Durin Life Sciences, Inc.
2 Medical Center Drive
Stratford, NJ 08084

Phone: 1-877-DURINLS
DurinLifeSciences.com

PATIENT CONSENT FORM FOR BLOOD BASED BIOMARKER TESTING

SIGNED CONSENTS SHOULD BE KEPT IN THE PATIENT MEDICAL RECORD

I _____ (Insert Patient's Name), authorize Durin Life Sciences to conduct blood-based biomarker testing for Alzheimer's disease as ordered by my physician or authorized healthcare provider.

What is the Biomarker Test?

Duritect is a noninvasive blood test that is used to accurately detect certain neurodegenerative diseases in adults aged 55+. The test combines analyzing a blood sample and machine learning analysis to provide a risk score for Alzheimer's disease.

How Does the Biomarker Test Work?

A blood sample will be collected from you, either by a blood draw or finger-prick, with minimal discomfort. Your blood sample will then be sent to Durin Life Sciences' laboratory and will be treated to isolate its serum for biomarker testing.

Neurodegenerative diseases such as Alzheimer's disease cause cell death in the body which results in the accumulation of debris. This debris is cleared out of the body by a process that involves autoantibodies which are antibodies produced by an individual's body that are directed against the individual's own proteins (the debris). These autoantibodies bind to the debris and aid in the body's removal of it.

The biomarker testing looks for the presence of these autoantibodies in your blood sample as an indicator of the presence of a neurodegenerative disease.

Based on the biomarker testing results, a predictive risk score will be created to indicate the likelihood of either Alzheimer's disease.

What are the Physical Risks?

Blood tests involve collecting a small amount of blood using routine collection procedures, also called a blood draw or finger-prick, that carry minimal risk. You may experience some discomfort at the site of needle entry, and there is a risk of a "black and blue" mark. There is also a remote risk of fainting or local infection.

What are Other Potential Risks?

Biomarker testing can reveal that the pathology of a disease has either already started in your body or that the disease will develop further in the future. Some of the information provided by a biomarker test may be important to your present or your future health, some of it may have nothing to do with your health, and it is also possible that much of it we will not know how it might or might not affect your health. Also, predictions about health and disease from biomarker testing are not 100 percent accurate. You should always contact your physician and follow their recommendations.

What if the Results are Uncertain?

You may learn that a test result came out as borderline. This means that the score generated by the biomarker test is not able to determine whether you have a neurodegenerative disease. Repeat testing within a certain time period may be recommended by your physician to find out if a new sample would provide a more definitive result.

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What Do the Test Results Mean?

The test results may indicate that you have the pathology of the disease that was ordered or are at increased risk of being affected by the condition in the future. It is important for you to understand that there is a possibility that the test results may not be able to determine whether you have the disease or will develop one in the future. If the results of the blood biomarker tests are positive, that means that an individual may be at an increased risk of having the pathology of the disease, be predisposed to developing disease in the future, or actually have the specific disease or condition that was ordered by your physician.

The biomarker test is not a diagnostic test, meaning the test result does not tell you that you do or do not have the disease. Your physician will consult with you regarding pursuing further testing to confirm the presence or not of the disease.

It is important to understand the limitations of testing and to discuss these limitations with your physician before testing. For example, the interpretation of test results could be based upon probabilities and may not provide a 100 percent definitive answer to whether you have a specific disease or are at-risk for developing the disease.

What Should Happen Before and After Testing?

Your physician or other authorized person should provide you with the following information:

1. The purpose and description of the test and a general written description of each specific disease or condition tested for.
2. Pre-test counseling regarding the expected outcomes of testing, the likelihood and type of incidental results that could be generated and what results will or will not be disclosed.
3. Discussion on the reliability of positive or negative test results, and the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease.
4. Post-test counseling to provide information about appropriate specialist interventions associated with clinically relevant results.

Will My Blood Sample or Test Results Be Used for Other Purposes?

Blood samples may be kept by Durin Life Sciences' laboratory for additional testing if requested by the ordering physician and may also be used for internal laboratory quality assurance purposes.

Durin Life Sciences also requests your permission to use your blood sample, clinical information and data that is developed by the biomarker test for research related to biomarker testing for neurodegenerative diseases, educational studies, and/or publications. Durin Life Sciences will de-identify your information so that your name and other identifying information is not used in any way. Your name or other personal identifying information will not be used in or linked to the results of any studies and publications. Any specimens that you have donated which are used in research may result in new products, tests or discoveries. In some instances, this may have potential commercial value and may be developed and owned by Durin Life Sciences and/or other parties. However, donors do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries. If you change your mind and do want to use your specimen for research, it will not be possible to reliably retrieve your specimen or data once they are de-identified. Your refusal to have your specimen used for research purposes will not affect your ability to take the biomarker test or receive the results. Please indicate your approval or denial on the Durin Test Requisition Form under Authorization to Use De-Identified Specimen or Data for Research.

PATIENT INITIAL HERE

Who Will Receive My Test Results?

Durin Life Sciences complies with HIPAA confidentiality laws. You can view Durin Life Sciences' Notice of Privacy Practices on their website. Your biomarker test results will only be released to the ordering physician or the physician's designee. Additionally, your test results could be released to any other party who, by law, may have access to such data.

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PATIENT CONSENT STATEMENT

I, the undersigned, have read or have had read to me the above informed consent information about the Duritect biomarker test for Alzheimer's disease. I have discussed the reliability of test results and the level of certainty a high-risk test result for a certain disease serves as a predictor of such disease with my healthcare provider. I have had the opportunity to ask questions of my healthcare provider regarding this test, including the reliability of the test results, the risks, and the alternatives prior to my informed consent. I have been informed about the test(s) purpose, procedures, possible benefits and risks, and I have received a copy of this consent.

By signing below, I hereby voluntarily agree to the blood based biomarker testing my physician has ordered for me.

_____

Signature of Patient

_____

Printed Name of Patient

Date: _____

If the person getting the biomarker test lacks the capacity to consent, this consent form will need to be signed by that person's legally authorized representative.

_____

Signature of Legally Authorized Representative

_____

Printed Name of Legally Authorized Representative

_____

Relationship to Participant

Date: _____