GENESYS Diagnostics INC.

Pharmacogenetics Requisition Form

*Information required for testing

Letter of Medical Necessity on reverse side is ***REQUIRED*** *for all Pharmacogenetic testing*

Patient Information

LAST NAME* | FIRST NAME* | MI | DOB* (MM/DD/YYYY) | SEX | GENDER

ADDRESS | CITY | STATE | ZIPCODE | PHONE NUMBER | EMAIL ADDRESS

Billing Information (Please include a copy of insurance card(s) for billing purposes.)

*☐ CLIENT BILL ☐ INSURANCE ☐ SELF PAY ☐ MEDICARE/MEDICAID (☐ PRIMARY ☐ SECONDARY) RELATIONSHIP: ☐ SELF ☐ SPOUSE ☐ DEPENDENT

INSURANCE NAME | MEMBER/POLICY ID | GROUP #

POLICY HOLDER NAME | POLICY HOLDER DOB (MM/DD/YYYY) | TEST INDICATION/ICD-10 CODE(S)*

Account Information

FACILITY/PRACTICE NAME* | PHONE NUMBER | FAX NUMBER | ORDERING PHYSICIAN NAME*

Specimen Information PREFERRED SPECIMEN IS BUCCAL SWAB

☐ BLOOD IN EDTA (5ml MIN) ☐ BUCCAL SWAB ☐ DNA (10 ug MIN) COLLECTION DATE:_____MM/DD/YYYY_____ COLLECTION TIME:_____00:00 AM/PM_____

Background Information (Please check all that apply)

RACE AND ETHNICITY: ☐ WHITE ☐ ASIAN ☐ HISPANIC ☐ AFRICAN AMERICAN ☐ ASHKENAZI JEWISH ☐ OTHER (PLEASE SPECIFY):_____

PANELS PROVIDED* (Must choose at least one)	
☐ **COMPREHENSIVE PANEL**: ABCB1, APOE, COMT, CYP1A2, CYP2B6, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, DRD2, Factor II, Factor V, GLP1R, MTHFR, OPRM1, PNPLA5, SLCO1B1, SULT4A1, VKORC1	☐ **MENTAL HEALTH/ PSYCHIATRY PANEL:** ANKK1/DRD2, COMT, CYP1A2, CYP2B6, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, MTHFR
☐ **CARDIOVASCULAR PANEL**: APOE, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, Factor II, Factor V, MTHFR, SLCO1B1, VKORC1	☐ **PAIN MANAGEMENT PANEL:** COMT, CYP1A2, CYP2B6, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, Factor II, Factor V, MTHFR, OPRM1
☐ **ORTHOPEDIC PANEL:** ABCB1, CYP2B6, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, Factor II, Factor V, MTHFR, OPRM1, VKORC1	☐ **ADHD/ NEUROLOGY PANEL:** COMT, CYP1A2, CYP2B6, CYP2C19, CYP2C9, CYP2D6, OPRM1
☐ **GASTROINTESTINAL PANEL:** ABCB1, CYP2C19, CYP2C9, CYP2D6, CYP3A4	☐ **UROLOGICAL PANEL:** CYP2D6, CYP3A4, CYP3A5

Clinical Utility of Tests*: How will pharmacogenetic results directly change treatment or management of the patient?

☐ Selection of new prescription medication(s)
☐ Alternative dosing of existing medication(s)
☐ Anti-coagulant, anti-thrombotic treatment
☐ Discontinuation of existing medication(s)
☐ Adjustment of current multi-drug regimen
☐ Clarification of prior equivocal diagnostics

Current Medication(s): _____

Intended Medication(s): _____

☐ Check here if current medications have failed more than once

Patient Authorization and Consent

It has been explained to me and I understand that I am voluntarily providing a specimen for a genetic test. I will provide the specimen in a collection device provided by Genesys. My DNA will be extracted from my specimen at Genesys, and the test will evaluate how my body responds to certain medications. The Genesys test will look for common genetic variations in genes that are important for response to medications. The test identifies the most common variants of these genes but is not designed to identify some rare mutations which may also affect response to medications. The test is a clinical laboratory test and may aid in my treatment plan; therefore, I or my health insurer will be billed for this test. A written report of the test results will be provided to my health care provider who will inform me of the results. Genesys will keep all my medical information confidential and only disclose it to pursuant to applicable state and federal laws. I understand that I am responsible for providing accurate information about my insurance to Genesys Diagnostics Inc. I understand that Genesys Diagnostics Inc. will be providing testing service and billing my insurance. However, I understand that charges that are not covered by my insurance, including any applicable copayments and deductibles are my responsibility and I agree to pay such charges promptly.

