SMA SPECIALTY MEDICAL LAB

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PHARMACOGENETIC (PGX)

PATIENT INFORMATION (REQUIRED)

Last Name: _____ First Name: _____

Street Address: _____ Apt#: _____

City: _____ State: _____ Zip: _____

Phone: _____ DOB: ___/___/___ SSN: _____ Gender: F ☐ M ☐

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

SPECIMEN INFORMATION (REQUIRED)

Date Collected: ___/___/___ Time Collected : _____

Collected and Registered By: _____

ICD10 CODES						

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

☐ **25D-PGX Comp Panel**

*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.

COLUMN 1* (SELECT ALL THAT MAY APPLY):

- ☐ **F32.1** Major Depressive Disorder, Single Episode, Moderate
- ☐ **F32.2** Major Depressive Disorder, Single Episode, Severe Without Psychotic Features
- ☐ **F32.3** Major Depressive Disorder, Single Episode, Severe With Psychotic Features
- ☐ **F32.4** Major Depressive Disorder, Single Episode, In Partial Remission
- ☐ **F32.9** Major Depressive Disorder, Single Episode, Unspecified
- ☐ **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 Features
- ☐ **F33.41** Major Depressive Disorder, Recurrent, in Partial Remission
- ☐ **F33.9** Major Depressive Disorder, Recurrent, Unspecified
- ☐ **F41.1** Generalized Anxiety Disorder

COLUMN 2* (SELECT ALL THAT MAY APPLY):

- ☐ **E78.00** Pure Hypercholesterolemia, Unspecified
- ☐ **E78.01** Familial Hypercholesterolemia
- ☐ **E78.1** Pure Hyperglyceridemia
- ☐ **E78.2** Mixed Hyperlipidemia
- ☐ **E78.49** Other Hyperlipidemia
- ☐ **I25.10** Atherosclerotic heart disease: Without hemodynamically significant stenosis

***Please 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.**

Patient Acknowledgement and Authorization: I acknowledge that I have provided accurate and true information to the best of my knowledge. If I have provided my insurance information for direct insurance / 3rd party billing: I hereby authorize my insurance benefits to be paid directly to SMA Specialty Medical Lab (SMA) and authorize SMA to release medical information concerning my testing, including upon request my genetic testing results, to my insurer and any business associate of insurer (TB, TPA, etc.) I authorize SMA to be my Designated Representative for purposes of appealing any denial of health benefits. I understand that I am responsible for any amounts that my insurer determines are my responsibility after calculating deductibles, co-payments and co-insurance due under my policy. I consent to the use of my DNA for pharmacogenetic testing (see the back of this form). **I understand that I am legally responsible for sending SMA Specialty Medical Lab any money received from my health insurance company for performance of this genetic test.**

➤ PATIENTS SIGNATURE: _____ DATE: _____

Check One: ☐ Self ☐ Parent ☐ Legal Guardian ☐ Durable Power of Attorney for Health Care

Informed Consent and Medical Necessity: I affirm that I am legally authorized to order these tests OR that I am an authorized representative of a legally authorized provider to order these tests; and hereby order the tests requested above, which includes any sample collection device for testing. I hereby confirm that the test(s) are medically necessary for the treatment and/or plan of care for the patient, that the patient has read and understands the informed consent on the back of this requisition, and to the best of my knowledge, the information herein is accurate. I hereby confirm that the information has been supplied by SMA about genetic testing. The undersigned herein provided all the information and answered any questions regarding the informed consent.

Did the patient opt-out for the use of their sample for research purposes in the consent? ☐ Yes ☐ No

PHYSICIAN SIGNATURE: _____ DATE: _____

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 CYP2C19 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 **amitriptyline** or **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 VKORC1 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 in a 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: _____

Informed Consent for Pharmacogenetic Testing

Pharmacogenetic testing is used to help understand why some people respond better than others to certain medications and why some people develop side effects while others do not. SMA Specialty Medical Lab ("SMA") is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity pharmacogenetic testing. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. This pharmacogenetic test involves using your DNA, which can be found in your cells of blood or saliva, to examine your genetic make-up. In order to have your pharmacogenetic testing completed, the following is important information for you to know and understand:

- You are having a sample of blood drawn or an oral specimen given to examine pharmacogenetic information which may help your provider understand how you may respond to different medications.

- The Genetic Information Nondiscrimination Act (GINA) generally protects you against discrimination based on your genetic information when it comes to health insurance and employment.

- Pharmacogenetic testing is available as a fee-for-service test. By signing this, you understand that you are responsible for what your insurance carrier does not pay. You will be responsible for payment after the testing has begun, even if you decide not to receive results.

- Test results will include:
  - your genotype, which is your personal genetic make-up;
  - your phenotype, which is the functional meaning of your genetic make-up (e.g. "altered gene function", "fast-", "normal-", or "poor metabolizer").
  - as a separate attachment, you will receive information compiled by another company on clinical consequences, drug dosing guidance, and potentially impacted medications. Depending on the ordering physician's selections, information on drug-drug interactions may be included in that attachment.

LIMITATIONS

Pharmacogenetic testing may yield uninterpretable results for the following reasons: 1) blood sample contamination, 2) insufficient sample collection, 3) incomplete knowledge of the available genetic markers, 4) technical reasons. This test does not account for all individual variations in the individual being tested. Absense of a detectable gene mutation does not rule out the possibility that a patient has different phenotypes due to the presence of an undetected polymorphism or due to other factors such as drug-drug interactions, comorbidities, and lifestyle habits.

GENETIC COUNSELING

It is recommended that you obtain pre-testing and post-testing counseling from someone professionally trained in genetics to consider the purpose, meaning, risks, benefits, and limitations of, as well as any alternatives to, genetic testing in your particular situation, including your personal and family medical history. Counseling may be provided by a genetic counselor (such as those found on the National Society of Genetic Counseling website), doctor and other qualified healthcare professional. Further testing or additional physician consults may be warranted.

PATIENT CONFIDENTIALITY AND TEST RESULTS DISCLOSURE

Your personal information and test results are confidential. While there can be no guarantee of privacy, SMA has established reasonable safeguards to protect it. Test results will only be released to the ordering healthcare professional, to those allowed access to test results by law, and to those whom you authorize in writing. By requesting payment by your insurance company, Medicare or other third-party payor, you specifically authorize the release of your Protected Health Information ("PHI"), including your lab test results, to such third-party payor or its authorized agents or representatives, as necessary for the purpose of determining coverage and facilitating payment.

I have discussed and understand the risks and benefits of this test. By signing this form, I authorize the use of my sample to obtain results for tests indicated above. Furthermore, I authorize SMA to retain, preserve, and use any data resulting from this test, as well as any leftover saliva, blood or DNA sample, for scientific or teaching purposes, or to dispose of at its convenience, unless initialed below.

Indicate your preference by checking one of the statements below:

☐ I do not wish for my specimen to be retained for Medical Research Purposes; discard within 60 days of collection.

☐ I agree to use of my de-identified biospecimen for medical research to improve genetic testing for all patients. I consent to my sample being retained beyond 60 days of collection; the retained sample will be de-identified by having all identifiers removed prior to re-testing. The de-identified sample and results obtained will remain anonymous.

Patient's Initials Here: _____