Pharmacogenetic Test Requisition Form

Pro-GeneX Laboratories, Inc.
669 Lanier Park Drive,
Gainesville, GA 30501
844-794-3637
CLIA#11D2166978
Gregory P. Marshall, Ph.D

Place Sticker Here

SAMPLE
P021093

Provider and Practice Name NPI #	Provider Phone # and E-mail	Specimen Collection Information
Provider Name:	Phone #:	Date & Time Collected:
Practice Name:		
NPI#:	E-mail:	Collector's Initials:

THIS SECTION IS REQUIRED: Patient Information

☐Male ☐Female

Last	First	Middle Initial	Date of Birth	Gender
Address		City	State	Zip
Phone	E-mail Address (for results)			Ethnicity

THIS SECTION IS REQUIRED: Insurance and/or Payment Information (Enclose copy of the front and back of patient's insurance card(s).

☐Commercial ☐Self-Pay ☐Client Bill ☐Medicare ☐Medicaid

Insurance company	Insurance Address	City	State	Zip
Insurance Phone	Policy or Member ID#	Group#		
Name of Insured	Relationship to Patient and/or Employer			

Current Medications. Please list any medications that you are taking below or attach a separate list of medications

_____ _____ _____ _____ _____

_____ _____ _____ _____ _____

Do you wear Dentures? Yes ☐ No ☐

ICD-10 Diagnosis Code(s) Please see commonly used codes on back. Visit www.cms.gov for a comprehensive list of ICD-10 codes.

_____ _____ _____ _____ _____

_____ _____ _____ _____ _____

Test Requested

My BestMed™ Clinical Panel:

ABCB1, ABCG2, ADRA2A, ADRB2, ANK3, ANKK1, APOE, BCHE, BDNF, C11orf65, CACNA1C, CACNA1S, COMT, CYP1A2, CYP2B6, CYP2C, CYP2C19, CYP2C8, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, DPYD, DRD2, F2, F5, FCGR3A, GRIK1, HLA-B, HLA-B/FLOT1, HTR2A, HTR2C, IL28B, MC4R, MTHFR, NAT2, NUDT15, OPRM1, SCN1A, SLC6A4, SLCO1B1, TNF, TPMT, UGT1A1, UGT1A4, UGT2B15,VKORC1

Only the specific DNA tests ordered will be performed on the biological sample; the sample will be destroyed after 60 days from the date it was collected.

I authorize the laboratory test(s) as ordered and affirm that each are both medically necessary and correspond to the patient's diagnosis as submitted to the laboratory for testing. I understand that each test I order is a billable event and the patient's medical record must clearly reflect my order. I understand that Pro-GeneX Laboratories, Inc. is NOT a specimen banking facility, and any specimens I submit on behalf of patients will NOT be available after 60 days or for future clinical studies.

As a courtesy, Pro-GeneX Laboratories, Inc. makes every reasonable effort to obtain reimbursement for ordered tests. I will provide Pro-GeneX Laboratories, Inc. with any information necessary to bill my patient's insurance and obtain remibursement. I have discussed with my patient that it is the patient's responsibility for the cost of these laboratory services if the patient's insurance does not pay for the services.

I have provided my patient with a Notice of Privacy Practices as required under HIPAA and I"ve discussed with my patient that these laboratory results and associated protected heath information (PHI) are confidential to the extent required by law. PHI will only be released to medical professionals or other parties with the patient's written consent or as otherwise allowed by law.

I have read and understand the statements above and I authorize Pro-GeneX Laboratories, Inc. to perform the ordered test(s).

Patient (or Guardian) Signature: _____ **Date:** _____

Provider Signature: _____ **Date:** _____

Please return form with your swab

MyBestMed®, Informed Consent for Pharmacogenetic Testing

Patient Name_____ **Date of Birth** _____**Sex** _____

We recommend that you consult with your physician or healthcare provider or obtain professional genetic counseling prior to consenting to MyBestMed® pharmacogenetic testing. You can find more information about MyBestMed® at www.Pro-GeneX.com or contact Pro-GeneX Laboratories, Inc. at (844) 794-3637. In some states, it is unlawful for an entity to obtain your biological sample to conduct testing without first obtaining your informed consent. This is additional information you need to consent to pharmacogenetic testing.