Patient/Guardian Signature:* Date:*

☐ I do not consent to having my deidentified DNA sample used for internal research purposes.

Healthcare Provider Authorization

I certify that (i) this test is medically necessary, (ii) the patient (or authorized representative on the patient's behalf) has given informed consent (which includes written informed consent or written authorization when required by law) to have this testing performed, and (iii) the informed consent obtained from the patient meets the requirements of applicable law. I agree to provide Genesys, or its designee, any and all additional information reasonably required for this testing to be performed.

Healthcare Provider Signature:* Date:*

Medical Necessity Statement: Tests ordered on Medicare patients must follow CMS rules regarding medical necessity and FDA approval guidelines and must include diagnosis, symptoms and reason for testing as indicated in the medical record. If testing does not come under Medicare guidelines for payment a 'signed' Advanced Beneficiary Notice must be included.

**Certain regions in various genes have poor coverage and are not included in the panel (if you would like more coverage information regarding any specific genes of interest, please contact Genesys Diagnostics Inc.). All genes that have pseudogenes will have poorer performance on the MiSeq instrument. Variants in genes with pseudogenes may not be reliably detected. DNA alterations in regions not covered by this test such as deep intronic or regulatory regions, or in poorly covered regions will not be detected using Next Generation Sequencing analysis. There are technical limitations on the ability of Next Generation Sequencing to detect small insertions and deletions and these types of alterations are not detected as reliably as single nucleotide variants. This assay is not designed or validated for the detection of low-level mosaicism or somatic mutations.

GENESYS Diagnostics INC.

Pharmacogenetics **Requisition Form**

Letter of Medical Necessity*

Dear Insurance Representative:

My patient,_____, has several medical conditions requiring prescription drugs. Given the conditions and drugs being used, testing for drug metabolism and/or certain genetic risk factors is medically necessary. These indications are clearly documented in the paperwork and supporting documentation provided to the laboratory at the time of test requisition.

I ordered the Pharmacogenetics test, performed by **Genesys Diagnostics Inc.**, for this patient in order to understand possible dangers and risks for suboptimal outcomes for specific medications currently prescribed under consideration. Specifically, to assess:

☐ Identify risk for an adverse drug reaction	☐ Drug therapy best matched to patient's metabolic genotype/phenotype
☐ Efficacy of current and/or future drug therapy	☐ Correct dosage(s) to maximize therapeutic effect
☐ Risk of thromboembolism, hyperhomocysteinemia, and hyperlipidemia	☐ Other:_____

Treatment Plan Statement

I plan to use the information from this test report to improve treatment care through the following:

☐ Identify current medications that may be causing adverse reactions, such as _____ _____	☐ Determine the optimal dosage(s) for current or potential future medications to ensure maximum effect.
☐ Identify and prescribe new medications that will provide maximum therapeutic effect without causing harmful adverse reactions.	☐ Other:_____ _____

Medical Considerations

☐ Current medication list enclosed ☐ Failed medication, patient history enclosed

Medications that are under consideration for this patient (if applicable):

_____

_____

Supporting Documentation

The following documents have been provided to further support the medical necessity of this testing.

☐ Clinical Notes (H & P)	☐ Medication List
☐ Problem Diagnosis List	☐ Other:_____

Required for every patient*: Please provide a brief explanation why this test is medically/clinically necessary for the patient below:

_____

_____

Provider Signature:*_____Date:*_____

ICD Codes*

Neurology Panel
☐ F84.X Pervasive Developmental Disorders (Autistic dis-0) (Rett's synd-2) (othr chld dis-3) (asp-5) (othr dis-8) (Pervasive dev dis, unsp-9)
☐ F90.X Attention-deficit hyperactivity disorder (inattentive-1) (hyperactive-2) (other-8)
☐ F91.X Conduct disorder (confined to family-0) (child onset-1) (adolescent onset-2) (oppositional defiant dis-3) (other-8)
☐ Other: _____

Pain Panel
☐ Z79.891 Long term (current) use of opiate analgesic
☐ K21.9 Esophageal Reflux
☐ G89.11 Acute pain due to trauma
☐ G89.18 Acute post-op pain
☐ R5.2 Generalized pain
☐ G89.4 Chronic pain syndrome
☐ G89.21 Chronic pain due to trauma
☐ G89.28 Chronic post-op pain
☐ G89.29 Chronic pain, other
☐ G43.909 Migrane, unspec wo ntrc mgrn
☐ M12.9 Arthropathy Unsp
☐ M47.892 Cervical Spondylosis
☐ M47.896 Lumbosacral Spondylosis
☐ M50.30 Cervical Disk Disease
☐ M51.36/37 Lumbar Disk Disease
☐ M48.02 Cervical Spinal Stenosis
☐ M54.2 Cervicalgia
☐ M54.13 Brachial neuritis NOS
☐ M54.6 Pain in thoracic spine
☐ M54.5 Lumbago/low back pain
☐ M54.15 Lumbosacral neuritis NOS
☐ M75.50 Burstis of unsp shoulder
☐ M60.9 Myakgia, myositis, unsp
☐ R03.0 Elevated BP w/o Hypertension
☐ M60.8X Other Myositis (shoulder-1) (upper arm-2) (forearm-3) (hand-4) (thigh-5) (lower leg-6) (ankle+foot-7) (othr-8)
☐ Other: _____

