

GENETICS AND GENOMICS DIAGNOSTIC LABORATORY

For local courier service and/or inquiries, please contact 513-636-4474 • Fax: 513-636-4373 www.cincinnatichildrens.org/moleculargenetics • Email: moleculargenetics@cchmc.org Mailing Address:

3333 Burnet Avenue, Room R1042 Cincinnati, OH 45229

GENETIC PHARMACOLOGY SERVICE REQUISITION

All Information Must Be Completed Before Sample Can Be Processed

PATIENT INFORMATION ETHNIC/RACIAL BACKGROUND (Choose All)	
Patient Name:,,,	 European American (White) African-American (Black) Native American or Alaskan Asian-American Pacific Islander Ashkenazi Jewish ancestry
Home Phone: MR# Date of Birth / / Gender:	Latino-Hispanic

BILLING INFORMATION (Choose ONE method of payment)

□ REFERRING INSTITUTION

COMMERCIAL INSURANCE*

Institution.	Insurance can only be billed if requested at the time of service. Policy Holder Name:	
Address:	Gender: Date of Birth / /	
City/State/Zip:	Authorization Number:	
Accounts Payable Contact Name:		
Phone:		
Fax:		
Email:	City/State/Zip:	
	Insurance Phone Number:	

* PLEASE NOTE:

- We will not bill Medicaid, Medicaid HMO, or Medicare except for the following: Cincinnati Children's Patients, Cincinnati Children's Providers, or Designated Regional Counties.
- If you have questions, please call 1-866-450-4198 for complete details.

SAMPLE/SPECIMEN INFORMATION

Each test requires 2 mL of whole blood in EDTA tube, saliva or 2 cytobrushes. Bone marrow and liver transplant recipients have special specimen requirements. See pages 2 and 3 for details.

Specimen Date: _____ / ____ / ____ Time: _____

Specimen Amount: ____

DRAWN BY:

*Phlebotomist must initial tube of specimen to confirm sample identity. Sample tubes for liver transplant patients must be labeled as DONOR or RECIPIENT.

	HYSICIAN
Physician Name (print):	
Address:	
Phone: ()	Fax: ()
Email:	
Genetic Counselor/Lab Contact Name: _	
Phone: ()	Fax: ()
Email:	
	Date:///
Referring Physician Signature (REQUIRE	D)

\Box Patient signed completed ABN

Medical Necessity Regulations: At the government's request, the Molecular Genetics Laboratories would like to remind all physicians that when ordering tests that will be paid under federal health care programs, including Medicare and Medicaid programs, that these programs will pay only for those tests the relevant program deems to be (1) included as covered services, (2) reasonable, (3) medically necessary for the treatment and diagnosis of the patient, and (4) not for screening purposes.



INDICATION FOR TESTING

Indication for drug prescription (or ICD-10 Code): ____

GPS TESTS AVAILABLE (Please choose ONE)

	Test Name	Relevant Drugs
	Comprehensive Pharmacogenetics Panel (CYP2C19, CYP2C9, CYP2D6, CYP3A5, NUDT15, TPMT)	6-mercaptopurine, 6-thioguanine, amitriptyline, aripiprazole, atomoxetine, azathioprine, citalopran clomipramine, codeine, desipramine, doxepin, escitalopram, fluoxetine, fluvoxamine, haloperidol, hydrocodone, imipramine, maprotiline, nortriptyline, olanzapine, oxycodone, paroxetine perphenazine, risperidone, sertraline, tacrolimus thioridazine, tramadol, trimipramine, venlafaxine voriconizole
	Psychiatry Pharmacogenetics Expanded Panel (CYP2C19/CYP2D6)	amitriptyline, aripiprazole, atomoxetine, citalopram, clomipramine, desipramine, doxepin, escitalopram, fluoxetine, fluvoxamine haloperidol, imipramine, maprotiline, nortriptyline, olanzapine, paroxetine, perphenazine, risperidone, sertraline, thioridazine, trimipramine, venlafaxine
	Opioid CYP2D6 Pharmacogenetics Panel	codeine, hydrocodone, oxycodone, tramadol
	CYP2D6/CYP2C19 Genotype Analysis (for Bone Marrow Transplant Patients)	codeine, hydrocodone, oxycodone, tramadol, voriconizole
	POST -BMT recipients <u>MUST</u> send both BLOOD and CYTOBRUSH samples for testing to be performed (See page 3 for additional information)	
	PRE-BMT patients can send one sample (blood or cytobrushes) for testing	
CYP3A5 Genotype Analysis (for Bone Marrow or Solid Organ Transplant Patients)		tacrolimus
	LIVER TRANSPLANT PATIENTS: A sample from the liver DONOR is <u>required</u> for testing. Liver Donor ID: Samples from the liver transplant recipient are <u>NOT</u> accepted for this assay. (See page 3 for additional information)	
	NON-LIVER SOLID ORGAN TRANSPLANT PATIENTS: A sample from the transplant recipient is required for testing	
	Thiopurine Pharmacogenetics Analysis (TPMT/NUDT15)	6-mercaptopurine, 6-thioguanine, azathioprine
┥	Warfarin Pharmacogenetics (CYP2C9/VKORC1)	warfarin

CYTOCHROME P450 GENOTYPING ONLY

Tests in this category provide genotype and phenotype information ONLY. Drug dosage and titration information is NOT provided.

