OMNIHEALTH DIAGNOSTICS

OmniHealth Diagnostics
1840 N Greenville Ave Ste 176, Richardson, TX 75081
Phone 972-887-3444 | Fax 972-887-3443
CLIA# 45D2089485 | Lab Director: Amy Gruszecki DO
www.OmniHealthDX.com

PHARMACOGENOMICS

PATIENT - PLEASE PRINT LEGIBLY — REQUIRED

First Name | Last Name

Date of Birth | Sex: ☐ Male ☐ Female | Ethnicity: ☐ African American ☐ Asian ☐ Caucasian ☐ Jewish (Ashkenazi) ☐ Hispanic ☐ Portugese ☐ Other:_____

Street Address | Apt/Suite #

City | State | Postal Code

ORDERING PHYSICIAN — REQUIRED

Office/Practice/Institution Name

Physician Name(s)

Street Address | Apt/Suite #

City | State | Postal Code

SPECIMEN INFORMATION — REQUIRED

Specimen Type | Date of Collection | Time of Collection : ☐ AM ☐ PM | Collectors Initials

Diagnosis (ICD-10) Codes

PATIENT INSURANCE — REQUIRED: ATTACH PATIENTS FACESHEET & COPY OF INSURANCE CARD

☐ Private ☐ Self Pay ☐ Workers Comp ☐ Medicare ☐ Medicaid

Insurance Company | Policy Number

REQUIRED: CLINICIAN MUST ESTABLISH MEDICAL NECESSITY FOR REFERRAL AND ATTACH MEDICATION LISTS, CLINICAL NOTES ON ADVERSE DRUG REACTIONS OR INEFFICACY

MEDICAL NECESSITY FOR GENETIC TESTS — REQUIRED

What clinical characteristics for this patient warrant referral for Pharmacogenomic testing?

- ☐ Drug Intolerance and Side Effects
- ☐ History of Thrombosis, DVT, Embolism, VTE
- ☐ Family History of Drug Side Effects
- ☐ Treatment with Multiple Medications
- ☐ Treatment Resistance and Lack of efficacy
- ☐ Hypercoagullable Scale (Contraceptives, Lupus)
- ☐ Multiple Medical Conditions of Hospitalization
- ☐ Elderly or Infirm vulnerable patient

What clinical characteristics for this patient warrant referral for Pharmacogenomic testing?

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

MEDICATIONS — REQUIRED

Current Medication:

New Medication:

TEST REQUESTED (SEE REVERSE PAGE FOR DESCRIPTION OF GENES) — SELECT ONE (REQUIRED)

- ☐ **CARDIOVASCULAR** - 14 Genes
- ☐ **HEMATOLOGY / ONCOLOGY**- 11 Genes
- ☐ **PAIN** - 9 Genes
- ☐ **DIABETES** - 3 Genes
- ☐ **INFECTIOUS DISEASE** - 6 Genes
- ☐ **PSYCHIATRY**- 14 Genes
- ☐ **GASTROENTEROLOGY** - 9 Genes
- ☐ **NEUROLOGY**- 3 Genes

PHYSICIAN CONSENT & MEDICAL NECESSITY FOR TESTING — REQUIRED

By signing below you confirm that the ordering healthcare provider: (a) has an on-going relationship with the patient, (b) will use the results in the management of the patients medical condition, (c) will follow up with the patient once the test results are received to render additional treatment decisions based on the test results, (d) will maintain a detailed chart with extensive SOAP notes specifying how the test results impacted the medical care and treatment of the patient in the follow-up visits, (e) understands that if the patient is a Medicare beneficiary that Medicare generally does not cover routine screening tests, and (f) certifies under the penalties of perjury that to be the best of your knowledge the test ordered is not classified as a screening test, and that all local and national CMS coverage guidelines to determine medical necessity of the ordered test have been met.

