Informed Consent for Molecular Genetic Testing

Tests/profiles covered by consent form (see reverse for information): DNA Methylation Pathway profile

Intended purpose is: ☐**Screening** ☐**Carrier status** ☐**Predictive** ☐**Diagnosis** ☐ **Other** _____

I request and authorize Doctor's Data Inc. and BioServe Biotechnologies, Ltd to test my (or my child's) sample for genetic mutations/condition(s). My signature below constitutes my acknowledgment that the benefits, risks, and limitations of this testing have been explained to my satisfaction by my physician or genetic counselor.

Genetic testing is used to determine if a person has genetic differences, known as mutations that caused or contributed to a disorder they have, puts them at risk for a disorder in the future, or may be used for screening purposes to look for mutations that are not currently associated with a specific disease or predisposition. This means that a genetic difference is found, but it is unclear whether this particular difference can contribute to or cause a specific disease. In addition, the test may uncover mutations that are not well-understood. In some instances, there is not enough information to determine if a mutation is associated with disease or not, and more research will need to be done before a definite answer is known. In other cases, a mutation may be associated with a different condition than the one your doctor ordered the test for.

1. DNA test results associated with specific condition(s) may:
    a) diagnose whether or not I have (or my child) this condition or am at risk for developing this condition
    b) indicate whether or not I (or my child) am a carrier for this condition
    c) predict another family member is a carrier or is at risk for developing this condition
    e) be indeterminate due to technical limitations or familial genetic patterns
    f) reveal non-paternity

2. Genetic counseling is recommended prior to, as well as following, genetic testing. The decision to consent or to refuse the testing is entirely your (or your legal guardian's) choice.

3. Although DNA testing usually yields precise information, several sources of error are possible. These include, but are not limited to, clinical misdiagnosis of the condition, sample misidentification, laboratory method limitations, and inaccurate information regarding family relationships. DNA testing will not detect all causative mutations.

4. Genetic tests are handled in a confidential manner, like all other personal health information. Test results are released to the ordering health care provider, and to those parties entitled to them by state and local laws, or to a person whom you have specifically authorized by signing a written release. Genetic test results are part of your medical record. If a genetic test is performed, your insurance company may have access to the result. Federal law extends some protections regarding genetic discrimination (www.genome.gov/10002328).

5. No other tests than the tests specifically authorized will be performed on your identifiable sample, unless specifically authorized by you/your guardian. The sample will not be used in any identifiable manner for research purposes without your consent. Your sample (tissue, blood, fluid and/or DNA) shall be discarded 60 days after testing or permanently deidentified, i.e. stripped of any identifiers that may be linked to you, and kept for test control/research purposes. You may also decline to allow your DNA to be de-identified and used for control/research purposes by initialing here: _____ patient/guardian initials.

6. The performance characteristics of this test(s) were validated by BioServe Biotechnologies, Ltd. The U.S. Food and Drug Administration (FDA) has not approved this test(s); however, FDA approval is currently not required for clinical use of this test(s). Doctor's Data, Inc. and BioServe Biotechnologies, Ltd are authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing. The results are not intended to be used as the sole means for clinical diagnosis or patient management decision. If a specific genetic diagnosis is suspected, please consult with a certified clinical geneticist for additional testing that may be recommended.

The patient/legal guardian has read or has been read the above and fully understands the significance, risk and benefits of having the test completed and wishes to proceed with testing. Genetic counseling is recommended prior to, as well as following, genetic testing.

Patient Name(print)	**Date of Birth:**
Patient/Legal Guardian Signature:	**Date Signed:**

DNA Methylation Pathway profile markers

Genetic Marker	Condition(s)
ACAT / 1-02	none; screening only
AHCY / 1	none; screening only
AHCY / 19	none; screening only
AHCY / 2	none; screening only
BHMT / 1	none; screening only
BHMT / 2	none; screening only
BHMT / 4	none; screening only
BHMT / 8	none; screening only
CBS / A360A	none; screening only
CBS / C699T	none; screening only
CBS / N212N	none; screening only
COMT / 61	none; screening only
COMT / H62H	none; screening only
COMT / V158M	none; screening only
MAO A / R297R	none; screening only
MTHFR / 3	none; screening only
MTHFR / A1298C	Hyperhomocysteinemia
MTHFR / C677T	Hyperhomocysteinemia
MTR / A2756G	none; screening only
MTRR / 11	none; screening only
MTRR / A66G	none; screening only
MTRR / H595Y	none; screening only
MTRR / K350A	none; screening only
MTRR / R415T	none; screening only
MTRR / S257T	none; screening only
NOS / D298E	none; screening only
SHMT / C1420T	none; screening only
SUOX / C370S	none; screening only
VDR / Fok	none; screening only
VDR / Taq	none; screening only