Psychiatry Panel
☐ F31.31 Bipol I cur depress-mild
☐ G43.909 Migraine
☐ I1.0 Hypertension
☐ F30.1X Recur manic episode mild w/o psychotic symptoms (mod-.2) (severe-.3)
☐ F20.89 Other schizophren
☐ F20.1 Disorganized schizo
☐ F20.2 Catatonia schizo
☐ F20.0 Paranoid schizo
☐ F20.81 Schizophreniform dis
☐ F20.89 Schizophrenia other
☐ F30.2 Bipol1 single manic with psychotic sym
☐ F32.X MDD single episode (mild-0) (mod-.1) (severe-.2) (severe w/psychotic feat-.3) (other depr epis-8)
☐ F33.X Recur depr psychosis (mild-0) (mod-.1) (severe.2
☐ F33.4X Recur depr psyc- (part rem-.1) (full rem-.2)
☐ F31.1X Bipol 1 current manic (mild-.1) (mod-.2) (sev-.3)
☐ F31.3X Bipol 1 current depres (mild-.1) (mod-.2) (severe-.3) (w/ psyc-.4)
☐ F31.75 Bipol 1 cur dep rem NOS
☐ F31.76 Bipol 1 currnt dep remis
☐ F31.61 Bipol 1 currnt mix (mild-.1) (mod-.2) (sev-.3) (w psy-.4)
☐ F31.7X Bipol 1 currnt mix (part term-7) (mild-8)
☐ F31.81 Bipolar II dis
☐ F3.9 Episodic mood dis
☐ F41.1 Generalized anxiety dis
☐ F34.1 Dysthymic dis
☐ F43.0 Stress react, emotional
☐ F43.21 Adjustment dis w depress
☐ F43.25 Adj dis-emotion/conduct
☐ F93.8 Misery & unhappiness dis
☐ G1.0 Huntington's chorea
☐ Other: _____

Cardiology Panel
☐ Z79.01 Long term (current) use of anticoagulants
☐ I25.2 Old myocardial infarction
☐ I70.0 Aortic Atherosclerosis
☐ D68.5 Hypercoagulable state (contraceptives, lupus)
☐ I10.0 Hypertension
☐ I21.09 AMI anterolateral, unsp
☐ I21.19 AMI inferior wall, unsp
☐ I21.11 AMI inferopost, unsp
☐ I21.4 Subendo infarct, unsp
☐ I21.29 AMI NEC, unsp
☐ I21.3 AMI NOS, unsp
☐ I24.1 Post MI syndrome
☐ I20.0 Intermed coronary synd
☐ I24.0 Acute cor ocdsn w/o MI
☐ I24.9 Aschemic hrt dis
☐ I25.2 Old Myocardial Infarction
☐ I20.8 Angina decubitus
☐ I20.1 Prinzmetal Angina
☐ I20.9 Angina pectoris NEC/NOS
☐ I25.10 Crnry athrscl natvs vssl
☐ I26.99 Pulm embol/infarct NEC
☐ I27.82 Chr pulmonary embolism
☐ I48.91 Atrial brillation
☐ I49.01 Ventricular brillation
☐ I50.22 Systolic hear failure, chronic
☐ I50.32 Diastolic heart failure, chronic
☐ I50.42 Chr syst/diastl hrt fail
☐ I65.29 Ocl ctrd art wo infrct
☐ I67.1 Nonrupt cerebral aneurysm
☐ I70.0 Aortic atherosclerosis
☐ I70.25 Ath ext ntv art ulcrtion
☐ I73.00 Raynaud's syndrome
☐ I82.409 Acute DVT, LE, unsp dep veins
☐ I82.4Y9 Acute DVT, PLE
☐ I82.509 Chronic DVT, LE
☐ I82.729 Chronic DVT, UE
☐ I82.629 Acute DVT, UE
☐ R55 Syncope and collapse
☐ E78.01 Familial Hypercholesterolemia
☐ Other: _____ _____

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