



DRUG METABOLISM TEST REQUISITION

Failure to complete all required fields may delay Patient results. Please contact 1-417-319-1047 for questions. Fax completed requisition to 1-417-319-7142.

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:

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. If my policy does not allow for direct payment, I agree to relinquish allocated funds to Dynamic DNA as compensation for services rendered. 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

X	Specimen Type
	Buccal Swab

Test Request	Diagnosis (ICD-10) Codes	Insurance & Payment												
Check the box beside the desired panel(s), based on Patient's medical needs	Please state why this test constitutes medical necessity for the Patient. A partial list of ICD-10 codes is provided below for reference. This list is not exhaustive. Reimbursement requires all diagnoses to be coded to the highest degree of specificity.	A photocopy of both sides of Patient's insurance card(s) must be included.												
<input type="checkbox"/> Dynamic PGx (Comprehensive)	<table border="1"> <tr> <th colspan="2">Clinical Diagnosis:</th> <th>ICD-10 Code:</th> </tr> <tr> <td>Primary</td> <td></td> <td></td> </tr> <tr> <td>Secondary</td> <td></td> <td></td> </tr> <tr> <td>Additional Diagnoses</td> <td></td> <td></td> </tr> </table>	Clinical Diagnosis:		ICD-10 Code:	Primary			Secondary			Additional Diagnoses			<input type="checkbox"/> Out of Pocket (See pg. 3 for pricing)
Clinical Diagnosis:		ICD-10 Code:												
Primary														
Secondary														
Additional Diagnoses														
<input type="checkbox"/> Pain Management		<input type="checkbox"/> Medicaid												
<input type="checkbox"/> Cardiovascular Health		<input type="checkbox"/> Medicare												
<input type="checkbox"/> Psychiatric		<input type="checkbox"/> Other Insurance												

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CARDIOVASCULAR HEALTH

ICD-10Code Description

R10.13	Epigastric pain
R10.9	Unspecified abdominal pain
D68.311	Acquired hemophilia
I48.91	Unspecified atrial fibrillation
I10	Essential (primary) hypertension
Z68.34	Body mass index (BMI) 34.0-34.9, adult
K59.00	Constipation, unspecified
E11.9	Type 2 diabetes mellitus without complications
Z84.81	Family history of carrier of genetic disease
Z82.49	Family history of ischemic heart disease and other disease of the circulatory system
M72.9	Fibroblastic disorder, unspecified
Z15.89	Genetic susceptibility to other disease
I20.0	Unstable angina
Z79.899	Other long term (current) drug therapy
E78.2	Mixed hyperlipidemia
M79.7	Fibromyalgia
E66.9	Obesity, unspecified
I20.9	Angina pectoris, unspecified
E78.5	Hyperlipidemia, unspecified
K59.09	Other constipation
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter
R53.1	Weakness
G93.3	Postviral fatigue syndrome
R53.83	Other fatigue
R53.81	Other malaise
E66.3	Overweight
M25.50	Pain in unspecified joint
I73.9	Peripheral vascular disease, unspecified
I80.209	Phlebitis and thrombophlebitis of unspecified deep vessels of unspecified lower extremity
Z13.220	Encounter for screening for lipid disorders
E03.9	Hypothyroidism, unspecified
T50.7X5A	Adverse effect of analeptics and opioid receptor antagonists, initial encounter
E88.9	Metabolic disorder, unspecified
E63.9	Nutritional deficiency, unspecified
E55.9	Vitamin D deficiency, unspecified
Z71.3	Dietary counseling and surveillance
R03.0	Elevated blood-pressure reading, without diagnosis of hypertension
K21.9	Gastro-esophageal reflux disease without esophagitis
N95.1	Menopausal and female climacteric states
Z83.3	Family history of diabetes mellitus
R94.5	Abnormal results of liver function studies
E66.9	Obesity, unspecified
R53.83	Other fatigue
E29.1	Testicular hypofunction
E66.3	Overweight

CARDIOVASCULAR HEALTH

ICD-10Code Description

E06.9	Thyroiditis, unspecified
E23.7	Disorder of pituitary gland, unspecified
E23.3	Hypothalamic dysfunction, not elsewhere classified
I10	Essential (primary) hypertension
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
I20.29	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
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
I25.700	Atherosclerotic of coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.710	Atherosclerotic of autologous vein coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.720	Atherosclerotic of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25.730	Atherosclerotic of non-autologous biological coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.750	Atherosclerotic of native coronary artery of transplanted heart with unstable angina
I25.760	Atherosclerotic of bypass graft of coronary artery of transplanted heart with unstable angina
I25.790	Atherosclerotic of other coronary artery bypass graft(s) with unstable 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

Z00.00	Encounter for general adult medical examination without abnormal findings
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
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
F33.49	Major depressive disorder, recurrent, unspecified
G10	Huntington's Disease
F90.2	Attention-deficit hyperactivity disorder, combined type
F81.0	Specific reading disorder
G47.9	Sleep disorder, unspecified
G10	Failure to thrive (child)
F95.2	Tourette's disorder

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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Insurance Information

Member ID:	Group Number:	Name of Insurance:	Claims Address:

Out of Pocket Pricing

Dynamic PGx (Comprehensive) \$600.00	Cardiovascular \$350.00	Pain Management \$350.00	Psychiatric \$350.00
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Patient List of Medications

Please list patient's current medications. If insufficient space, attach a list from Patient's record.

