

This Test Requisition Information Kit includes:

- PGXL Laboratories Test Requisition Form
- Frequently Asked Questions (FAQs)
- Sample Collection and Specimen Transport Information Forms

To receive timely testing results and ensure proper submission of patient insurance claim information, please include and ship to us:

- Fully completed Test Requisition Form
- Photocopies of the front and back of patient insurance I.D. card
- Properly packaged blood or buccal sample

Thank you for choosing PGXL Laboratories for your diagnostic testing needs.

Account Bill Insurance Bill Patient Bill



PGXL Laboratories Test Requisition Form
201 East Jefferson Street, Suite 309, Louisville, KY 40202
Phone: 502-569-1584 Fax: 502-569-1586
CLIA # 18D0983143

Patient and Insurance Information

Patient Name (Last, First, MI) Date/Time Collected

Address City State Zip Code

Social Security No. Medical Record No.

Home Phone Work/Cell Phone E-mail

DOB Height Weight Male Female Married Single Divorced

African American Asian Caucasian Hispanic Jewish (Ashkenazi) Other (please specify)

Complete only if NOT attaching front & back copies of insurance ID card

Medicare Number & Suffix Relationship to Insured Self Spouse Dependent

Primary	Insurance co. Name <input type="text"/>	Secondary	Insurance co. Name <input type="text"/>
	Member/Insured ID# <input type="text"/> Group # <input type="text"/>		Member/Insured ID# <input type="text"/> Group # <input type="text"/>
	Insurance Address <input type="text"/>		Insurance Address <input type="text"/>
	City, State, ZIP <input type="text"/>		City, State, ZIP <input type="text"/>

Physician Ordering Test

Physician Name ICD9 Code, for Diagnosis or Symptoms

Facility/ Group Name

Phone

Fax

Address

City, State, ZIP

NPI #

Physician Signature

Did You Remember?

To Include the ICD9 Code?	<input type="checkbox"/>
To Provide a Copy of Insurance Card?	<input type="checkbox"/>
To Obtain Patient Signature?	<input type="checkbox"/>
To Request the Test(s)?	<input type="checkbox"/>
To Obtain Physician Signature?	<input type="checkbox"/>

Test Menu

<input type="checkbox"/> CYP2D6	<input type="checkbox"/> Warfarin genotype (CYP2C9/VKORC1)	<input type="checkbox"/> 5-HTT Serotonin Transporter
<input type="checkbox"/> CYP2C9	<input type="checkbox"/> NAT2	<input type="checkbox"/> HLA-B*5701 Abacavir Hypersensitivity
<input type="checkbox"/> CYP2C19	<input type="checkbox"/> Factor II (Prothrombin)	<input type="checkbox"/> DNA Isolation (required for all genotyping tests)
<input type="checkbox"/> CYP1A2	<input type="checkbox"/> Factor V Leiden	<input type="checkbox"/> Miscellaneous (please specify) <input type="text"/>
<input type="checkbox"/> KRAS	<input type="checkbox"/> MTHFR	<input type="checkbox"/> Mycophenolic acid, serum

Patient Release Statement

STATEMENT OF CONSENT AND RELEASE

I hereby certify that the information provided is true and accurate. I consent to the collection of specimens from myself and any listed child for the purpose of DNA testing. PGXL reserves the right to re-collect samples for retesting and to store samples for future additional tests, if necessary. I understand that while DNA testing is highly accurate and widely accepted, as in all testing there is a possibility of delay or error. I understand that samples and the DNA they contain become the exclusive property of PGXL. I also understand that this testing is for informational purposes and prescription drug regimes should never be altered without consulting a physician. PGXL will not release any personal, identifiable information of any kind to a third party without my express written instructions. I also understand that PGXL reserves the right to provide de-identified information of a statistical nature to accrediting agencies and reserves the right to use such anonymous information.

Signature of tested adult or legal guardian of tested child under age 18

Date

Print Form



(A) Notifier(s):

(B) Patient Name:

(C) Identification Number:

ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: If Medicare doesn't pay for (D) _____ below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the (D) _____ below.