1. Participation in MyBestMed® testing is completely voluntary.
2. You must provide a biological sample for this test to be performed; the sample will be obtained via an oral swab, which is non-invasive and possess very little risk to your health.
3. Your biological sample will be used for the purpose of obtaining MyBestMed® results that may determine how your body interacts with certain pharmaceuticals/medications.
4. A positive result is an indication that you may be predisposed to or have a specific condition related to the use of certain pharmaceuticals/medications. Further testing and/or consultation with a healthcare provider or genetic counselor may be needed to confirm or understand your results.
5. The tests offered are the best available at this time. MyBestMed® testing is complex and utilizes specialized materials; however, there is always a small chance an error may occur.
6. Due to limitations in technology and incomplete knowledge of genes, some changes in DNA or protein products that cause interactions with pharmaceuticals may not be detected by the test.
7. There may be a possibility that the laboratory findings will be uninterpretable or of unknown significance.
8. Pro-GeneX will not disclose your results to anyone other than you and the healthcare provider that ordered your test. Your test results will not be disclosed to any person, entity, or employer unless you authorize such a release in writing, or a disclosure is required by law, or ordered by a court for legal proceedings or investigation. Only persons within our company or under contract with our company who have a need to know about your testing and your test results will have access to your information unless one of the aforementioned situations apply.
9. Your personal information, excluding test results, may be disclosed to your insurer if you supply health insurance information & Pro-GeneX or your healthcare provider seek reimbursement from your insurer for this test.
10. Your electronic tests results will be provided to your healthcare provider within 10 days of processing your sample.
11. Your biological sample will only be used for the MyBestMed® testing as authorized by this consent. There will be no tests performed on your biological sample other than MyBestMed® testing except such testing that is necessary or required to demonstrate the integrity of the sample tested or to resolve the analysis of a test with a previously indeterminate result performed on your biological sample.
12. Pro-GeneX does not retain your biological sample; your sample will be destroyed within 60 days of the date of testing.

My signature below acknowledges that I have read and understand this notice, constitutes my express consent to MyBestMed® **pharmacogenetic testing, is my consent to release my test results to the ordering healthcare provider, and is my consent to release my personal information (not my test results) to my health insurer for reimbursement. I understand that the pharmacogenetic analysis performed by Pro-GeneX Laboratories, Inc. does not definitively determine disease and in no way guarantees my health, the health of an unborn child, or the health of other family members.**

Requesting Provider & Credentials

_____ **DATE** _____

Patient Signature. If Guardian/Authorized Representative, please sign your name and relation to the patient.

_____

Updated 6/20/22 in consideration of the genetic testing laws in the following states: AK, AL, AZ, AR, CA, DE, FL, GA, HI, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, OR, RI, SC, SD, TX, UT, VT, VA, WA, WY. Informed Consent, V 7,7.28.22

LETTER OF MEDICAL NECESSITY

PHARMACOGENOMIC (PGX) TESTING

Patient Name: _____ Patient Date of Birth: _____/_____/_____

Date of Service: _____/_____/_____ ICD-10 Diagnosis Codes: _____

DEAR CLAIMS SPECIALIST:

Please consider this Letter of Medical Necessity a formal request for full coverage of the pharmacogenomic testing services that I have prescribed for your subscriber (Patient Name Listed above). Pharmacogenomic testing laboratory services that have been performed by **PRO-GENEX LABORATORIES, INC**, a CLIA-certified laboratory (NPI# 1427610674), and the results will assist me in making patient- specific clinical decisions regarding the medical management of your subscriber.

To provide the safest, most effective, and affordable medical care possible, the requested genetic testing is medically necessary for my patient for several reasons. The primary reason(s) for my request apply specifically to the patient listed above:

☐ Determine Drug-Gene interactions, better predicting how the patient will metabolize medications
☐ Determine Drug-Drug interactions based on the patient's genetic-determined phenotype
☐ Reduce the number of medications that my patient is currently taking
☐ Determine the potential effectiveness of medications prescribed to my patient
☐ Determine the best course of therapy for my patient
☐ Acquire specific dosing recommendations to avoid toxicity and adverse drug reactions (ADR's)
☐ Patient has a family history of thrombosis
☐ Patient is not responding to the drugs he/she has been prescribed
☐ Patient has suffered recent or previous Severe Adverse Drug Reactions (SADR)
☐ Other (please specify): _____

ADDITIONAL CLINICAL INFORMATION:

Previously failed medication(s): _____

Currently failing medication(s): _____

Proposed new medication(s): _____

SADR symptoms/presumed associated medication: _____

SEE ATTACHED CLINICAL NOTES FROM DATE OF SERVICE

Progress notes for date of service include clinical reason for ordering PGX test and medication list as well as other various notes.

The FDA recommendations for genetic testing are currently listed on the labels of over 150 prescription medications. Please visit (http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm) for more information. Recommendations typically include pharmacologic treatment contraindications and dose-selection strategies based on patient genetic status. As a health-care prescriber, I am obligated to provide the best medical care possible for my patients. Medical management based on patient-specific pharmacogenomic testing can improve clinical outcomes and PREVENT unnecessary suffering and costs.

Billing for genetic testing services will be initiated upon completion of services. As completion of genetic testing can take several months, **I am requesting your authorization for claims payment be valid for 12 months.**

Best regards,

Name of Practice: _____

Ordering Clinician Signature: _____ Date: _____/_____/_____

MD/DO, Clinical Nurse Specialist, Nurse-Midwives, Nurse Practitioner, Physician Assistant, Genetic Counselor
(Clinician prescribing requirements vary by state)