Physician Signature:_____ **Date:** _____

PATIENT ACKNOWLEDGEMENT & CONSENT — REQUIRED

ATTENTION PATIENT: OMNIHEALTH DIAGNOSTICS is committed to serving the needs of its patients in compliance with all applicable federal and state health care laws, rules and regulations. By signing below, you acknowledge that you have a physician-patient relationship with the treating physician(s) identified below and have been examined by, or consulted with, the treating physician(s) for medical condition and understand the laboratory test(s) that are being ordered on your behalf. Further, you acknowledge that your representations herein will be relied upon by **OMNIHEALTH DIAGNOSTICS** in performing the test services ordered by your treating physician. Your treating physician(s) has been instructed that a claim may only be submitted by **OMNIHEALTH DIAGNOSTICS** when appropriate documentation supports the test(s) ordered is medically necessary and the test results are used in the management of a medical problem to treat your medical condition. By signing this form, I hereby authorize **OMNIHEALTH DIAGNOSTICS** to submit the medical information regarding this testing to my designated insurance carrier for reimbursement if necessary. I also authorize benefits to be payable to **OMNIHEALTH DIAGNOSTICS**. I understand that I am responsible for any amounts not paid by insurance for reasons, but not limited to non-covered and non-authorized services. I permit a copy of this authorization to be used in place of the original.

Patient Signature: _____ **Date:** _____

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PHARMACOGENOMICS

CARDIOVASCULAR - 14 Genes

Gene	Therapeutic Class	Drug Examples
ABCG2	Statins	fluvastatin (Lescol®), rosuvastatin (Crestor®)
CYP2C9	Anticoagulants	warfarin (Coumadin®)
	Angiotensin II Receptor Antagonists	losartan (Cozaar®)
	Diuretics	torsemide (Demadex®)
	Statins	fluvastatin (Lescol®)
CYP2C19	Antiplatelets	clopidogrel (Plavix®)
CYP2D6	Antianginal Agents	ranolazine (Ranexa®)
	Antiarrhythmics	flecainide (Tambocor®), propafenone (Rythmol®)
	Beta Blockers	carvedilol (Coreg®), propranolol (Inderal®)
CYP3A4	Statins	atorvastatin (Lipitor®), simvastatin (Zocor®)
CYP4F2	Anticoagulants	warfarin (Coumadin®)
SLCO1B1	Statins	atorvastatin (Lipitor®), rosuvastatin (Crestor®)
VKORC1	Anticoagulants	warfarin (Coumadin®)

Risk Management

APOE	Type III Hyperlipoproteinemia
F2	Thrombosis
F5	Thrombosis
F13A1	Thrombosis
ITGB3	Platelet Reactivity
MTHFR	Hyperhomocysteinemia - Thrombosis

DIABETES - 3 Genes

Gene	Therapeutic Class	Drug Examples
CYP2C8	Meglitinides	repaglinide (Prandin®)
	Thiazolidinediones	pioglitazone (Actos®), rosiglitazone (Avandia®)
CYP2C9	Meglitinides	nateglinide (Starlix®)
SLCO1B1	Meglitinides	nateglinide (Starlix®), repaglinide (Prandin®)

GASTROENTEROLOGY - 9 Genes

Gene	Therapeutic Class	Drug Examples
ABCB1	Antiemetics	granisetron (Sancuso®), ondansetron (Zofran®)
CYP2C9	Antiemetics	dronabinol (Marinol®)
CYP2C19	Proton Pump Inhibitors	lansoprazole (Prevacid®), omeprazole (Prilosec®)
CYP2D6	Antiemetics	dolasetron (Anzemet®), ondansetron (Zofran®)
G6PD	Other Antirheumatic Agents	sulfasalazine (Azulfine®)
MTHFR	Antifolates	methotrexate (Trexall®)
NUDT15	Thiopurines	azathioprine (Imuran®), mercaptopurine (Purinethol®)
TPMT	Thiopurines	azathioprine (Imuran®), mercaptopurine (Purinethol®)

Risk Management

UGT1A1	Gilbert Syndrome

HEMATOLOGY / ONCOLOGY - 11 Genes

Gene	Therapeutic Class	Drug Examples
CYP2C8	Taxanes	paclitaxel (Taxol®)
CYP2C9	Protein Kinase Inhibitors	erdaftinib (Balversa®)
CYP2D6	Anti-Estrogens	tamoxifen (Nolvadex®)
	Protein Kinase Inhibitors	gefitinib (Iressa®)
DPYD	Fluoropyrimidines	capecitabine (Xeloda®), fluorouracil (Efudex®)
F2	Hemostatic Agents	avatrombopag (Doptelet®), eltrombopag (Promacta®)
F5	Hemostatic Agents	avatrombopag (Doptelet®), eltrombopag (Promacta®)
G6PD	Detoxifying Agents	rasburicase (Elitek®)
	Protein Kinase Inhibitors	dabrafenib (Tafinlar®)
MTHFR	Antifolates	methotrexate (Trexall®)
NUDT15	Thiopurines	azathioprine (Imuran®), mercaptopurine (Purinethol®)
TPMT	Thiopurines	azathioprine (Imuran®), mercaptopurine (Purinethol®)
UGT1A1	Histone Deacetylase Inhibitors	belinostat (Beleodaq®)
	Protein Kinase Inhibitors	erlotinib (Tarceva®), nilotinib (Tasigna®)
	Topoisomerase Inhibitors	irinotecan (Camptosar®), sacituzumab-govitecan (Trodelvy®)