(D)	(E) Reason Medicare May Not Pay:	(F) Estimated Cost:

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the (D) _____ listed above.
Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

(G) OPTIONS: Check only one box. We cannot choose a box for you.

OPTION 1. I want the (D) _____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

OPTION 2. I want the (D) _____ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**

OPTION 3. I don't want the (D) _____ listed above. I understand with this choice **I am not responsible for payment, and I cannot appeal to see if Medicare would pay.**

(H) Additional Information: This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

(I) Signature:	(J) Date:
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Note: Your health information will be kept confidential. Any information that we collect about you on this form will be kept confidential in our offices. If a claim is submitted to Medicare your health information on this form may be shared with Medicare. Your health information which Medicare sees will be kept confidential by Medicare.

What are the advantages of pharmacogenetic diagnostic testing?

Pharmacogenetics links variation in drug metabolism and response with specific variation in genes encoding drug metabolizing enzymes and receptor proteins. These genetic differences between individuals can have profound effects on the relationship between drug-dosage, plasma concentrations, and drug response. PGXL Laboratories pharmacogenetic diagnostic testing provides a detailed genotype analysis that can be used to help select and dose medications as part of the physician's overall patient management strategy.

How Often Should Patients Be Tested?

Only once. A patient's genetic make-up does not change. Throughout the patient's life, the physician can continue to consult these one-time diagnostic testing results.

How Long Does It Take to Receive Test Results?

Test results are delivered within three to five days, provided that the physician provides PGXL Laboratories with:

- Fully completed PGXL Laboratories Test Requisition Form
- Photocopies of the front and back of patient insurance I.D. card
- Properly packaged blood or buccal sample

Does Insurance Cover Diagnostic Testing?

PGXL Laboratories routinely bills all patient insurance on behalf of the physician office. In order to ensure accurate insurance claims submission, physicians must fully complete the PGXL Laboratories Test Requisition Form and provide photocopies of the front and back of the patient insurance I.D. card. It is critical that the physician include:

- ICD9 code(s)
- Photocopies of the front and back of the patient insurance I.D. card
- Patient signature
- Physician signature

All of these components are included on the PGXL Laboratories Test Requisition Form.

It is important to emphasize that every insurance carrier is different. PGXL Laboratories is committed to submitting every claim, but cannot guarantee payment by any insurance carrier. PGXL Laboratories will invoice patients for any personal responsibility after insurance reimbursement.

Does PGXL Laboratories Accept Other Forms of Payment?

If the patient prefers direct payment, PGXL Laboratories accepts Visa, MasterCard, Discover, American Express and personal checks.

Blood Specimen Collection

1. No special patient preparation necessary.
2. Collect 5 mL of whole blood in an EDTA (lavender-topped) tube.
3. Label sample with patient name, date of birth and date of collection.
4. Samples may be kept at room temperature for up to 48 hours, or at 4°C for up to one week.

Do not freeze!

Buccal Swab Specimen Collection

When collecting a whole blood sample is not feasible, buccal (cheek) swabs may be collected as an alternative sample type. Please call PGXL Laboratories at (502)569-1584, ext. 1 to request more information and a swab kit.

Materials

- Four Sterile Whatman Omni Swabs (Fisher, WB 100035)
- Sealable paper envelope

Collection Procedure

- Patient preparation: The patient must not have had anything to eat or drink but water for at least 30 minutes prior to DNA collection.
1. Do not touch the cotton collection tips of the swabs.
 2. Label collection envelope with patient name or number, birth date, date of collection and collector's initials, if other than the patient.
 3. To collect sample, scrape the cotton tip end of swab 1 **firmly** against the inside of one cheek **for 30 seconds**, then scrape the same swab on the opposite cheek for another **30 seconds (1 swab = 1 minute)**. Be careful not to depress the plastic plunger that ejects the cotton tip.
 4. Repeat this process for the remaining three swabs (total scraping time is four minutes).
 5. Allow the swabs to air-dry for **at least 1 hour** after collection of cells. Swabs should be upright (in rack or cup) during drying.
 6. Be sure not to contaminate the cotton tips of the swabs (do not touch with your hands or lay on a table without the outer package).
 7. After air drying, eject the head of the swab into the labeled collection paper envelope by firmly pressing the plunger at the end of the handle. Be sure the envelope is labeled with the patient's name or number, birth date, date of collection, and collector's initials. Do not touch the swab tip. Secure the envelope flap with tape; do not lick to seal.