Sample Submission Instructions

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| 1) Complete this requisition form in full and send to info@dynamicdnalabs.com or fax to (417) 319-7142. | 4) If not hand delivered or picked up by DDNA Labs, place samples in the pre-paid and pre-labeled white envelope and place in mail. |
| 2) Write Patient's last name and DOB on the sample tube in ink. | 3) Carefully follow "Instruction Card" for collection of DNA. |

Reporting of Results

Your results will be delivered through a HIPPA compliant Patient Portal. Once we receive your requisition form, you and 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 both you and your physician.

Informed Consent Information

- Submission of a requisition for any test listed on this DDNA Requisition Form constitutes acknowledgement by the Ordering Physician and Patient that:**
- | | |
|--|---|
| <p>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.</p> <p>2) The Ordering Physician has obtained <u>written Informed Consent for each test ordered</u>, as required by applicable state and federal laws. (An Informed Consent form is available at www.dynamicdnalabs.com/pgxforms for your convenience. A copy of the Informed Consent is not required by DDNA in order to process a sample, but a copy must be available in Ordering Physician's records.)</p> <p>3) The Patient has provided written authorization for DDNA to report the results of each test directly to the Ordering Physician.</p> <p>4) These DNA results may:</p> <ol style="list-style-type: none"> Indicate whether the Patient is a carrier for a certain condition. Predict whether another family member is a carrier of a certain condition. Diagnose whether the Patient has a condition, or is at increased risk for developing that condition. Predict whether another family member has, or is at increased risk for developing a condition. Provide undetermined results due to technical limitations or familial genetic patterns. <p>5) This DNA test pertains only to drug metabolism and cardiovascular risk factors; it will not detect all causative gene mutations.</p> <p>6) The significance of a positive or a negative test result, based on the Patient's family history, have been explained to the Patient.</p> | <p>7) 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.</p> <p>8) All test results will be released directly to the Ordering Physician, or on their behalf, as state and local laws allow.</p> <p>9) 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 patient care decisions.</p> <p>10) DDNA recommends genetic counseling for the Patient prior to, as well as after, genetic testing.</p> <p>11) 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 or specimen for research and 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.</p> <p>12) The Patient acknowledges their right to obtain a copy of their written Informed Consent Form from the Ordering Physician, and that test information sheets are available at www.dynamicdnalabs.com/patients.</p> <p>13) Samples will be stored and destroyed within our accreditation timelines.</p> <p>14) No Clinical Research or Publications will be conducted on patient data/samples.</p> |
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Letter of Medical Necessity

Date: _____

Patient Name: _____ DOB: _____

Insurance: _____

Subscriber Name: _____ Policy Number: _____

Diagnosis: _____

Claim Specialist:

This letter is a request for coverage for Pharmacogenomics Testing for my patient. This genetic test will provide knowledge that can help avoid harmful and costly adverse drug events, optimize drug dosing and increase the changes for successful treatment by analyzing certain liver proteins that are responsible for pharmaceutical drug metabolism.

Referenced genes include: CYP1A2, CYP2C19, CYP2D6, CYP3A4, CYP3A5, F2, F5, MTHFR, OPRM1, SLC01B1, VKORC1. The genetic testing panels are validated and are Clinical Improvement Amendments (CLIA) compliant.

Genetic disposition can account for much of the variability seen in patient's response to drug therapies. Benefits of pharmacogenomics testing have been well documented in providing a better standard of care for patients. There are over 150 FDA-approved drugs that provide pharmacogenomics information on their drug labeling. This information includes specific actions to be taken based on a patient's genetic profile which is obtained by performing pharmacogenomics tests.

Given this patient's clinical medical history and current prospective prescribed medications, this testing is medically necessary.

If you have any questions or need additional information, please do not hesitate to contact me. I can be reached at the contact information for my medical practice listed in the requisition form. Thank you in advance for your consideration.

Sincerely,

Physician Signature

Date



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	\$350.00
<input type="checkbox"/> Pain Management		Pain Management	\$350.00
<input type="checkbox"/> Psychiatric/Mental Health		Psychiatric/Mental Health	\$350.00
<input type="checkbox"/> Comprehensive		Comprehensive	\$600.00

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.

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.

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.**

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:

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.