MAINSTREAM DIAGNOSTIC LABORATORY

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PGX REQUEST FORM

PATIENT INFORMATION (REQUIRED)

Last Name: _____ First Name: _____

Street Address: _____ Apt#: _____

City: _____ State: _____ Zip: _____

Phone: _____ DOB: ____/__/__ ____ SSN: _____ Gender: F ☐ M ☐

Primary Ethnicity:
☐ African
☐ Ashkenazi Jewish European (Non-Finnish)
☐ European (Finnish) East
☐ Asian
☐ Near/Middle Eastern
☐ Latino
☐ South Asian
☐ Other

SPECIMEN INFORMATION ☐ Diagnostic ☐ Presymptomatic ☐ Family History ☐ Family Variant (REQUIRED)

Date Collected: ____/____/_____ Time Collected : _____

Collected and Registered By: _____ Specimen Type: ☐ Buccal ☐ Blood

There are many factors which may affect genetic diagnostic testing: such as gene-gene interactions, high-risk ethnicity groups, and transplants. Please list any that may apply.

Clinical Details Check all that apply:
☐ Known Chromosomal Gain/Loss ☐ Known Gene Gain/Loss ☐ Consanguinity
☐ Mosaicism ☐ Bone Marrow Transplant ☐ Organ Transplant

Please specify any that are checked above: _____

ORDERING PROVIDER (REQUIRED)

Last , First Name: _____

Street Address: _____

City, State, Zip: _____

Phone: _____ Fax: _____

NPI#: _____ Title: _____

PAYMENT OPTIONS (REQUIRED)

☐ INSURANCE BILLING Attach front and back of all insurance cards, ABN, medical criteria form

INSURANCE NAME: _____ INSURANCE ADDRESS: _____

INSURANCE PHONE NUMBER: _____ PREAUTH/CERTIFICATION: _____

PRIMARY INSURANCE ID: _____ GROUP# _____

NAME OF INSURED: _____ RELATIONSHIP TO PATIENT: _____

DATE OF BIRTH: ____/____/_____

☐ SELFPAY Use patient information above for billing

☐ INSTITUTIONAL BILLING Use ordering provider information for billing

TEST OPTION ☐ Seq & Del/Dup ☐ Sequencing Only ☐ Del/Dup Only

It is the ordering party's responsibility to order only those tests medically necessary for the diagnosis and treatment of the patient.

☐ PGx Focus NGS Panel

GENES TESTED 18

BCHE, CYP2B6, CYP2C19, CYP2C9, CYP2D6, CYP3A5, CYP4F2, DPYD, G6PD, HLA-B, IFNL4, NAT2, NUDT15, RYR1, SLCO1B1, TPMT, UGT1A1, VKORC1

☐ PGx Comprehensive NGS Panel

GENES TESTED 44

ABCB1, ACE, ANKK1, APOE, ATM, BCHE, CES1, COMT, CYP2B6, CYP2C19, CYP2C8, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, DPYD, DRD2, ERCC1, F2, F5, G6PD, GGCX, GRIK4, GSTP1, HLA-B, HTR1A, HTR2A, HTR2C, IFNL4, ITPA, KIF6, MTHFR, NAT2, NQO1, NUDT15, OPRM1, RYR1, SLCO1B1, TPMT, UGT1A1, UGT1A4, VKORC1, XRCC1

COLUMN 1* (SELECT ALL THAT MAY APPLY):