Local Specimen Transport (in Louisville, KY)

1. In Louisville, KY, please call PGxL Laboratories at (502) 569-1584, ext. 1 to request courier pickup of the sample and the fully completed **PGxL Laboratories Test Requisition Form**.
2. All samples for local courier transport are to be placed in sealed biohazard bags, with the Test Request form in the outer pouch. Please call PGxL Laboratories at (502) 569-1584, ext.1 to request biohazard bags.
3. Once the Lab receives the pickup request, PGxL will send the courier no later than within one business day (depending on time of day of the request).

Specimen Shipping

Shipping instructions provided herein are in accordance with all applicable federal guidelines (49 CFR 173.199). A diagnostic specimen, referred to as Biological Substance, Category B after January 2007, means any human or animal material including excreta, blood and its components, tissue, and tissue fluids, being transported for diagnostic or investigational purposes. Please call PGxL Laboratories at (502) 569-1584, ext.1 to request any of the required shipping supplies detailed below.

1. Packaging Requirements

Regulations require that packages containing biological substances include four basic requirements as follows:

- A. **Primary receptacle** –watertight glass or plastic test tubes, or envelopes in the case of dried buccal swabs.
- B. **Secondary packaging** – protects the primary receptacle from breakage and leakage, typically a watertight receptacle such as a styrofoam container within a sealable biohazard bag (for fluid specimens) or a sealable biohazard bag (for dried buccal swab envelopes).

C. **Absorbent material** – for fluids (but not dried buccal swab specimens), absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging.

D. **Outer packaging** – packaging of adequate strength for its capacity, mass, and intended use, typically a corrugated or chipboard box, or strong sealable plastic such as the FedEx Clinical Pak. Standard commercial or FedEx outer envelopes are not permitted for fluid specimens, but can be used for dried buccal swab specimens when properly marked (see below).

2. Marking requirements

Fluid specimens:

If using the FedEx Clinical Pak as the outer packaging, the shipper must **check the box on the back of the pack** indicating that the specimen meets the requirements of a Biological Substance Category B.

If using a cardboard shipping box as the outer packaging, the shipper must clearly mark the package as **“Biological Substance Category B”** with a diamond-shaped marking and the characters **“UN3373”** (Minimum 2 inches x 2 inches).



Biological Substance B

Buccal swab specimens

Exemptions to the above markings exist for substances being transported for diagnostic purposes that, to the best of the shipper's knowledge, are unlikely to cause disease in animals or humans. Common exemptions include dried buccal swabs and dried blood spots.

Dried buccal swabs for diagnostic testing must be enclosed in the buccal swab collection envelope (primary receptacle), in a sealable plastic bag (second receptacle), and shipped in a sturdy outer container or commercial envelope. Use of the FedEx Clinical Pak is optional for dried buccal swabs, and absorbent material is not necessary.

The only required marking for dried buccal swab specimens on a Standard FedEx outer envelope of is **"Exempt Human Specimens."** If using the FedEx Clinical Pak, **do NOT check the box** for a Biological Substance Category B listed on the back of the pack.

3. Once the specimens are properly packaged and marked, affix a FedEx Express airbill preprinted with PGxL Laboratories as the recipient. Shipper assumes responsibility of the shipping charges unless previously negotiated with PGxL Laboratories.
4. The specimens are now ready to be shipped. **Call FedEx at 1-800-GOFEDEX (1-800-463-3339)** to schedule a pickup, or call **PGxL Laboratories at (502) 569-1584, ext. 1** and we will schedule the pickup. NO clinical samples may be dropped off in a FedEx drop box, and Category B Biological Substances may NOT be dropped off at FedEx Kinko's centers.
5. **Shipping Address:**
PGxL Laboratories
201 E. Jefferson St., Suite 309
Louisville, KY 40202
Attention: Dr. Kristen Reynolds

PGxL Laboratories will provide a written interpretation of the results within 3 to 5 business days of sample receipt.