

DRUG METABOLISM TEST REQUISITION

Failure to complete all required fields may delay results. Completed requisition may be emailed to info@dynamicdnalabs.com, faxed to 417-319-7142, or included with the sample when returned/shipped to Dynamic DNA Laboratories at 2144 E. Republic Road Suite B204 Springfield, MO 65804.

Sample Information

Collection Date:	Collection Time:	Sample Collected By:	Requisition Completed By:	Accession Number:

Physician Information

Physician Name and NPI #:	Practice Name:	Office Phone:	
Practice Address:	City, State:	Zip:	Fax Number:

Ordering Physician/Authorizing Medical Professional Signature: I hereby authorize testing for this Patient. I have provided information regarding genetic testing, and the Patient has given consent for testing to be performed. I attest that the ICD-10 Diagnosis Codes provided are accurate and supported by Patient records. I attest that these tests are medically necessary. I hereby authorize Dynamic DNA Laboratories to send this Patient's test results to the Patient's third party payer, if needed, to appeal a denial of reimbursement prior to attempts to obtain reimbursement without the release of Patient results. I understand that each test panel may include a combination of CYP2D6, CYP2C19, CYP2C9, CYP3A4, CYP3A5, CYP1A2, CYP2B6, OPRM1, SLCO1B1, ANKK1, COMT, UGT2B15 VKORC1, ApoE, Factor V, Factor II, and MTHFR.

X

Patient Information

Patient Last Name:	Patient First Name:	Patient Date of Birth: (MM/DD/YYYY)	Patient Gender
Patient Email:	Ethnicity:	Patient MRN:	Phone:
Patient Address:	City:	State:	Zip:

Patient Consent Signature: I authorize the release of my medical information (including genetic test results) for submission of personalized reports to my healthcare providers and insurance carrier(s). I request that payment of benefits be made to Dynamic DNA Laboratories on my behalf. I also acknowledge that I will be liable for payment of deductible, co-payment and/or co-insurance as detailed by my healthcare insurer. I understand that I am liable for charges not covered by my healthcare insurer. I also authorize Dynamic DNA Laboratories to appeal insurance claims on my behalf. I acknowledge the benefits, risks, and limitations of this testing as described to me by a qualified healthcare provider. I understand that my sample may be used for confidential training, quality control, and validation purposes.

X

Specimen Type

Test Request	Diagnosis (ICD-10) Codes	Insurance & Payment																
Check one box below for desired panel based on Patient's medical needs: <ul style="list-style-type: none"> <input type="checkbox"/> Comprehensive (All Panels) 180+ Meds <input type="checkbox"/> Mental Health Panel: 70+ Meds <input type="checkbox"/> Pain Management Panel 40+ Meds <input type="checkbox"/> Cardiovascular Health Panel 30+ Meds <input type="checkbox"/> Diabetes Panel 30+ Meds <input type="checkbox"/> ADHD Medication Panel 25+ Meds 	Please list the ICD-10 codes that constitute medical necessity for the Patient. A partial list of ICD-10 codes is provided below for reference. This list is not exhaustive. Please list all ICD-10 codes applicable. <table border="1" style="width: 100%; margin-top: 10px;"> <tr> <th>Clinical Diagnosis:</th> <th>ICD-10 Code:</th> </tr> <tr> <td>Primary</td> <td> </td> </tr> <tr> <td>Secondary</td> <td> </td> </tr> <tr> <td>Additional Diagnoses</td> <td> </td> </tr> </table>	Clinical Diagnosis:	ICD-10 Code:	Primary		Secondary		Additional Diagnoses		A photocopy of both sides of Patient's insurance card(s) <u>must</u> be included. <table border="1" style="width: 100%; margin-top: 10px;"> <tr> <td><input type="checkbox"/></td> <td>Medicaid</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Medicare</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Other Insurance</td> </tr> <tr> <td> </td> <td>Self Pay</td> </tr> </table>	<input type="checkbox"/>	Medicaid	<input type="checkbox"/>	Medicare	<input type="checkbox"/>	Other Insurance		Self Pay
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Insurance Information (REQUIRED)

* Please attach a scanned front and back photocopy of Insurance Card*

Primary Insurance:

Policy #: _____

Group#: _____

Primary Policy Holder: _____

Secondary Insurance:

Policy #: _____

Group#: _____

Secondary Policy Holder: _____

Patient List of Medications

Please list patient's current medications.