- ☐ I25.10 Atherosclerotic heart disease of native coronary artery without angina pectoris
- ☐ I25.110 Atherosclerotic heart disease of native coronary artery with unstable angina pectoris
- ☐ I25.111 Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
- ☐ I25.118 Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
- ☐ I25.5 Ischemic cardiomyopathy autologous artery coronary artery bypass grafts with unstable angina pectoris
- ☐ autologous artery coronary artery bypass grafts with angina pectoris with documented spasm
- ☐ I25. 728 Atherosclerotic autologous artery coronary artery bypass grafts with other forms of angina pectoris
- ☐ 125. 760 Atherosclerotic bypass graft of coronary artery of transplanted heart with unstable angina
- ☐ I25.761 Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm
- ☐ I25.768 Atherosclerosis of bypass of coronary artery of transplanted heart with other forms of angina pectoris
- ☐ I25.790 Atherosclerosis of other coronary artery bypass grafts with unstable anginapectoris
- ☐ I25.791 Atherosclerosis of other coronary artery bypass grafts with angina pectoris with documented spasm
- ☐ I25. 798 Atherosclerosis of other coronary artery bypass grafts with other forms of angina pectoris
- ☐ I25.810 Atherosclerosis of coronary artery bypass grafts without angina pectoris
- ☐ I25.812 Atherosclerosis of bypass graft of coronary arter of transplanted heart without angina pectoris
- ☐ I25.83 Coronaryatheroscleros is due to lipid rich plaque
- ☐ I25.84 Coronary atherosclerosis due to calcified coronary lesion
- ☐ I25.89 Otherformsofchronicischemic heart disease
- ☐ I25. 9 Chronic ischemic heartdisease, unspecified
- ☐ I63.59 Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
- ☐ I66.01 Occlusion and stenosis of right middle cerebral artery
- ☐ I66.02 Occlusion and stenosis of left middle cerebral artery
- ☐ I66.03 Occlusion and stenosis of bilateral middle cerebral arteries

COLUMN 2* (SELECT ALL THAT MAY APPLY):

- ☐ I66.8 Occlusion and stenosis of other cerebral arteries
- ☐ F33.9 Major depressive disorder, recurrent, unspecified
- ☐ F33.0 Major depressive disorder, recurrent, mild
- ☐ F33.1 Major depressive disorder, recurrent, moderate
- ☐ F33.2 Major depressive disorder, recurrent, severe without psychotic features
- ☐ F33.3 Major depressive disorder, recurrent, severe with psychotic symptoms
- ☐ F33.41 Major depressive disorder, recurrent, in partial remission
- ☐ F33.42 Major depressive disorder, recurrent, in full remission
- ☐ F31.30 Bipolar disorder, current episode depressed, mild or moderate severity, unspecified
- ☐ F31.31 Bipolar disorder,current episode depressed, mild
- ☐ F31.32 Bipolar disorder, current episode depressed moderate
- ☐ F31.4 Bipolar disorder, current episode depressed, severe, without psychotic features
- ☐ F31.5 Bipolar disorder, current episode depressed, severe, with psychotic features
- ☐ F31. 75 Bipolar disorder, in partial remission, most recent episode depressed
- ☐ F31.76 Bipolar disorder, in full remission, most recent episode depressed
- ☐ F31.60 Bipolar disorder, current episode mixed, unspecified
- ☐ F31.61 Bipolar disorder, current episode mixed, mild
- ☐ F31.62 Bipolar disorder,current episode mixed, moderate
- ☐ F31.63 Bipolar disorder,current episode mixed, severe, w/o psychotic features
- ☐ F31.64 Bipolar disorder,current episode mixed, severe, w/ psychotic feat.
- ☐ F31.77 Bipolar disorder, in partial remission, most recent episode mixed
- ☐ F31.78 Bipolar disorder, in full remission, most recent episode mixed
- ☐ F32.89 Other specified depressive episodes
- ☐ F33.40 Major depressive affective disorder, recurrent, in remission unspecified
- ☐ G10 Huntington's disease
- ☐ Z79.02 Longterm (current)use of antithrombotics / anti platelets
- ☐ OTHER _____

Medical Necessity (Please check one or more boxes):

- ☐ Patient has acute coronary syndrome and is undergoing percutaneous coronary interventions, and needs genetic testing of the CYP2C 19 to guide the initiation or re-initiation of **Clopidogrel (Plavix)** therapy, or any medication derivatives.
- ☐ Patient has a depressive disorder, and needs genetic testing of the CYP2D to guide medical treatment of the patient and/or dosing of **amitriptylineor nortriptyline,** or any medication derivatives.
- ☐ Patient needs genetic testing of CYP2D6 to guide initial dosing or re-initiation of Tetrabenzine, at a rate greater than 50 mg/day, or any medication derivatives.
- ☐ Patient (1) has not been previously tested for the CYP2C9 or VKORC 1 alleles, (2) has received *fewer* than (5) days' warfarin in the anticoagulation treatment plan for which the genetic testing is requested, and (3) the patients enrolled ina prospective, randomized, controlled study meeting Medicare requirements under NCD90.1.
- ☐ The patient had an adverse reaction to one or more drug combinations and is currently taking the following medications. Please list below:

_____

*Note: The provided ICD-10 codes are listed as a convenience. Ordering practitioners should report the diagnosis code that best describes the reason for performing the test, regardless of whether the code is listed above or not.