INFECTIOUS DISEASE - 6 Genes

Gene	Therapeutic Class	Drug Examples
CYP2B6	Anti-HIV Agents	efavirenz (Sustiva®)
CYP2C19	Antifungals	voriconazole (Vfend®)
DPYD	Antifungals	flucytosine (Ancobon®)
G6PD	Antibiotics	nitrofurantoin (Macrobid®, sulfamethoxazole hydroxychloroquine
	Antimalarials	(Plaquenil®), quinine
IFNL3/IFNL4	Interferons	peginterferon alfa-2a (Pegasys®), peginterferon alfa-2b (Pegintron®)
UGT1A1	Anti-HIV Agents	atazanavir (Reyataz®)

***Infectious Disease report minimum should be CYP2C19 and at least one other**

NEUROLOGY - 3 Genes

Gene	Therapeutic Class	Drug Examples
CYP2C9	Anticonvulsants	fosphenytoin (Cerebryx®), phenytoin (Dilantin®)
CYP2C19	Anticonvulsants	brivaracetam (Briviact®), phenobarbital (Luminal®), primidone (Mysoline®)
	Benzodiazepines	clobazam (Onfi®)
	Other Neurological Agents	flibanserin (Addyi®)
CYP2D6	Antidementia Agents Other Neurological Agents	donepezil (Aricept®), galantamine (Razadyne®) tetrabenazine (Xenazine®), valbenazine (Ingrezza®)

Risk Management

UGT1A1	Gilbert Syndrome

PAIN - 9 Genes

Gene	Therapeutic Class	Drug Examples
COMT	Opioids	morphine (MS Contin®)
CYP1A2	Muscle Relaxants	tizanidine (Zanaflex®)
CYP2B6	Opioids	methadone (Dolophine®)
CYP2C9	NSAIDs	celecoxib (Celebrex®), flurbiprofen (Ansaid®)
CYP2C19	Muscle Relaxants	carisoprodol (Soma®)
CYP2D6	Opioids	codeine, hydrocodone (Vicodin®), oxycodone (Percocet®), tramadol (Ultram®)
OPRD1	Opioids	buprenorphine (Butrans®), methadone (Dolophine®)
OPRK1	Opioids	cocaine vaccine (investigational)
OPRM1	Opioids	fentanyl (Actiq®), hydrocodone (Vicodin®)

PSYCHIATRY - 14 Genes

Gene	Therapeutic Class	Drug Examples
ADRA2A	Anti-ADHD Agents	dexmethylphenidate (Focalin®), methylphenidate (Ritalin®)
ANKK1	Antiaddictives	bupropion (Wellbutrin®)
COMT	Anti-ADHD Agents	amphetamine (Adderall®), methylphenidate (Ritalin®)
CYP1A2	Antipsychotics	clozapine (Clozaril®), olanzapine (Zyprexa®)
CYP2B6	Antiaddictives	bupropion (Wellbutrin®)
CYP2C19	Antidepressants	amitriptyline (Elavil®), citalopram (Celexa®), sertraline
	Benzodiazepines	diazepam (Valium®)
CYP2D6	Antiaddictives	lofexidine (Lucemyra®)
	Anti-ADHD Agents	atomoxetine (Strattera®)
	Antidepressants	amitriptyline (Elavil®), paroxetine (Paxil®), venlafaxine (Effexor®),
	Antipsychotics	vortioxetine (Trintellix®)
DRD2	Antipsychotics	aripiprazole (Abilify®), haloperidol (Haldol®), thioridazine (Mellaril®)
GRIK4	Antidepressants	risperidone (Risperdal®)
HTR2A	Antidepressants	citalopram (Celexa®)
	Antipsychotics	citalopram (Celexa®)
HTR2C	Antipsychotics	clozapine (Clozaril®)
OPRM1	Antiaddictives	clozapine (Clozaril®), olanzapine (Zyprexa®), risperidone naltrexone (Vivitrol®)

