Genecept Assay® Requisition

Please select one:

☐ **Kit given to patient**

☐ **Ship kit to patient** at address indicated below. Note: Please fax this requisition to **450.901.3075** to request a shipment to patient's home.

PATIENT INFORMATION

Last Name _____

First Name _____

Date of Birth _____
Year / Month / Day

Health Ins. No. _____

Sex ☐ F ☐ M

Address _____
No Street Apt.

_____
City Province Postal code

Tel _____

E-mail _____

Current smoker ☐ Yes ☐ No

Ethnicity

- ☐ African
- ☐ East Asian
- ☐ South Asian
- ☐ Hispanic or Spanish
- ☐ Middle Eastern
- ☐ Eastern European
- ☐ Northwestern European
- ☐ Southern European
- ☐ Caucasian
- ☐ Other

PATIENT CONSENT

I authorize Dynacare or its designate to collect a biological specimen from me or from an individual for whom I have the legal right to authorize the collection and testing of a specimen. I further authorize Genomind, Inc., their agents and contractors to test that specimen. My treating clinician has satisfactorily explained the benefits, risks and limitations of this testing. I have fully reviewed this Requisition, including the Patient Informed Consent and the Statement of Consent and Release, and agree to the terms. I understand that my specimen will be sent to a laboratory in the United States for testing. I understand that personal information, including but not limited to my name, date of birth and the test result itself will be part of the data file created in the United States. Personal information held in countries outside of Canada could be subject to disclosure to government or other authorities (whether of that country or of another country).

☐ Optional: I consent to the storage beyond 90 days and use of my DNA sample for future genomic testing and research (in which my identity will not be known by the researchers).

Patient signature _____

Date _____
Year / Month / Day

PRESCRIBER INFORMATION

Last Name _____

First Name _____

Clinic _____

Address _____
No Street Office

_____
City Province Postal code

Tel _____

Fax _____

Fax CC _____

E-mail _____

TEST INFORMATION

☒ Genecept Assay®

Includes: SLC6A4, CACNA1C, ANK3, 5HT2C, MC4R, DRD2, COMT, ADRA2A, MTHFR (A1298C/C677T), BDNF, OPRM1, GRIK1, CYP1A2, CYP2B6, CYP2C9, CYP2C19, CYP2D6, CYP3A4/5

CLINICAL INDICATIONS

- ☐ ADHD, combined type
- ☐ ADHD, predominantly inattentive type
- ☐ Anxiety disorder
- ☐ Autistic disorder
- ☐ Bipolar disorder
- ☐ Bipolar II disorder
- ☐ Dysthymic disorder
- ☐ Generalized anxiety disorder
- ☐ MDD, recurrent, moderate
- ☐ MDD, recurrent severe without psychotic features
- ☐ MDD, single episode
- ☐ MDD, recurrent, in partial remission
- ☐ MDD, single episode, severe without psychotic features
- ☐ Panic disorder (episodic paroxysmal anxiety) without agoraphobia
- ☐ Post-traumatic stress disorder
- ☐ Sleep disorder
- ☐ Other: _____

CLINICIAN SIGNATURE

I confirm this test is medically necessary for the diagnosis provided and the results will be used in treatment decisions for the patient. I have explained DNA testing to the Patient or Patient's Legal Representative and discussed its benefits, risks and limitations and have satisfactorily answered all related questions.

Clinician Signature _____

Date _____ Licence No. _____
Year / Month / Day

Patient Informed Consent

Dynacare Services

Dynacare ("Dynacare") or its designate will collect a biological specimen from you and Dynacare will send your sample to Genomind Inc. ("Genomind"), located at 2200 Renaissance Blvd, Suite 100, King of Prussia, PA, USA, for testing. Dynacare will also collect the personal health information that is required to perform the test and Dynacare will transmit this personal health information to Genomind. By submitting your sample to Dynacare, you consent to your sample and personal health information being sent to the United States where the collection, use, and disclosure of your sample and personal health information will be subject to US laws and regulations. Upon completion of the Test, Dynacare will obtain your result and transmit it to the healthcare provider (clinician) who prescribed your test. Dynacare Customer Care is available to assist you and your healthcare provider with any questions regarding the Test.