If insufficient space, attach a list from Patient's record.

Doctor's Notes/Progress Notes (REQUIRED)

Please provide or attach notes pertinent to listed ICD-10 codes. If insufficient space, attach a list from Patient's record.

Sample Submission Instructions:

- 1) Complete this requisition form in full and fax to (417) 319-7142
- 2) **Clinic Collection:** Write Patient's last name and DOB on the sample in ink.
- 3) **Lab Collection:** If patient is local please contact DDNA to schedule appointment.

- 4) All samples collected at physician visit can be mailed to:
Dynamic DNA Laboratories
2144 E. Republic Rd. Ste. B204
Springfield, MO 65804

Reporting of Results

Your results will be delivered through a HIPAA compliant portal to the signing Physician. Once we receive your requisition form, your physician will receive an email with a username and password to log in and access your results. Reports will always be accessible via this portal to your physician. Patient may contact their Physician for a copy of results.

Informed Consent Information

Submission of a requisition for any test listed constitutes acknowledgement that the consumer agrees that:

- 1) Each genetic panel may include a combination of the following tests: CYP2D6, CYP2C19, CYP2C9, VKORC1, CYP3A4/3A5, CYP1A2, CYP2B6, OPRM1, SLCO1B1, ANKK1, COMT, UGT2B15 ApoE, Factor II, Factor V, and MTHFR.
- 2) These DNA results may:
 - a. Indicate whether the consumer is a carrier for a certain condition
 - b. Predict whether another family member is a carrier of a certain condition
 - c. Diagnose whether the consumer has a condition, or is at increased risk for developing that condition.
 - d. Predict whether another family has, or is at increased risk for developing a condition.
 - e. Provide undetermined results due to technical limitations or familial genetic patterns.
- 3) This DNA test pertains only to drug metabolism and cardiovascular risk factors; it will not detect all causative gene mutations.
- 4) DNA testing usually provides precise information; however, several sources of error are possible. These include, but are not limited to, clinical misdiagnosis of the condition, sample misidentification, and inaccurate information regarding familial relationships.

- 5) DDNA is authorized to perform high-complexity testing under the Clinical Laboratory Improvement Amendments (CLIA). The results are not intended to be used as the sole means for clinical diagnosis or care decisions.
- 6) DDNA recommends genetic counseling for the consumer prior to, as well as after, genetic testing
- 7) The requested DNA test may contain additional Quality Control (QC) markers that are reviewed and the data retained regarding specific genetic locations. These QC markers may be used for specific QC steps of the testing process. In addition, de-identified, extracted DNA may be used as blinded validation specimen for test development. No additional results beyond the genetic test requested and the QC markers will be interpreted on this sample. Once testing and QC are completed, the sample will be destroyed.
- 8) Samples will be stored and destroyed within our accreditation timelines.
- 9) No clinical research or publications will be conducted on patient data/samples by DDNA.

DRUG METABOLISM TEST REQUISITION

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Please contact 1-417-319-1047 for questions. Fax completed requisition to 1-417-319-7142.