PHYSICIAN SIGNATURE: _____

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5354 GULF DRIVE NEW PORT RICHEY, FL 34652 MAINSTREAMLAB.COM

Satish Patel M.D., *Laboratory Director* **CLIA** #10D2177660

Informed Consent Form

Patient Informed Consent

This Informed Consent Form is to be **filled out and signed by the patient.** This form reviews the benefits, risks and limitations of genetic testing that is ordered by your healthcare provider to assess your risk for developing certain types of inherited heart diseases. Genetic testing is confidential and voluntary and you are not required to have the test. You may wish to obtain genetic counseling prior to signing this consent form. If so, a request should be made to your healthcare provider. Please read carefully and discuss any questions you may have with your healthcare provider before signing the consent below.

Purpose of Testing

Genetic changes or mutations can occur in certain gene(s) that are associated with medication efficacy. This test analyzes these particular gene(s) to determine if there are genetic changes present in your test sample that significantly increase your risk for developing a drug efficacy issue. Genetic testing provides a more precise estimate of a person's risk for being a hypometabolizer or hypermetabolizer rather than using your personal and family history alone. In some cases, the results of this test may also provide information about risks for medical conditions that are not related to medication metabolism conditions.

Test Procedure

Your healthcare provider typically obtains an oral buccal or cheek swab *(saliva sample)* and sends it to Mainstream Diagnostic Lab for analysis. Mainstream Diagnostic Lab will analyze the DNA of the specific gene(s) to check for genetic changes related to medication metabolism conditions.

Test Results & Interpretation

Your test results should be explained in support with your personal and family health history, results of your physical examination, other laboratory and hospital tests, and the clinical expertise of your healthcare provider. There are three possible results from this test: *positive, negative, or uncertain.*

A Positive Result

A mutation(s) was identified in your DNA that is associated with an increased risk for medication interference. **This means you are at increased risk for complications due to medication.** Knowing that you have a mutation in one or more of the genes analyzed may help you make more informed choices with your doctor about your medical care. You and your healthcare provider can use this information to make a personalized screening and prevention plan. Following your plan may lower your chance of developing complication or may increase the chance of detecting an improperly used medication earlier and can increase the efficacy of your medication plan. Additional screenings for family members may be recommended. A positive result does not mean that you have a conditions or that you will definitely develop a condition in your lifetime.

A Negative Result

No mutations were identified in any of the genes that were tested using the test method specified. **This result greatly reduces the likelihood that you have a mutation in the genes that were tested** and known medication related conditions associated with these genes. If you are the first person in your family being tested, a negative result means that you still have at least the same risk for medication related conditions as a person in the general population. You may still be at a greater than average risk for medication related conditions due to a genetic predisposition that cannot be detected by this test.

If you test negative for a mutation that is known to be in your family, then you may be considered to have the same risk for medication related conditions as a person in the general population. If you are found to carry a mutation in any of the genes analyzed, this may be informative for your blood relatives.

The results of your Pharmacogenetic test will be sent to your ordering physician and may be sent to a third-party genetics counseling service to provide genetics counseling services as selected by Mainstream Diagnostic Lab and its affiliates and will become part of your medical record. All other parties can only obtain results by submitting an ***Authorization for Release of Information Form.***

Benefits of the Test

Your genetic test results may help you make more informed decisions with your healthcare provider about your health such as screening and prevention medication therapies. If a gene mutation is identified, blood relatives may choose to be tested to determine whether or not they share the same risks for Pharmacogenetic conditions. If you get a positive result, you should discuss with your healthcare provider how pharmacogenetic conditions are inherited and learn about the likelihood that your children or blood relatives may inherit the same mutation(s) in the gene(s) tested. If you test negative for a known mutation in your family, then you cannot pass that mutation onto your children, and you may be considered as having the same risk as a person in the general population.

