>	PEG-3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, and Ascorbic Acid109	Drospirenone and Ethinyl Estradiol50	Fluorouracil (2)60	Clozapine35
Carvedilol22	Rabeprazole125	Galantamine65	Fulvestrant64	Desipramine44
Clopidogrel34	Metoclopramide89	Phenytoin114	Ibritumomab Tiuxetan69	Diazepam48
Isosorbide and Hydralazine78	<u>Genitourinary</u>	Tetrabenazine141	Imatinib (4)74	Doxepin49
Metoprolol90	Tolterodine145	Valproic Acid (2)153	Irinotecan77	Fluoxetine61
Prasugrel117	<u>Hematology</u>	Vortioxetine157	Lapatinib81	Fluvoxamine 63
Propafenone120	Eltrombopag (2)52	<u>Oncology</u>	Letrozole83	Loperidone70
Propranolol121	Lenalidomide82	Ado-Trastuzumab Emtansine⁴	Mercaptopurine87	Imipramine75
Quinidine123	Methylene Blue88	Afatinib5	Nilotinib (1)96	Modafinil 92
Ticagrelor144	Succimer134	Anastrozole7	Nilotinib (2)97	Nefazodone95
Warfarin (3)160	<u>Infectious Diseases</u>	Arsenic Trioxide9	Obinutuzumab100	Nortriptyline99
<u>Dental</u>	Abacavir3	Bosutinib14	Ofatumumab101	Paroxetine107
Cevimeline26	Boceprevir13	Brentuximab Vedotin¹⁵	Omacetaxine102	Perphenazine112
<u>Dermatology</u>	Chloroquine27	Busulfan16	Panitumumab (2)105	Pimozide115
Dapsone (1)40	Dapsone (2)41	Capecitabine17	Pazopanib108	Protriptyline122
Fluorouracil (1)59	Mafenide85	Cetuximab (2)²⁵	Pertuzumab113	Risperidone128
<u>Endocrinology</u>	Maraviroc86	Cisplatin29	Ponatinib116	Thioridazine143
Atorvastatin11	Nalidixic Acid94	Crizotinib37	Rasburicase126	Trimipramine151
Chlorpropamide28	Nitrofurantoin98	Dabrafenib (2)³⁹	Rituximab129	Venlafaxine155
Glimepiride66	Peginterferon alfa-2b110	Dasatinib42	Tamoxifen (3)138	<u>Pulmonary</u>
Glipizide67	Primaquine119		Thioguanine142	Indacaterol76
Glyburide68	Quinine Sulfate124		Tositumomab146	Ivacaftor79
Lomitapide84	Rifampin, Isoniazid, and Pyrazinamide127		Trametinib148	<u>Rheumatology</u>
Mipomersen91	Simeprevir131		Trastuzumab149	Azathioprine12
Pravastatin118	Sofosbuvir133		Tretinoin150	Carisoprodol21
Rosuvastatin130	Sulfamethoxazole and Trimethoprim135		Vemurafenib154	Celecoxib23
	Telaprevir139			Flurbiprofen62
	Terbinafine140			Pegloticase111
	Voriconazole156			<u>Transplantation</u>
				Mycophenolic Acid93