CARDIOVASCULAR HEALTH

ICD-10Code Description

I10	Essential (primary) hypertension
I20.0	Unstable angina
I20.1	Angina pectoris with document spasm
I20.8	Other forms of Angina pectoris
I20.09	ST elevation (STEMI) myocardial infraction involving other coronary artery of anterior wall
I21.11	ST elevation (STEMI) myocardial infraction involving right coronary artery
I21.19	ST elevation (STEMI) myocardial infraction involving other coronary artery of inferior wall
I21.29	ST elevation (STEMI) myocardial infraction involving other sites
I21.3	ST elevation (STEMI) myocardial infraction of unspecified sites
I21.4	Non-ST elevation (NSTEMI) myocardial infraction
I21.9	Accute myocardial infraction, unspecified
I21.A1	Myocardial infraction type-2
I21.A9	Other myocardial infraction type
I24.0	Acute coronary thrombosis not resulting in myocardial infraction
I24.1	Dressier's syndrome
I24.8	Other forms of acute ischemic heart disease
I24.9	Acute ischemic heart disease, unspecified
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
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified of angina pectoris
I25.700	Atherosclerotic of coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.701	Atherosclerotic of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasms
I25.708	Atherosclerotic of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris
I25.709	Atherosclerotic of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris
I25.710	Atherosclerotic of autologous vien coronary artery bypass graft(s) with unstable angina pectoris
I25.711	Atherosclerotic of autologous vien coronary artery bypass graft(s) with unstable angina pectoris with documented spasm
I25.718	Atherosclerotic of autologous vien coronary artery bypass graft(s) with other forms of angina pectoris
I25.719	Atherosclerotic of autologous vien coronary artery bypass graft(s) with unspecified angina pectoris
I25.720	Atherosclerotic of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25.721	Atherosclerotic of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.728	Atherosclerotic of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris

CARDIOVASCULAR HEALTH

ICD-10Code Description

I25.729	Atherosclerotic of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris
I25.730	Atherosclerotic of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris
I25.731	Atherosclerotic of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.738	Atherosclerotic of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris
I25.739	Atherosclerotic of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris
I25.750	Atherosclerotic of native coronary artery of transplanted heart with unstable angina
I25.751	Atherosclerotic of native coronary artery of transplanted heart with angina pectoris with documented spasm
I25.758	Atherosclerotic of native coronary artery of transplanted heart with other forms of angina pectoris
I25.759	Atherosclerotic of native coronary artery of transplanted heart with unspecified angina pectoris
I25.760	Atherosclerotic of bypass graft of coronary artery of transplanted heart with unstable angina
I25.761	Atherosclerotic of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm
I25.768	Atherosclerotic of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris
I25.769	Atherosclerotic of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris
I25.790	Atherosclerotic of other coronary artery bypass graft(s) with unstable angina pectoris
I25.791	Atherosclerotic of other coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.798	Atherosclerotic of other coronary artery bypass graft(s) with other forms of angina pectoris
I25.799	Atherosclerotic of other coronary artery bypass graft(s) with unspecified angina pectoris

PAIN MANAGEMENT

ICD-10Code Description

G89.4	Chronic pain syndrome
G89.29	Other chronic pain
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter
T50.7X5A	Adverse effect of analeptics and opioid receptor antagonists, initial encounter
Z79.1	Long term (current) use of non-steroidal anti-inflammatory (NSAID)
Z79.899	Other longterm (current) drug therapy

PSYCHIATRIC / MENTAL HEALTH

ICD-10Code Description

F20.0	Paranoid schizophrenia
F20.1	Disorganized schizophrenia
F20.2	Catatonic schizophrenia
F20.3	Undifferentiated schizophrenia
F20.5	Residual schizophrenia
F20.8	Other schizophrenia
F20.81	Schizophreniform disorder
F20.89	Other schizophrenia
F20.9	Schizophrenia, unspecified
F25.9	Schizoaffective disorder, unspecified
F29	Unspecified psychosis not due to a substance or known physiological condition
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
F31.60	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 without psychotic features
F31.64	Bipolar disorder, current episode, mixed, 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
F31.77	Bipolar disorder, in partial remission, most recent episode mixed
F31.78	Bipolar disorder, in full remission, most recent episode mixed
F31.9	Bipolar disorder, unspecified
F32.9	Major depressive disorder, single episode, 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 features
F33.40	Major depressive disorder, recurrent, in remission, unspecified
F33.41	Major depressive disorder, recurrent, in partial remission
F33.42	Major depressive disorder, recurrent, in full remission
F33.9	Major depressive disorder, recurrent, unspecified
F41.0	Panic disorder [episodic paroxysmal anxiety]
F41.1	Generalized anxiety disorder
F41.3	Other mixed anxiety disorders
F41.8	Other specified anxiety disorders
F41.9	Anxiety disorder, unspecified
F53.0	Postpartum depression
G10	Huntington's Disease