\checkmark	Test Name
	CYP2C19 Genotyping Only
	CYP2C9 Genotyping Only
	CYP2D6 Genotyping Only
	CYP2D6/CYP2C19 Genotyping Only



GENE TEST FOR MEDICINES: PATIENT/PARENT INFORMATION

Throughout this document, references to "You" and "Your" may stand for either an adult patient or for the parents or legal guardians of a pediatric patient.

WHAT ARE GENES?

Genes are pieces of DNA that we inherit from our parents. Genes provide the instructions to make our bodies look and work as they do.

WHAT DO GENES HAVE TO DO WITH MEDICINE?

Some genes affect the way medicines work in the body. When comparing a group of people, there can be slight differences in each gene's structure. These differences can affect how people react to medicine.

- 1. Some gene differences might make it harder for the body to get rid of some medicines. This means that usual doses of the medicine could give some people unexpected side effects.
- Some gene differences can cause the body to use up a medicine too fast. This means that normal doses won't work as well and the person may need higher doses.
- 3. Some gene differences won't let certain medicines work in the body at all. This means a different medicine may work better.

WHAT IS THE GENE TEST CALLED?

The gene test being considered for you is called a pharmacogenetic test. It is easier to call it a PG test.

IS THE PG TEST REQUIRED?

Most PG tests are optional. A few new medicines are designed for people with certain cancers or infectious diseases. A PG test of a tumor or a person's blood may be needed to know if a medicine will work. Most times you can be treated with standard medicine doses without this PG test. Make sure you understand why your doctor is recommending a PG test for you.

WHAT DO YOU NEED FOR THE PG TEST?

About ½ teaspoon of your blood is needed for the PG test. It is also possible to do the test on saliva or scrapings from the inside of your cheek. Special brushes are needed to obtain the cheek scrapings and saliva collection kits can be obtained by calling our office at 513-636-4474. However, there are special conditions for liver transplant and bone marrow transplant patients.

WHAT IS NEEDED FOR LIVER TRANSPLANT PATIENTS?

A sample from the liver donor (instead of the patient) is needed for PG testing

- The genes tested by a PG test make products that break down medications in the liver.
- Genes from your blood sample or cheek scraping may be different than the genes from your donor's liver.
- To predict how well your new liver will react to medications, we need to test the genes in your liver donor's DNA.
- We can do this by obtaining a blood sample or cheek scrapings from the donor or by testing a small piece of the donor liver before placing the liver in you.

WHAT IS NEEDED FOR BONE MARROW TRANSPLANT PATIENTS?

A blood sample and cheek scrapings are needed for patients who have received a bone marrow transplant.

- We want to test genes in the cells that are most likely to match the genes in your liver because the liver is where the genes make products to break down medications.
- The cells in your cheek scrapings are likely to match the genes we want to test, but the cheek scrapings of bone marrow transplant patients can also contain donor cells that we do not want to test.
- We use your blood sample to identify your donor cells because your donor's bone marrow helps to makes the blood cells in your body.
- We use this information to check your cheek scrapings to see how many cells are your cells and how many cells are from your donor.
- If there are too many donor cells in your cheek scrapings, we will ask for a new sample to do the PG test in the future.



WHY DO YOU WANT TO DO A PG TEST?

A PG test can be done before or after a medicine is given to you.

- Before a medicine is given:
 - A PG test may help your doctor choose the medicine and dose that will work best for you.
- After a medicine is given:

A PG test may help the doctor understand why you are having problems with a medicine. The test may also help your doctor decide if a different dose or different medicine should be tried.

WHAT ARE THE POTENTIAL BENEFITS OF A PG TEST?

- The test may improve the chances that the medicine will help you as intended.
- The test may lower the chance of severe side effects from the medicine.
- The PG test for the medicine may only need to be done once in a lifetime. The test looks at common gene differences. If the common gene differences are found in your blood, then the test will not need to be repeated.
- The gene tested today may be important for medicines that you need in the future.

WHAT ARE SOME OF THE LIMITATIONS OF THE PG TEST?

- The test only looks at common gene differences. This means if the test does not find any of the common gene differences, you could still have one or more rare gene differences. The test will not detect rare gene differences. Some of these rare differences might affect how you react to the medicine.
- Gene differences are only one of many factors that can affect how you react to medicine. A few examples of other factors are your age, weight, other medicines and illnesses. Your doctor will need to consider these factors along with the PG test results.

IS THERE ANYTHING ELSE I SHOULD KNOW ABOUT THE PG TEST?

In the future, some of these common gene differences may be found to be associated with other medical conditions.

The test results may be important for other family members. Biologic brothers, sisters and parents may have one or more of the same tested genes in common.

HOW MUCH DOES THE PG TEST COST?

The cost of the PG test depends on many factors. Insurance companies usually cover the costs of genetic tests that are used to guide medical management. Insurance companies vary in their coverage policies. It is wise to ask them directly whether or not they will cover the cost of PG testing.

HOW LONG DOES IT TAKE TO GET THE TEST RESULTS?

Test results will be ready in 2 business days.

HOW WILL I LEARN ABOUT THE TEST RESULTS?

The doctor or nurse will discuss the test results. The doctor will receive a report from the laboratory. The report will describe how your doctor can adjust your medicine based on your test results.

WILL THE GENE RESULT BE IN THE MEDICAL RECORDS?

Yes. Cincinnati Children's strictly follows HIPAA guidelines to protect medical information.

WHAT WILL HAPPEN TO MY SAMPLE?

Your DNA from the blood sample may be stored for up to two years in case future tests are needed. Neither your sample nor DNA will be used for research purposes.