OmniHealth Diagnostics
1840 N Greenville Ave Ste 176, Richardson, TX 75081
Phone 972-887-3444 | Fax 972-887-3443
CLIA# 45D2089485 | Lab Director: David Mehr, MD
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 & ICD CODES) — SELECT ONE (REQUIRED)

- ☐ **CARDIOVASCULAR** - 13 Genes
- ☐ **HEMATOLOGY / ONCOLOGY**- 9 Genes
- ☐ **PAIN** - 7 Genes
- ☐ **DIABETES** - 3 Genes
- ☐ **INFECTIOUS DISEASE** - 3 Genes
- ☐ **PSYCHIATRY**- 14 Genes
- ☐ **GASTROENTEROLOGY** - 7 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 - GENES

CARDIOVASCULAR - 13 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
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 - 7 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®)
MTHFR	Antifolates	methotrexate (Trexall®)
NUDT15	Thiopurines	azathioprine (Imuran®), mercaptopurine (Purinethol®)
TPMT	Thiopurines	azathioprine (Imuran®), mercaptopurine (Purinethol®)

HEMATOLOGY / ONCOLOGY - 9 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®)
	Antifolates	methotrexate (Trexall®)
MTHFR	Thiopurines	azathioprine (Imuran®), mercaptopurine (Purinethol®)
NUDT15	Thiopurines	azathioprine (Imuran®), mercaptopurine (Purinethol®)
TPMT		

INFECTIOUS DISEASE - 3 Genes

Gene	Therapeutic Class	Drug Examples
CYP2B6	Anti-HIV Agents	efavirenz (Sustiva®)
CYP2C19	Antifungals	voriconazole (Vfend®)
DPYD	Antifungals	flucytosine (Ancobon®)

***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	donepezil (Aricept®), galantamine (Razadyne®)
	Neurological Agents	tetrabenazine (Xenazine®), valbenazine (Ingrezza®)

PAIN - 7 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®)
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 ICD CODES

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PHARMACOGENOMICS - ICD 10 CODES

CARDIOVASCULAR

Code	Description
I10	Essential (primary) hypertension
I11.9	Hypertensive heart disease without heart failure
I20.0	Unstable angina
I11.0	Hypertensive heart disease with heart failure
I24.9	Acute ischemic heart disease, unspecified
I25.2	Old myocardial infarction
I49.9	Cardiac arrhythmia, unspecified
I50.9	Heart failure, unspecified
I50.89	Other heart failure
I95.89	Other hypotension

DIABETES

Code	Description
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications
E16.1	Other hypoglycemia
E16.2	Hypoglycemia, unspecified
E50.9	Vitamin A deficiency, unspecified
E53.9	Vitamin B deficiency, unspecified
E55.9	Vitamin D deficiency, unspecified
E56.9	Vitamin deficiency, unspecified
E78.2	Mixed hyperlipidemia
E78.9	Disorder of lipoprotein metabolism, unspecified

GASTROENTEROLOGY

Code	Description
K11.9	Disease of salivary gland, unspecified
K12.2	Cellulitis and abscess of mouth
K13.70	Unspecified lesions of oral mucosa
K11.9	Disease of salivary gland, unspecified
K38.8	Other specified diseases of appendix
K38.9	Disease of appendix, unspecified

NEUROLOGY

Code	Description
G00.9	Bacterial meningitis, unspecified
G03.1	Chronic meningitis
G03.9	Meningitis, unspecified
G20.C	Parkinsonism, unspecified
G30.9	Alzheimer's disease, unspecified
G30.8	Other Alzheimer's disease
G47.09	Other insomnia
G47.10	Hypersomnia, unspecified
G47.19	Other hypersomnia
G47.30	Sleep apnea, unspecified
G47.39	Other sleep apnea
G47.9	Sleep disorder, unspecified
G72.89	Other specified myopathies
G72.9	Myopathy, unspecified
F09	Unspecified mental disorder due to known physiological condition
F10.20	Alcohol dependence, uncomplicated
F10.90	Alcohol use, unspecified, uncomplicated
F11.10	Opioid abuse, uncomplicated

PAIN

Code	Description
G89.11	Acute pain due to trauma
G89.18	Other acute postprocedural pain
G89.29	Other chronic pain
R11.2*	Nausea with vomiting, unspecified
R52	Pain, unspecified

PSYCHIATRY

Code	Description
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
F33.9	Major depressive disorder, recurrent, unspecified
F41.0	Panic disorder [episodic paroxysmal anxiety]
F41.1	Generalized anxiety disorder

HEMATOLOGY / ONCOLOGY

Code	Description
C45.1	Mesothelioma of peritoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C68.0	Malignant neoplasm of urethra
C68.1	Malignant neoplasm of paraurethral glands
C68.8	Malignant neoplasm of overlapping sites of urinary organs
C68.9	Malignant neoplasm of urinary organ, unspecified
C61	Malignant neoplasm of prostate
D29.1	Benign neoplasm of prostate
D40.0	Neoplasm of uncertain behavior of prostate
N40.0	Benign prostatic hyperplasia without lower urinary tract symptoms
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms
N40.2	Nodular prostate without lower urinary tract symptoms
N40.3	Nodular prostate with lower urinary tract symptoms
N42.31	Prostatic intraepithelial neoplasia
N42.32	Atypical small acinar proliferation of prostate
N42.39	Other dysplasia of prostate
N42.83	Cyst of prostate
R31.1	Benign essential microscopic hematuria
R31.29	Other microscopic hematuria
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
Z85.030	Personal history of malignant carcinoid tumor of large intestine
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.040	Personal history of malignant carcinoid tumor of rectum
Z85.048	Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus

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:**_____