Insurance coverage is not required for genetic testing. The diagnostic code (ICD-10) information provided herein is for insurance information purposes only and does not guarantee insurance coverage for any genetic test, nor is it intended to be a definitive list of diagnosis codes that may be applicable for any individual patient. The testing laboratory will pursue reimbursement directly from the patient should the patient's insurance carrier refuse to provide coverage.



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Letter of Medical Necessity: Pharmacogenomics (PGx) Testing **(REQUIRED)**

Date of Service: _____

Patient Name: _____

Patient Date of Birth: _____

ICD-10 Diagnosis Codes: _____

Dear Claims Specialist:

Please consider this Letter of Medical Necessity a formal request for full coverage of the pharmacogenomic testing services that I intend to prescribe for your subscriber (Patient Name Listed above). Pharmacogenomic testing laboratory services will be performed only by a CLIA-certified laboratory, and the results will assist my making of patient-specific clinical decisions regarding the medical management of your subscriber.

In order to provide the safest, most effective and affordable medical care possible, the requested genetic testing is medically necessary for my patient for several reasons. The primary reason(s) for my request apply specifically to the patient listed above:

- Acquire specific dosing recommendations to avoid toxicity and adverse drug reactions (ADR's)
- Patient has a family history of thrombosis
- Patient is not responding to the drugs he/she has been prescribed
- Patient has suffered recent or previous Severe Adverse Drug Reactions (SADR)
- Other (please specify): _____

Below is a list of the medication(s) where Adverse Drug Reactions (ADRs) were experienced and why Genetic Testing is necessary:

The FDA recommendations for genetic testing is currently listed on the labels of over 150 prescription medications. Please visit (<http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm>) for more information.

Recommendations typically include pharmacologic treatment contraindications and dose-selection strategies based on patient genetic status. As a health-care prescriber, I am obligated to provide the best medical care possible for my patients. Medical management based on patient-specific pharmacogenomics testing can improve clinical outcomes and PREVENT unnecessary suffering and costs.

Billing for genetic testing services will be initiated upon completion of services. As completion of genetic testing can take several months, so I am requesting your authorization be valid for **6 months**.

Best regards,

Name of Practice _____

Ordering Clinician Signature: _____ Date _____

(MD/DO, Clinical Nurse Specialist, Nurse-Midwives, Nurse Practitioner, Physician Assistant, Genetic Counselor*)

* Clinician prescribing requirements vary by state

***MEDICARE PATIENTS ONLY**

A. Notifier: Dynamic DNA Laboratories, LLC

B. Patient Name:

C. Identification Number:

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for D. _____ below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the D. _____ below.

D.	E. Reason Medicare May Not Pay:	F. Estimated Cost
<input type="checkbox"/> Cardiovascular	Medicare believes that there is insufficient evidence to demonstrate that genetic testing for the gene improves clinical outcomes for all indications. Consequently, genetic testing for this gene could be considered investigational in certain cases and may not be a covered benefit.	Cardiovascular \$199.00
<input type="checkbox"/> Pain Management		Pain Management \$199.00
<input type="checkbox"/> Psychiatric/Mental Health		Psychiatric/Mental Health \$199.00
<input type="checkbox"/> Comprehensive		Comprehensive \$299.00

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the D. _____ listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.
<input type="checkbox"/> OPTION 1. I want the D. _____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
<input type="checkbox"/> OPTION 2. I want the D. _____ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.
<input type="checkbox"/> OPTION 3. I don't want the D. _____ listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

I. Signature:	J. Date:
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According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.