How will my samples be used?

Your samples will be used to test for genetic markers. These genetic markers form the Genecept Assay®, which provides information to clinicians that can be used to inform treatment decisions based on an individual patient's genetic profile. The results of the specific DNA test ordered may: a) predict your ability to absorb, distribute, metabolize and/or eliminate medications properly; b) identify whether or not you are at increased risk of having an adverse drug reaction or therapeutic failure to standard dosages of a particular drug or class of drugs; c) indirectly reveal non-paternity; and/or d) be indeterminate due to technical limitations.

Optional: By providing my consent to storage beyond 90 days, I hereby authorize Genomind to use my DNA sample for future research. I acknowledge that information derived from my DNA will be de-identified prior to research use. I understand that my information may contribute to new findings and treatment options for psychiatric patients, and I will not be receiving any financial benefits. I understand that I can withdraw my consent at any time by calling Dynacare Customer Care. If I do not choose to store my sample beyond 90 days for future research, my sample will be destroyed in accordance with Genomind's standard operating procedures 90 days after the test has been completed and the results have been sent to my clinician.

What are the risks of this genetic testing?

The DNA test result reported to the clinician is specific only for the genes described on the previous page. It will not detect all variants possible within these genes. Although genetic variant analysis usually yields precise information, several sources of error are possible. These include, but are not limited to, clinical misinterpretation of the gene, sample misidentification, and sample contamination. While DNA testing is highly accurate and widely accepted, as in all testing, there is a possibility of delay or error. It is possible that the test may disclose non-paternity or some previously unknown information about a family relationship and I consent that this finding be reported to the referring specialist designated on the Requisition Form.

What are my rights?

Your clinician has ordered this testing for you. However, allowing your samples to be tested is completely voluntary and you have the absolute right not to agree to have your DNA sampled. You may also direct that your sample not be used for future research. Your decision will not affect your right to treatment in any way. You may refuse testing without any consequences to your treatment. Once you agree to the testing, you may withdraw from the testing at any time until your results are received by your clinician. Your test results will be released to the clinician who ordered the test. Additional genetic counselling may be warranted or desired, either before signing this form, after testing, or after going over the test results with your clinician.

Statement of Consent and Release

I hereby certify that the information provided is true and accurate. I understand that the Genecept Assay® is an analysis of a group of genes that are being tested for variations. This variation can be used to help inform my clinician(s) as to the medication options that they decide may help treat the condition(s) for which I am currently seeking their care. The significance of this test has been explained to me.

I acknowledge that I have been informed that Genomind (CLIA No. 39D2088097) has validated the Genecept Assay® consistent with the Clinical Laboratory Improvement Amendments (CLIA) standards for high-complexity testing but the assay has not been approved by the Food and Drug Administration (FDA). Genomind will comply with applicable US laws and regulations. The DNA test results are not intended to be used as the only tool for patient management decisions. I understand that prescription drug regimens should never be altered without consulting a clinician.

I consent to the collection of specimens from myself or any listed minor or other dependent for the purpose of DNA testing by Genomind, its agents or contractors. I understand that Dynacare, Genomind and their representatives are not responsible for any medical or other decisions made based on the results of the DNA test ordered by my clinician. I hereby release and hold harmless Dynacare and Genomind, and their employees, contractors, successors, and assigns from any liability arising from such decisions, including from any course of treatment chosen using the test results. If I choose to share my genetic, or other personal information with third parties - whether intentionally or inadvertently - I agree to hold harmless Dynacare and Genomind, and their employees, contractors, successors, and assignees from any and all liability arising from such disclosure or use of my genetic information or other personal data. I agree that I have the authority, under the laws of the state or jurisdiction in which I reside, to provide this consent and release.