Risk Management

ANKK1	Antipsychotic-Induced Hyperprolactinemia, Tardive Dyskinesia, Weight Gain
MTHFR	Hyperhomocysteinemia - Depression

CONTINUE TO INFORMED CONSENT

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INFORMED CONSENT FOR GENETIC TESTING

My Signature below acknowledges that a physician has ordered genetic testing. I authorize **OMNIHEALTH DIAGNOSTICS** to perform the genetic testing that was ordered. I understand the potential outcomes, including the benefits, risks and limitations of the screening as described below. I have had the opportunity to ask questions of a physician prior to giving my informed consent, and my questions have been satisfactorily answered. I also acknowledge that it is my responsibility to contact my personal physician, medical provider or genetic counselor and discuss the reported result.

PURPOSE

This Genetic Screening test analyzes specific changes in my DNA for the ordered disorders. The purpose of this test is to determine if I have specific genetic changes related to one or more of the ordered genes. Possessing one or more copies of one of these changes may increase the risk of disease associated with these genetic changes. This test does not assess my risk of any other genetic disorder beyond what was ordered. I may use this information to inform my medical treatment decisions.

TEST RESULTS AND INTERPRETATION

Most of the disorders on this test are inherited in an autosomal recessive manner, meaning that I must possess two copies of the mutation in the same disease gene in order to be at risk of being affected. Severity of symptoms or disease can be variable, even within family members with the same mutations. For certain conditions on the panel test, it is possible to be diagnosed with an adult or late-onset form of the condition. Depending on the panel ordered, there may be a few diseases on the panel (e.g., Fragile X) that can be transmitted when only one parent is a carrier due to a different mode of inheritance. The possible results from this test are as following: Positive: If you possess a disease-causing mutation for one of the genetic conditions, genetic counseling is recommended as a next step to discuss the implications of the test results, and any further testing, if needed. Negative: A negative test means that there is a reduced risk of being affected with one of the disorders screened for in this test.

LIMITATIONS OF THE TESTING

A "negative" result does not rule out all genetic causes of disease. It is still possible that I may have one or more genetic conditions that this technology is unable to detect or that are caused by one or more genes that are not included as part of the specific test ordered. A "positive" result will not necessarily predict the prognosis or severity of disease. This test may identify variants of uncertain significance, which will not be included in the result report.

DNA SAMPLE AND TEST RESULTS DISCLOSURE

I understand that DNA samples will only be used for testing that is authorized by the ordering physician. Any leftover DNA will be stored for at least 30 days. I understand that some samples may be maintained indefinitely after all testing has been completed for research purposes in an effort to advance scientific knowledge. In such a case, all personal identifiers will be removed in a HIPAA compliant manner, and any new results will not be returned or shared since they are generated from de-identified samples. I understand that I can opt-out of specimen storage by checking the box in the signature section below.

The original test results may be released to any entity that, by statute or law, has the legal authority to request and receive genetic results. **OMNIHEALTH DIAGNOSTICS** may discuss summaries of genetic test results in scientific presentations, publications, or marketing pieces. No names or personal identifiers will be revealed.

GENETIC COUNSELING

I understand that genetic screening results can be complex. Genetic counseling, which involves an in-depth discussion of the interpretation of this testing and the impact on me/my family may be useful and can be performed by a physician as well as a medical geneticist and/or a genetic counselor. Additionally, **OMNIHEALTH DIAGNOSTICS** staff is available to answer any questions I may have.

PATIENT CONFIDENTIALITY

To maintain confidentiality, the test results will only be released to the referring health care provider, to the ordering laboratory, to me, to other health care providers involved in my care and treatment or to others as entitled by law. The United States Genetic Information Nondiscrimination Act (GINA) of 2008 prohibits discrimination on the basis of genetic information with respect to health insurance and employment. GINA does not include protections from discrimination in life insurance, disability insurance or long-term care insurance.

☐ I have read the Informed Consent document and I give permission to **OMNIHEALTH DIAGNOSTICS** to perform genetic testing as described.

☐ Check here if you wish to opt out of indefinite storage of your specimen.

Patient Signature:_____ **Date:**_____