Risks of the Test

Oral buccal swab collection is not invasive. Genetic screening test may cause you to discover sensitive information about your health or disease risks, including disease risks other than the one you are testing for, or for diseases that currently have no treatment. The US Genetic Information Discrimination Act, *GINA,* of 2008 prohibits discrimination on the basis of genetic information in regard to health insurance and employment. The results of genetic testing are considered Protected Health Information, *PHI,* as described in the Health Insurance Portability & Accountability Act, *HIPPA,* of 1996 (Public Law 104.191). Federal legislation prohibits unauthorized disclosure of confidential personal information.

Limitations of the Test

This test only analyzes for certain specific genetic changes that are associated with an increased risk for developing pharmacogenetic complications. Genetic testing provides a risk assessment only for those cardiac condition gene(s) being analyzed. If your test results are positive, there may be differing opinions amongst physicians as to which treatment option is best to take. **Your course of treatment and medical care is best determined by you in consultation with your doctor or healthcare provider.**

Financial Responsibility

Genetic testing of appropriate persons is generally reimbursed by health insurance. You are responsible for any cost of the genetic test that is not reimbursed by your health insurance.

Sample Retention

After testing is complete, your de-identified submitted specimen may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring health care providers unless specific prior arrangements have been made. Samples from residents of New York state will not be included in the de-identified research studies described in this authorization and will not be retained for more than 60 days after test completion, unless specifically authorized by your selection below. The authorization is optional, and testing will be unaffected if you do not check the box for the New York authorization language.

Patient Signature	Today's Date

MAINSTREAM
DIAGNOSTIC LABORATORY

Informed Consent Form - *continued*

Participation in Research

You have the option of consenting to the use of your anonymized sample, genetic information and results in research to develop new tests for all patients. *Participation in research is voluntary.* If you consent to participating in research and later change your decision, Mainstream Diagnostic Laboratory will destroy any remaining portion of your test sample that was stored and remove your information from the research database.

Patient Consent Statement

By signing below, I, the patient acknowledge that:

- Pharmacogenetic Genetics testing is done to determine a person's predisposition to developing drug interaction or efficacy
- This test is not done to diagnose whether I have or will get a certain disease in the future. This test is intended to tell me about my hereditary risk related to pharmacogenetic conditions as discussed with my healthcare provider and selected on my test order form.
- I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits and limitations of the genetics test(s) to be performed as indicated on the Test Requisition form or on the follow-up tests ordered by my healthcare provider.
- I have discussed with the healthcare provider ordering this test the reliability of positive and negative test results and the level of accuracy that a positive result has for a specific disease or condition and serves as a predictor of such a disease.
- I understand that I should not make any medical decisions based on my results without speaking with my healthcare provider first. I understand that I should discuss my results and appropriate medical management with my healthcare provider.
- I have not been offered anything of value to induce me to provide my genetic sample.
- I understand that I am the owner of my medical history and test results. My healthcare provider cannot discuss nor disclose my test results and associated medical history to a third party unless related to treatment or payment for treatment, without my written authorization.
- I understand it is entirely my decision to have or not to have any genetic testing.
- I have read this document in its entirety, and understand that I can keep a copy of the signed document for my records.

_____ **I have read and fully understand the above.**
(Initial)

☐ **I consent** to being tested for predisposition to Pharmacogenetic conditions, and I will discuss my test results and appropriate medical management with my healthcare provider.

☐ **I decline** to being tested for predisposition to pharmacogenetic conditions.

I understand the following information regarding use of my test sample for research: Mainstream Diagnostic Laboratory is committed to improving genetic testing for all patients and contributing to scientific research.

Please NOTE: If left blank, the consent for research is interpreted as "NO".

☐ *Optional:* **I consent** to use of my de-identified test samples for research.

☐ *Optional:* In addition to the above, **I consent** to be contacted by Mainstream Diagnostic Laboratory regarding research opportunities.

☐ *Optional:* I am a New York State resident, and **I consent** to storing my test samples at Mainstream Diagnostic Laboratory beyond 60 days for future use or testing.

Patient Signature	Today's Date	Name of Patient	Relationship to Patient